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The Global Guide to **Pharma Marketing Codes**

Vol.4.2

This unique guide was produced with the insight and expertise of the largest independent public relations group dedicated exclusively to health and medical communications worldwide.

VOL.4.2

GLOBALHealthPR

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LEGAL DISCLAIMER

The Global Guide to Pharma Marketing Codes is designed to provide information on country-specific codes and regulations surrounding the promotion of medicines. Every effort has been made to ensure that the information about relevant codes of practice is accurate and up-to-date and that guidance offered is in line with existing regulations. This document should in no way be seen as a substitute for the relevant regulations or statutes that govern the behaviour of those involved in the promotion of medicines. GLOBALHealthPR cannot accept responsibility for any breach of Codes of Practice or statutes that may result from following the advice or guidance in this document.

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ASIA-PACIFIC

PREFACE

During the course of my 20-year career in healthcare communications, I have seen a massive transformation in the pharmaceutical industry. When I started, my clients' pipelines were dominated by incremental improvements and "me too" drugs. Now, thanks to new technology and a shift in the way the industry thinks about R&D, innovative new products are being developed at a rate unseen in decades. Drug developers are pushing the envelope of science to create cutting edge treatments for previously untreated diseases or radical improvements to treatment paradigms for diseases that were once not well understood. The pharmaceutical and biotechnology industries provide incredible value to society; as communicators, it's our privilege to tell their stories of scientific endeavor.

It's an exciting time to be involved in healthcare communications. We have a unique opportunity to help take advanced science and make it understandable for the public. We get to provide patients and doctors with the information they need to make informed decisions about when and how to best use these new innovations, and show payers their value to society. However, we also need to make sure we are communicating ethically and accurately.

As healthcare communicators, we are bound by standards of conduct, both voluntarily and enforced by regulatory bodies. What is and is not acceptable in the way we communicate with patients, healthcare practitioners, payers and the public at large varies significantly based on location. Additionally, what is culturally appropriate is just as dependent on the local norms as the legal regulations. Consequently, PR strategies can never be "plug and play" from market to market. Local expertise and experience are essential to both legally and successfully communicating the value of a client's innovative products.

At GLOBALHealthPR, we are acutely aware of this fact. As the largest independent healthcare communications agency network worldwide, our partners around the globe have come together to assemble this updated volume of the Global Guide for Pharmaceutical Marketing Codes. This unique guidebook provides insight into local regulations to help plan, prepare and execute healthcare communications campaigns around the world.

No other healthcare communications network has the footprint, knowledge or culture of collaboration to rival GLOBALHealthPR. For more than 17 years we've been working together to provide meaningful insights around the world and are pleased to share with you Vol. 4 of the Global Guide. If you have feedback or questions, our lights are always on and the door is always open.

Best,

JONATHAN WILSON

THE AMERICAS

ARGENTINA

In Argentina, the promotion of medicines is controlled by national legislation and codes of practice. Direct-to-consumer promotion of prescription-only medicine is not permitted, and all information about medicines delivered by pharmaceutical companies must be accurate, verifiable and updated.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

Within the private sector, there is the Ethical Code of Pharmaceutical Marketing Practices from the Argentine Chamber of Medical Specialties. This code applies to the promotion of prescription medicines from pharmaceutical companies and medical professionals within the health sector.

Another private code, the Ethical Code of Good Advertising Practices from the Argentinean Chamber of Non-Prescription Medical Specialties, is based on the statement that every advertisement for over-the-counter products (OTC) must respect the principles of morality and decency and must respect general advertisement laws. Therefore, advertising must be honest, truthful and trustworthy. All member companies of The Argentine Chamber of Over-the-Counter Medicines (CAPEMVel) must adhere to this code.

The Argentinian Medical Association (AMA) has its own Health Team Ethical Code. Section No. 365 states that 'companies related to the provision of medicines and health teams shall strictly respect and adhere to current national legislation on the subject. Any conduct that could lead to mistakes, confusion or concealment of medicinal side effect and secondary effects, or misleading health teams' claims, shall be considered an ethical violation'. For example, the phrase 'cures rheumatic disease' is not true because not all rheumatic disease can be cured.

A recent law passed by the City of Buenos Aires (Law 5709) 'Law for the advertising of benefits or prizes to doctors' states that manufacturers, importers and distributors of medical, biological and pharmaceutical products that grant and/or deliver goods, services, benefits or prizes that may be subject to pecuniary valuation to physicians within the scope of the city of Buenos Aires must inform the local health authority.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Public relations and advertising are not separately defined and there are no special rules for public relations activities.

Who is responsible for the enforcement of these rules?

The Argentinean Health Authority (ANMAT) and the National Communication Entity (ENACOM), together with the Undersecretary of Consumer Defense, are legally responsible for the enforcement of these rules. Private ethical codes are mandatory for chamber members.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

According to Camara Argentina de Especialidades Medicinales (CAEMe) Ethical Code 6.1, 'Delivery of promotional items (also called merchandising or gimmicks) for the purpose of serving as product brand and/or company logo reminder,' is allowed, but the promotion items must be related to the area of medicine or pharmacy and/or be beneficial to patients. Promotional items given at events must also be related to the scientific and/or medical activities relevant to the heathcare professional (HCP) they are given to. The Code also states that 'promotional and medical utility items should not be provided on a frequent basis to the same recipient and they must have a minimal and modest value'.

Pharmaceutical companies may hire HCPs for 'the provision of advisory or consulting services such as lecturer or moderator at meetings, training activities, expert meetings, etc., where such participation involves the payment of remuneration and/or expenses related to the provision of the service' (6.8). The following provisions must be followed in order to contract an HCP

(individually or as a group):

- Clear identification of a legitimate and genuine need for these services in advance of requesting the services and entering into agreements with the prospective consultants.
- Prior to the provision of these services, existence of a written agreement specifying the nature of the services to be provided and the fees to be paid.
- The hiring of healthcare professionals should not be an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicine.
- The agreement must include a provision pursuant to which the healthcare professional commits to state, in a clear and express manner, that he/she provides services to the company, whenever he/she makes a public statement about an issue that is subject matter of his/her agreement with the company.

The Code states that companies should appoint a qualified employee to be in charge of Code compliance.

Who receives concerns and complaints? How does this process operate?

The Supervisory Committee is responsible for investigating any complaints filed regarding promotional activities that do not adhere to the Code. After a complaint is made, the Supervisory Committee performs an investigation. After the investigation, the committee will put forth penalties, which the Board of Directors will ratify or rectify as it sees fit.

What promotional or media materials must be approved by authorities?

OTC advertising is controlled post publication/broadcast by the Monitoring and Control of Advertising and Promotion of Products Subject to Health Surveillance. In 2005, the 'prior authorisation' system was repealed, so pieces are monitored and evaluated once they are issued. Also, any communication with medical professionals or pharmacists related to prescription-only medicines to be published in print or broadcast media needs approval from the programme mentioned above.

What are the most recent significant developments in regulations, and are there planned changes to codes of conduct and regulations in the next few years?

The most recent development is Resolution No. 627/2007, which regulates the promotion of prescription medicines to medical professionals. It discourages and sanctions 'promotional practices' that may motivate medical doctors to prescribe one product in place of another as a result of marketing activities and not based on scientific reasons.

The local regulatory authority (ANMAT) is working on a new guide of recommendations and regulations for the promotion of prescription medicines, including topics like sponsorship, communication in media and websites. The document is in development and is being discussed with the different chambers that regulate pharmaceutical companies in Argentina.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

In broadcasting, promotional activity or advertisement is defined as 'the transmission of any announcement, made as a result of payment or exchange, to generate consumer interest in the acquisition of the products or services offered'. Annex IX of ANMAT Disposition No.4980/05 defines advertising as 'an organised technique applied through general media to inform or promote features, benefits or qualities of goods or services in order to provoke and obtain its purchase'.

Advertising is also classified as the promotion of people, services, goods, activities or organisations in such a way that exhibits a direct or indirect commercial aim (Section 3, Decree 286/81). Nevertheless, there is no clear line between promotional activities and what is usually presented as 'provision of information' for educational purposes. Promotional activity to medical professionals, according to Resolution No. 627/2007, Section 4, should include:

- Essential product information, such as generic and commercial names, composition, pharmaceutical form, indication, contraindication, adverse effects and product dosage information
- The prescription regime and sales conditions.

Per Resolution 6516 of 2015, manufacturers of prescription-only medicines must notify ANMAT the promotion of products for health professionals and attach the corresponding promotional communicational piece in the format that it will be released (http://www.anmat.gov.ar/boletin_anmat/BO/Disposicion_6516-2015.pdf). In the past, this Resolution applied to OTC products, but Resolution 9660 in 2016 invalidated notification in the products. (http://www.anmat.gov.ar/boletin_anmat/BO/Disposicion_9660-2016.pdf)

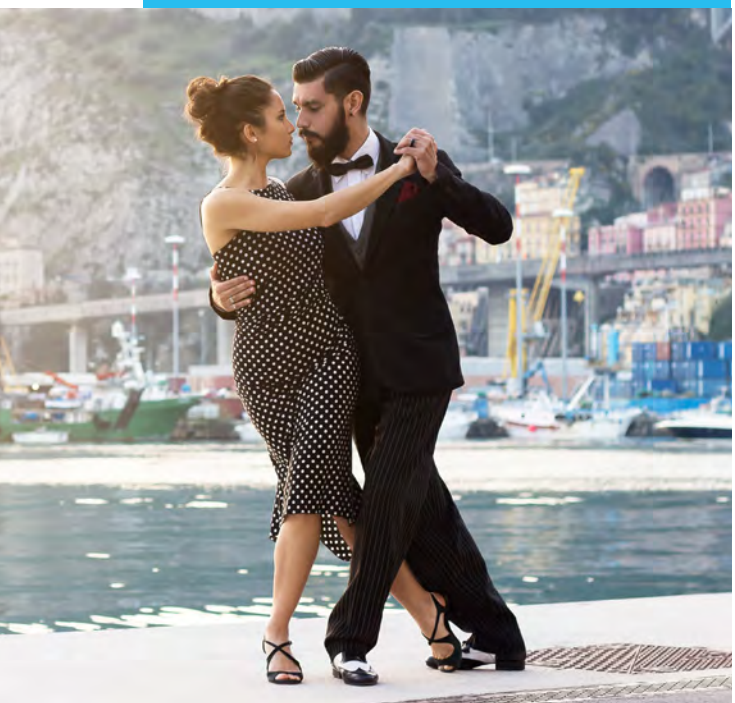
How is a media event defined?

There are no legal provisions regarding media events for medicines promotion as a distinct entity.

Do the regulations differentiate between consumer and clinical publications?

Resolution No. 627/2007 in Section 6 establishes that promotional materials for medical professionals should not be accessible to the general public in any format such as magazines, books or audiovisual media including CDs, DVDs or memory sticks. Sections 9° and 12° state that prescription medicines should only be promoted through media targeted to people who are qualified to prescribe or deliver medications.

However, since there is not a 'Press Law' or anything similar in Argentina, there are no regulations aimed directly at the content of publications. This situation is of special relevance because in the case of publications directed at medical professionals, the editors are the



ones who regulate and limit information access to the general public.

Do regulations differentiate between print and broadcast media?
No, they do not.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?
Both the CAEMe Ethical Code and Resolution No. 627/2007, Section 3, forbid the promotion of a medication that has not been approved by ANMAT for its commercialisation.

Nevertheless, there are no objections by law to communicate scientific and technical information about medicines in ongoing clinical trials at professional educational events if they are based on scientific investigations and publications.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
There are no specific regulations governing press releases or media materials, nor media attending clinical events.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
No reference is made to the distribution of press releases and media materials.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
There are no rules about how the press should cover these kinds of congresses and meetings.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
The copy should be independent. Journalists who work for a media outlet are subject to the ethical code or principles established by the employer. In general, reports are owned by the publication itself or occasionally by the journalist. Because of that, the content is not under the control of the sponsor company. The AMA´s Ethics Code rules under sections No.383 and No. 384 state that it is a serious breach of professional standards—related to health news dissemination—to make claims or exaggerated results about a therapy that has not been verified through scientific methods.

In the same way, it is a serious breach of professional ethics to lead people to self-medicate under the guise of imparting objective information.

Do regulations cover the use of case studies or other third-party advocacy in the media?
No specific mention is made.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

Law No. 26032 specifies that research, reception and dissemination of information and ideas through the internet is legally considered within the framework of the freedom of the press. Responsibilities are established in the civil and penal code as if it were a print newspaper. However, as is stated in Section 11 of the Ethics Code for the Promotion of Medicines, scientific information should only be accessible by professionals.

Although Law No. 16463 prohibits any direct promotion of prescription-only medicines to consumers, scientific information online is not restricted only to healthcare professionals. It can also be available to consumers without restriction and without including any kind of advertising claim.

What levels of web security are required?

The promotion of medicine or medical practices through the web is limited under Resolution No. 627/2007 of the Department of Health and the Ethics Code, which requires that it must be stated in a very noticeable way that the information is designed for professional use only.

However, non-governmental organisations (NGOs) supported by scientific institutions and professional groups usually have a process of monitoring such websites to evaluate quality and assess if they fulfil the principle of separating professional information from patient information. The use of the mark of approval (WMC) is considered certification of quality.

Do the regulations cover funding of, or provision of information to, non-company owned websites?

Websites are expected to comply with what is stated in the Medicines Law. In terms of advertising funding, Article 37 orders the prohibition of any kind of public advertisement of medicine products that have to be sold under written prescription.

What are the most popular social networks in your region?

Social media has achieved widespread penetration in Argentina: as of 2018 it is estimated that 70% of the population (31 million) are active users who, on average, spend three and a half hours a day on social media sites or apps. YouTube and Facebook are the most popular channels. In Argentina, it is estimated that 68% of active Facebook users connect daily. Regarding the number of followers, Twitter ranks third, slightly above Instagram, which has experienced strong growth in recent years.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

While there are no rules about social media, the CAEMe Code states that "Whenever a member company finances, ensures, or directly or indirectly organizes the publication of promotional material and/or information in newspapers, magazines, radio, television and any other social communication media, it should be expressly stated that such material and/or information is not presented as an independent editorial topic, and the sponsoring company should be included in a visible place," (5.1).

Are there any self-imposed regulations from social media companies?

There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

For OTC products, content in forums, including interaction between the company and costumers, must respect ANMAT Disposition No. 4980/05. These interactions can never involve the commerce of medicines.

For prescription-only medicines, any kind of promotional direct interaction between the company and patient is forbidden, according to Article 19, including Law No. 16463 that states, 'it is prohibited any public announcement of medicines whose retail sale condition is authorised only by prescription'.

What is mobile adoption like in your region? Are there separate regulations for it?

More than 30 million Argentinians have mobile phones and 84% of those users have smartphones. By 2019, more than 32.9 million will have mobile phones, when the penetration rate will be 73.0%. The main use of mobile is for instant messaging (WhatsApp and Facebook messenger).

There are no separate regulations for mobile.

What are the disclosure laws like in your region for non-branded websites?

There is not a specific regulation from ANMAT. Websites developed by pharmaceutical companies with health information or information on specific diseases that do not mention commercial brands or include any symbol that could identify the brand are considered disclosure of scientific or technical information.

What is the response level needed for adverse event reporting?

Resolution 706/93 of the Ministry of Health implemented the National Pharmaco Surveillance System, a formal mechanism that bases its work on spontaneous, voluntary and confidential reporting of adverse reactions by health professionals. The Pharmaco Surveillance System depends upon the National Direction of Medical Evaluation (DEM). Its aim is the detection, assessment, understanding and prevention of adverse effects and other problems related to drugs.

One of the main regulatory concerns is that pharmaceutical companies quickly report serious or unexpected adverse effects of their drugs and that they regularly report mild to moderate adverse events, mainly for products with less than five years on the market. In

regards to working with health professionals, the task is focused on growing the network of peripheral effectors in the link with medical associations, pharmacists and so on. It also works closely with international bodies involved in adverse event reporting, especially with the Collaborating Center of the World Health Organisation (WHO), located in Uppsala, Sweden.
The release of information is a key activity for the maintenance of the Pharmaco Surveillance System. In Argentina, information is released through the ANMAT website (www.anmat.gov.ar) and Newsletter for Professionals, which features letters to professional associations like the Argentinean Pharmaceutical Confederation (COFA) and Argentinean Medical Confederation (COMRA). Specific cases are also published in national and international medical and scientific journals.

Reports of adverse events can be done by courier (Av. de Mayo 869, piso 11°, CP AAD1084, Buenos Aires, Argentina), e-mail (snfvg@anmat.gov.ar) or by filling out the form listed on the ANMAT website.

ANMAT's Pharmaco Surveillance Department can receive both internal and external information. There are four possible external suppliers of information:

- Peripheral notifiers: hospitals, universities, etc., that signed an agreement with ANMAT.
- Particular notifiers: healthcare professionals, including physicians, pharmacists, dentists and nurses, from public hospitals, private institutions or private offices, that detect adverse events and directly report to ANMAT.
- Consumers: patients who, either by themselves or through consumers associations, send their reports.
- Pharmaceutical industry: through ANMAT Dispositions No. 3870/99 and 2438/00, the pharmaceutical industry is included in the National Pharmacovigiliance System (SNFVG), and it must report serious or unexpected adverse reactions of its drugs according to terms stablished in Disposition 5358/12. Those reactions that are not classified as serious or unexpected must be periodically communicated, always indicating that events are reported in Argentina.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

Regulations do not refer specifically to advocacy/patient groups, but the fact that the legal framework does not allow direct-to-consumer promotion of prescription medicines needs to be taken into account.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

There are no regulations regarding honoraria for healthcare professionals or advocacy organisations as payment for their collaboration in media activities or events. The AMA Ethics Code accepts that medical doctors sometimes work as employees for pharmaceutical companies and, as such, will participate in promotional activities of the company.

But in that case, the code suggests they should not actively practice medicine at the same time.

Regarding travel outside Argentina, the CAEMe Ethics Code does not allow companies to pay honoraria to professionals for their time nor organise or sponsor an event for health professionals out of the country, with exceptions. International meetings and symposia abroad to be attended by professionals from different countries are permitted to be sponsored, with restrictions.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Resolution 627/2007, Section 16° allows companies to offer funding or scholarships to healthcare professionals in order to participate in congresses, seminars and scientific meetings. Companies must publicly inform, in advance, the conditions of access to those funds or scholarships and the selection process of applicants, with fair and transparent mechanisms for granting. It is expressly forbidden to prescribe certain drugs or products for such purposes.

CAEMe specifies that sponsorship is limited to travel expenses, accommodation, meals and fees. Paying for the time dedicated outside of the meeting or encouraging the prescription of particular drugs through payment of expenses is strictly prohibited.

What is possible in terms of media or message training for health professionals or advocacy organisations?

There are no specific rules.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

Section 11° of Resolution No. 627/2007 states that all information about a medicine issued by the producing company must be exact, verifiable and updated.
The pharmaceutical company must allow access to referenced bibliographical material to any professional who may require it.

Although it is not specifically expressed, it is ethical that materials issued from a pharmaceutical company on behalf of third parties should disclose the involvement of the company.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

There are no legal restrictions.

KEY TAKEAWAYS/ SUMMARY

Locally, the major pharmaceutical companies, both in terms of revenues and sales, are Argentinean. In Argentina, the pharmaceutical industry represents an annual market of $500 million U.S., in which the share of that market is 69.5% for national companies and 30.5% foreign. The two companies that lead the local market are from Argentina and were founded more than 70 years ago as family businesses (Laboratorio Roemmers and Laboratorios Bagó). They also have an established presence in several other countries but are focused mainly in Latin America. Unlike other Latin American countries, the local pharmaceutical industry in Argentina has shown an important growth during the last 10 years with the introduction of technology. The industry mainly develops with local technology news and innovative pharmaceutical forms, some of which are also licenced in other countries.

Many top worldwide pharmaceutical companies make important local investments in clinical research. Argentina participates with prestigious centers in several multicentric clinical trials.

Pharmaceutical companies are gathered in Argentina are members of several chambers:

- Argentine Chamber of Medical Specialties (CAEME): gathers international companies. See http://www.caeme.org.ar.
- Industrial Chamber of Argentinean Pharmaceutical Laboratories (CILFA): includes main national pharmaceutical companies. See http://www.cilfa.org.ar/.
- Business Chamber of Pharmaceutical Laboratories (COOPERALA): includes national pharmaceutical companies. See http://www.cooperala.com.ar/.
- Argentinean Chamber of Non-prescription medical Specialties (CAPEMVeL): includes both national and international companies with OTC products in their portfolio. See http://www.capemvel.org.ar/.
- CAPGEN: Argentinean Chamber of Generic Drugs and Hospital Drug use manufacturers. See: http://www.capgen.org.ar/

Social Security services are represented by Obras Sociales and medicine plans that provide affiliates with a discount in the purchase of medicines, medical attention and diagnostics that by law (Plan Médico Obligatorio, PMO) cannot be less than 40 percent. PAMI is the National Social Security System for retired people who are older than 65 years and plays a key role in the local market. The Argentinean public health system provides free medical assistance in public hospitals and free distribution of certain medicines for people not affiliated to social security services. The Programme REMEDIAR freely distributes ambulatory medicines in Prime Care Health Public Centers.

Different actors are now discussing the need of having a medical technology assessment agency. The project is already being discussed in Parliament and the new agency is expected to be functioning in Argentina in the next two years.

Regulatory bodies in Argentina are contemplating patent protection but nothing has been implemented to date. The local environment of the pharmaceutical industry is very competitive. Leading innovation companies face a strong competition from generic drug-producing laboratories. These companies invest few resources in research and development and benefit from the production of drugs whose patents have expired or from drugs without patent protection. In general, their prices are lower as they do not have to deal with the cost of large structures.

Since 2002, Prescription of Medicines by Generic Name, Law No. 25.649, states that every medical prescription must be written expressing first the generic name of the drug, then the pharmaceutical form, then the number of units and the drug concentration. Pharmacists must inform consumers of the availability of every commercial brand containing the same drug, same amount of units and same concentration, and the different prices of each product. Changing of the drug prescription by the professional is not permitted.

BRAZIL

The Agência Nacional de Vigilância Sanitária (ANVISA) is an independently managed and financially autonomous governing agency that acts as Brazil's sole regulator of the manufacturing and distribution of prescription medicines. Advertising prescription medicines by any means that promote the medicine's name is strictly prohibited and enforced by ANVISA.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

In Brazil, the regulating body for medicines and food, inside the Ministry of Health is ANVISA. Advertising of prescription medicines to the public is prohibited. Advertising campaigns are allowed only for over-the-counter (OTC) medicine that needs no medical prescription. ANVISA also restricts medical congresses, meetings and events, from distributing product samples if it is a prescription or controlled medicine. Promoting a company's or pharmaceutical laboratory's name, however, is allowed.

As medicine advertising becomes extremely controlled, this factor is making the relationship with physicians and health professionals increasingly restricted and difficult.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

In Brazil, public relations and advertising activities are separate. Public relations efforts are the sole communication element with the pharmaceutical market for prescription and controlled medicines. The sector has specific regulations for the relationship with the market, and ANVISA has created rules for it. A communications plan may be interpreted by ANVISA in several ways, therefore, the work of public relations agencies specialised in health is key, because they know the market and its legislation well. Poorly planned communication actions may result in severe fines from the regulating body.

Who is responsible for the enforcement of these rules?

Technical areas, consultants, external advisors and ANVISA experts are responsible.

What are the regulations regarding healthcare professionals engagement by pharmaceutical companies? How are these regulations enforced?

Engagement with HCPs is strictly regulated by the ANVISA code prohibiting promotion of prescription medicines. As mentioned, HCPs cannot be provided with any branded materials, even while at medical conferences. As such, it is very difficult to establish effective partnerships with the HCP community.

Who receives concerns and complaints? How does this process operate?

ANVISA has a call center service for consumers to report any kind of event or complaints about food, pharmaceutical products or health devices. Denouncements will be investigated and the agency may apply fines, interrupt operations, shut down establishments, withdraw products from the market and prohibit imports and exports.

What promotional or media materials must be pre-approved by authorities?

It is not mandatory to send public relations materials for previous analysis or approval by ANVISA, but they need to get the agreement from the company's health professionals or responsible areas before being published. It is rare for companies to consult the regulatory agency.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

In 2000, ANVISA created a resolution/ordinance to regulate publicity/advertising/promotion activities for medicines and rules governing the creation of advertising materials for medicines manufactured and/or marketed in Brazil. Since then, this ordinance has undergone several updates. In a 2011 ordinance, the agency communicated plans to regulate public relations actions, pharma and public relations professionals must comply with all of these rules.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

As advertising for prescription medicines is not allowed, in general, it is very easy to make a distinction between basic information and advertising.

How is a media event defined?

Two ways:

1. Awareness situations, and support to medical societies and for the government.
2. Introduction of new products under an ethical positioning, with no promotional actions or actions that state that the product is the best or the most revolutionary in its segment. The focus of the actions is to always emphasise the scientific information.

Do the regulations differentiate between consumer and clinical publications?

Yes, because the materials have different purposes. The promotional material is exclusive for physicians. In this case, ANVISA is even more attentive about these materials. Overall, the content carries information of the label and clinical trials.

Do regulations differentiate between print and broadcast media?

No, the regulation is the same for all media outlets, including newspapers, magazines, radio, television or the internet.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

There are no specific rules in place for these events. public relations agency recommendations can include specific actions with journalists, such as press conferences and workshops in a separate setting from medical events.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

While Brazil has restrictive regulations, there are no regulations specific to press releases and media materials. The laboratories' compliance departments and public relations agencies will follow the general rules that govern the issue or production of scientific and information materials that are appropriate for each type of audience and event to be carried out.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

In these cases, when publications receive press releases from the international agencies, they tend to reproduce them, and in some cases they do not follow ANVISA's rules. However, when the Brazilian PR agencies receive press releases sent by their clients from abroad, they tend to tailor them to local style.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

There is no specific regulation, but the rules already determined by ANVISA are followed. Companies can sponsor actions and events, except for the media, and they cannot use the medicine's brand name if it is a prescription or controlled medicine. For OTC medicines, sponsorship activities are allowed if ethical standards are observed.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?

There is no difference for employed journalists or

freelancers in Brazil. Neither must they submit their reports either to the regulating agency or to the inviting company. The decision about whether a journalist may or may not accept an invitation from laboratories remains with directors, editors or editors-in-chief, or the journalist if he or she is a freelancer. Accepting an invitation does not obligate the journalist to write a report, either favourable or unfavourable, for the laboratory. The writer is free to decide.

Do regulations cover the use of case studies or other third-party advocacy in the media?

Patients' groups are free to talk to the media on their own, and they can organize such actions independently. Officially, pharmaceutical companies and physicians are not allowed to encourage patients to talk about medicines. If a journalist needs to talk to a source, he or she must find interviewees independently or ask the patients' associations throughout the country.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

An important phenomenon has been found to occur in the healthcare area in Brazil, different from other countries. A recent survey coordinated by Tino Comunicação and conducted by Ibope (a major market research institute in Brazil) has found that Brazilians search for information about prevention, treatment and diseases on the internet, even before seeing a physician. As opposed to other media, there are no clear rules in place for the social networks. However, in general pharmaceutical companies and public relations agencies will follow the rules already established by ANVISA for other types of media.

What levels of web security are required?

There are no specific regulations regarding web security; however, it is recommended that companies develop PR strategies to respond to potential crises related to their websites and social media channels.

Do the regulations cover funding of, or provision of information to, non-company owned websites?

ANVISA has no specific regulation for the internet yet. As any kind of advertising involving prescription medicines is prohibited, the pharmaceutical companies cannot have portals, websites or blogs that showcase ads with the medicines' brand names. However, on sites, blogs and independent media outlets that have no connections with companies, one can post comments and information, provided that it is done in compliance with the local legislation. The Federal Board of Medicine (CFM) has created specific rules for physicians on the internet. Health professionals are not allowed to promote themselves or medicines, clinics, hospitals or any healthcare-related commerce. If they do, they are subject to the board's sanctions.

What are the most popular social networks in your region?
In Brazil the most popular networks are Facebook, Twitter and LinkedIn. There are many bloggers in beauty, cosmetics and healthcare and quality of life that comment on these subjects openly.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Brazil has not yet passed legislation that regulates the use of the internet. This issue is still under discussion. Each new situation is analysed under existing laws or regulations of agencies such as ANVISA.

Are there any self-imposed regulations from social media companies?
There are no specific self-regulations from social media companies related to healthcare beyond their general terms of service.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Yes, for prescription and controlled medicines. The company cannot have a direct relationship with the consumers to talk about this kind of medicine. However, a direct relationship may be established to talk about the disease and awareness.

What is mobile adoption like in your region? Are there separate regulations for it?
As of 2017, there were 242 million mobile phones in Brazil. However, there are not specific regulations for mobile devices.

What are the disclosure laws like in your region for non-branded websites?
Non-branded websites have to show who initiated and supports them.

What is the response level needed for adverse event reporting?
Pharmaceutical companies, hospitals and other organisations have pharmacovigilance services in place that report to ANVISA. The Brazilian agency also carries a direct service for the population and the industry for reporting irregularities and denouncements.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

The industry can have relationships with patients, but they must be restricted to informative and scientific initiatives. Sponsorship to non-governmental organisations (NGOs) or patient associations is legitimate provided that they comply with ANVISA's ordinances. Patient associations and NGOs have total freedom, even if sponsored.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

In Brazil, it is not common and not advisable to offer fees for physicians and patients to meet with the press. It is allowed, though, to pay a fee for physicians if they participate in media trainings for journalists or lectures, workshops and courses for other healthcare professionals.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

The industry can support meetings and patient associations to participate in events, covering tickets, lodging and meal expenses, but they cannot be paid to participate in any action. This is restricted to awareness actions and campaigns, which are meant to be informative, educational or scientific, never mentioning the product's name. Physicians, however, can receive a fee when participating in this kind of action.

What is possible in terms of media or message training for health professionals or advocacy organisations?

Companies are allowed to conduct media training, speaker training, and message training sessions and awareness events and the like, always bearing in mind the educational, informative or scientific objective.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

The rules are the same as for the pharmaceutical industry. Patient associations and NGOs have more freedom to discuss with patients, society and the government about new treatments and the inclusion of medicines than the pharmaceutical companies.

These associations play a key role in access to high cost medicines. It is often through these associations that patients get access to high cost medicines, since the Brazilian Constitution ensures universal right to health.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

ANVISA states that there can be no advertising or action that involves prescriptions or controlled medicines. Pharmaceutical companies, patient associations, NGOs and reputable healthcare services vendors, such as public relations agencies, will already know ANVISA's regulations, and take them into consideration before creating any kind of action.

KEY TAKEAWAYS/ SUMMARY

- The regulatory environment in this market is highly controlled. ANVISA has technicians who constantly watch the market and its movement.
- Media training, speaker training, message training sessions and awareness events are permitted, always bearing in mind the educational, informative or scientific objective.
- The industry is free to develop relationships with patients, but interactions must be restricted to information and scientific initiatives.

CANADA

In Canada the promotion of medicine falls under the jurisdiction of 'The Food and Drugs Act and Regulations' and the 'The Distinction between Advertising and Other Activities' policy. Promotion of drugs prior to approval is prohibited, while the promotion of a prescription drugs to the general public is limited to name, price and quantity. Regulations clearly differ between consumer and clinical publications. There are no formal regulations pertaining to healthcare provider (HCP) engagement by pharmaceutical companies;however, each company has its own internal rules and regulations.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

- **The Food and Drugs Act and Regulations:** An act of the Parliament of Canada regarding the production, import, export, transport across provinces, and sale of food, drugs, contraceptive devices and cosmetics (including personal cleaning products such as soap and toothpaste). First passed in 1920 and most recently revised in 1985., the Act attempts to ensure that these products are safe, that their ingredients are disclosed and that drugs are effective and are not sold as food or cosmetics. It also states that cures for diseases listed in Schedule A (including cancer, obesity, anxiety, asthma, depression, appendicitis, and sexually transmitted diseases), cannot be advertised to the general public.
- **The Distinction between Advertising and Other Activities:** This policy was created by Health Canada to clarify the distinction between advertising to promote the sale of a drug and activities that are not primarily intended to promote the sale of a drug (e.g., education, scientific exchange, labelling, shareholder's report, etc.). This policy is NOT intended for use in determining whether or not the drug advertising provisions of the Food and Drugs Act and Regulations are observed.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

There are numerous provisions within the Food and Drugs Act and Regulations that apply to drug advertising. In order to determine the applicability of those provisions it is first necessary to determine whether or not a particular message can be considered to be advertising. For the purposes of the Act, advertising is defined as including 'any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device'. If a message regarding a drug is not considered to promote sale or disposal, it is not subject to the advertising provisions of the Food and Drugs Act and Regulations.

There is a particular need to distinguish between advertising and non-promotional information in the following situations:

Prior to market authorisation:

- Promotion of a drug prior to market authorization is not permitted (Section 9(1) of the Act, Section C.08 002 of the Regulations) because the terms of such authorization have not been established and the proposed indication(s) for use have not been verified.

After market authorisation when information on a drug is disseminated to the general public:

- Promotion of a prescription drug (Schedule F) to the general public is limited to name, price and quantity (Section C.01.044 of the Regulations).
- A drug (prescription or nonprescription) may not be advertised to the general public for the treatment, prevention or cure for any Schedule A disease (Section 3 of the Act).

Who is responsible for the enforcement of these rules?

Health Canada is the federal department of the Government of Canada that is responsible for national public health. Health Canada is the national regulatory authority for health product advertisements.

What are the regulations regarding HCP engagement by pharma companies? How are these regulations enforced?

Continuing medical education (CME) events and scientific symposia related to drugs are sometimes sponsored by pharmaceutical manufacturers.

Such activities may not be considered advertising when they provide a forum for exchange of information on related clinical and scientific issues. The key factor in determining the status of such an activity is the degree to which the programme is independent of the drug manufacturer. The information may be not promotional in the following circumstances:

- Sponsorship by a drug manufacturer is not targeted to specific aspects of the agenda
- The sponsor's role is adequately disclosed
- The programme is directed to scientists and/or health professionals
- The programme allows for exchange of information/ debate
- The content of the agenda is not influenced by the sponsor
- The content of an individual presentation is not influenced by the sponsor where it concerns a drug manufactured by that sponsor
- There is no inducement provided to participants
- There are no ancillary commercial or promotional activities relating to drug products
- The limitations of the data and of the drug are adequately discussed
- Discussion of an unauthorized drug or indication for use includes a statement indicating that the drug/indication has not been authorized for marketing in Canada, and
- No reference is made to the availability of unauthorized drugs through the Special Access Programme.

Such activity may be considered advertising when any of the aforementioned conditions are not met or where other factors indicate that the primary purpose of the activity is to promote the sale of a specific drug. Moreover, reports, edited scripts or recorded videos of the proceedings, in whole or in part, that concern a specific drug may be deemed advertising if they are disseminated by the sponsor, or the sponsor's agent, to a wider audience after the meeting.

While there are no formal regulations related to pharmaceutical companies, engagement of HCPs for media purposes, each pharmaceutical company has their own internal rules and regulations that govern these relationships. During the past few years, the industry has come under increasing pressure to voluntarily divulge how much funding they provide to physicians and health organisations annually. So far, 10 Canadian-based pharmaceutical companies have agreed to disclose this information in an effort to make their financial ties more visible – and help neutralise charges of conflict of interest.

Who receives concerns and complaints? How does this process operate?

Heath Canada receives concerns and complaints. When addressing advertising complaints, Health Canada's first priority is protecting the health and safety of Canadians. Health Canada's approach to addressing and resolving complaints uses the most appropriate level of intervention proportional to the health risk.

All complaints are treated with the same vigilance, whether Health Canada identifies a potential advertising issue itself, receives a complaint directly or is referred a complaint from an Advertising Preclearance Agency (APA). Each complaint is asked to confirm whether the advertisement complies with legislative and regulatory requirements and to determine the potential health risk posed. Health Canada prioritises and takes action to address complaints based on whether they pose a potential health risk and the degree of that risk.

Health Canada takes a staggered approach and will escalate measures if and as needed. In most cases, compliance is successfully achieved using a cooperative approach. This involves Health Canada informing the party of their non-compliance, usually through a compliance letter. The letter may request corrective action or discontinuation of the advertisement.

In general, for advertising activities considered to pose a low health risk to Canadians, the company is informed

of the non-compliance and asked to take the appropriate corrective measures. In cases where the health risk is higher, Health Canada follows up as needed to verify that the requested action has been completed to Health Canada's satisfaction.

Health Canada may consider stronger action for advertising activities determined to pose a high health risk. These actions could include seizing the non-compliant advertising materials, site visits, issuing a public communication, or initiating enforcement proceedings (e.g., seeking an injunction or fines where a court order has been breached), to minimize the potential health risk to Canadians. For complaints that involve the advertising of an unauthorised health product, Health Canada takes action to confirm that the company stops both the advertising and sale of the non-compliant health product in Canada, as the sale of unauthorised health products is not permitted.

What promotional or media materials must be pre-approved by authorities?

Materials developed by pharmaceutical manufacturers directed at Canadian healthcare professionals for the purpose of advertising or promoting a product to increase their awareness of that brand should be reviewed by the Pharmaceutical Advertising Advisory Board (PAAB).

Materials directed at consumers should be reviewed by Advertising Standards Canada (ASC), a national not-for-profit advertising self-regulatory body. Note: both PAAB and ASC approvals are voluntary. However, Health Canada strongly recommends that industry have their health product advertising material reviewed before dissemination.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

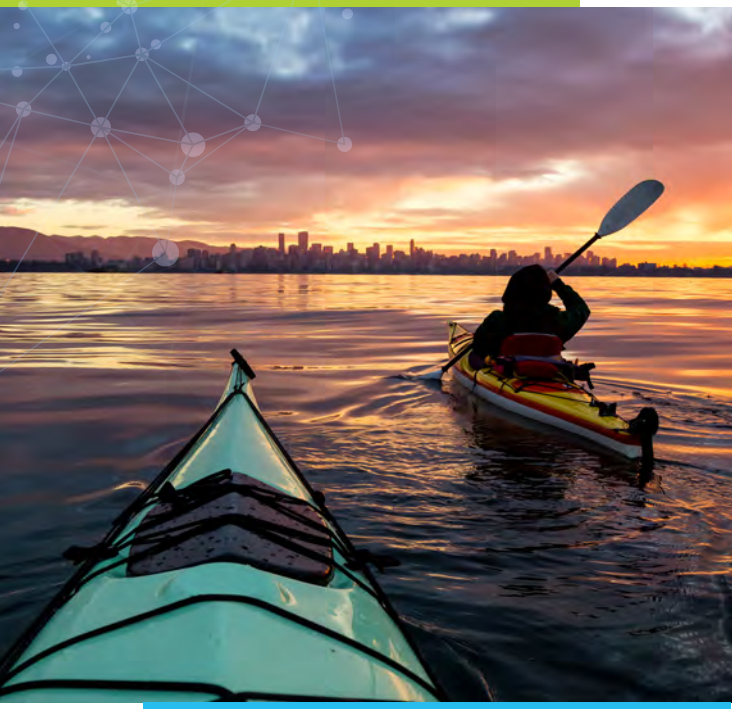
In early 2017, ASC issued new rules that will require full disclosure by sponsored bloggers and influencers of any paid endorsements or mentions of products and services. These new rules apply to bloggers and individuals who use social media--including Twitter, Instagram, Facebook and Snapchat.

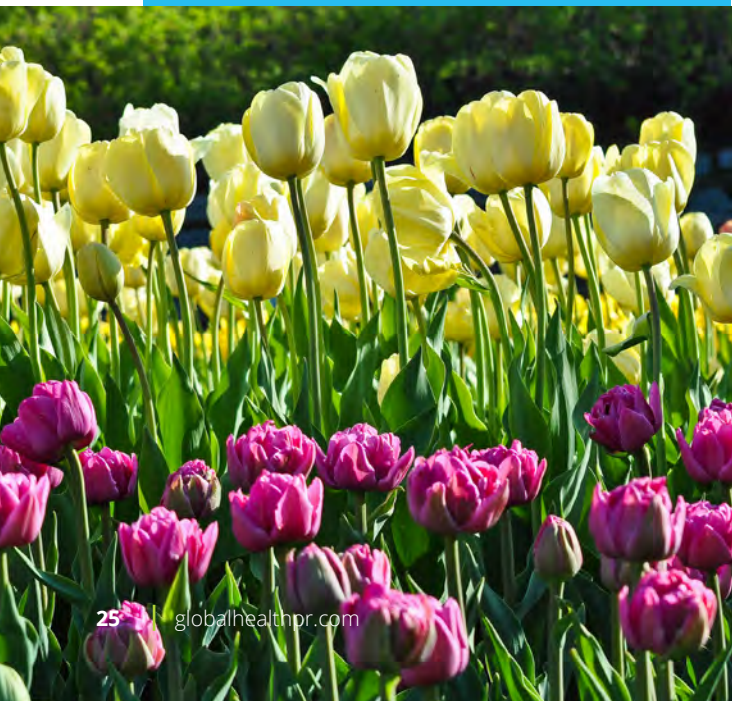
THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

To determine if a message is advertising, the purpose of the message is very significant. It must be determined whether the primary purpose of the message is to promote the sale of a drug or to provide information. When the primary purpose is not clear, the following factors should be considered in determining whether the message is primarily intended to promote the sale of a drug:

- What is the context in which the message is disseminated? For example, when and how is the message delivered? What is the milieu or medium of dissemination? Is it a science-based message delivered to scientists/healthcare professionals by an expert, e.g., researcher at a conference with a varied agenda, or is it a product-related message delivered to a





group of practicing physicians by the pharmaceutical manufacturers sales representative at a meeting with a limited agenda?

- Who are the primary and secondary audiences?
- For example, are the target audiences limited or unlimited in scope? Are the primary and the secondary audiences the same? Where they are different, the message to the secondary audience is more likely to be advertising.
- Who delivers the message (the provider)? e.g., the drug manufacturer/its agent or an independent third party (e.g., patient support group)? Where delivered by an independent party, the message is less likely to be considered as advertising.
- Who sponsors the message and how? Is it the drug manufacturer/its agent or an independent third party? is the sponsorship funding targeted to a specific message, or is it added to the general operating budget for an organisation, conference etc.? If the message is sponsored by an independent third party and the funding is added to the general operating budget, the message is less likely to be advertising. Where any fee is paid by the manufacturer to have the message disseminated, it is more likely to be advertising.
- What influence does a drug manufacturer have on the message content i,e, what are the linkages between the information, the provider and the manufacturer, the provider and the writer, etc.? Where the drug manufacturer exerts influence (e.g., preparing, editing) on the message content, it is more likely to be advertising.
- What is the content of the message? Are the facts described objectively in a balanced manner, or is emphasis placed n a particular drug or its merits? Is the message balanced with respect to description of risks as well as benefits of a treatment option? Can the message withstand a test for scientific rigour? Is the information set in an appropriate context, e.g., a discussion of disease management, scientific research?
- With what frequency is the message delivered? For example, is it delivered once or repeatedly? Where the same message is delivered repeatedly, the message is more likely to be considered as advertising.

No one factor in itself will determine whether or not a particular message is advertising. Each message must be evaluated on its own merit and other factors may apply. This clarification should assist in distinguishing between advertising and non-promotional information. It is only after having determined that the primary purpose of a message is advertising that an assessment can be made regarding compliance with the regulations pertaining to drug advertising.

How is a media event defined?

An event to generate media attendance and interest in a particular issue and/or product.

Do the regulations differentiate between consumer and clinical publications?

Yes.

Consumer Publications

Consumer brochures include leaflets/brochures that may make reference to, but do not accompany, a drug product,

and are made available directly or indirectly to the consumer by a drug manufacturer, or other organisation, by various means, e.g., by mail, in retail outlets, in health professionals waiting rooms, and so on.
Declaration of sponsorship of such a brochure by a drug manufacturer does not in itself render the information promotional. Consumer brochures may be considered non-promotional information in the following circumstances:

1. The content is disease related rather than product related
2. The various treatment options (drug and non-drug) and their respective
3. No emphasis is placed on one drug product, e.g., excessive use of a brand name or description of a product as a "breakthrough", and no emphasis is accorded to the merits of one drug product
4. No reference is made to an unauthorised drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained),
5. No reference is made to the availability of unauthorised drugs through the Special Access Programme.

Consumer brochures may be advertising when any of the aforementioned conditions are not met, or where other factors indicate that the primary purpose of the publication is to promote the sale of a drug.

- Consumer brochures also include leaflets/brochures that are not product-specific but expound on the pharmacological properties/actions of an ingredient, e.g., herb, vitamin, mineral, etc., and are made available in retail outlets selling products containing the same ingredients.

Such information packages may be considered to be advertising for a drug product when displayed in close proximity to or distributed with products containing the same ingredient, in the same retail outlet.

Clinical Publications

Journal supplements are usually comprised of a collection of articles that deal with related issues or topics, are published as a separate issue of the journal, or as a second part of a regular issue, and are funded by sources other than the journal publisher, e.g., by the pharmaceutical manufacturer
Where publication is sponsored, in whole or in part, by a drug manufacturer, it may be considered not a promotional activity in the following circumstances

- The content of the insert comprises unedited symposium proceedings that address a variety of issues relating to different disease entities or drug treatments
- The content of the insert reports on a variety of treatment approaches for the same medical condition, the publication is targeted to its customary readership
- No link is established between conventional advertising and the articles, e.g., by proximity, sponsorship by the pharmaceutical manufacturer is declared in such a way that there is no obvious link to a drug discussed
- The supplement is identified in such a way that it is distinct from the regular journal edition

In contrast, a journal supplement may be advertising where the aforementioned conditions are not met and where other factors indicate that the primary purpose of the publication is to promote the sale of a drug, for example:

- the supplement, in whole or part, is disseminated by the sponsor rather than by the publisher of the journal itself, the publication or an article contained in it is edited by the sponsor, or
- a conventional advertisement is placed in close proximity to an article discussing an unauthorized use for the same chemical entity/drug product.

Do regulations differentiate between print and broadcast media?

No.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

According to the Distinction Between Advertising and Other Activities, promotion of a drug prior to market authorisation is not permitted (Section 9(1) of the Food and Drugs Act, Section C.08 002 of the Regulations) because the terms of such authorisation have not been established and the proposed indication(s) for use have not been verified.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

Press Releases/Press Conferences

It is common practice for a pharmaceutical manufacturer to release information on new developments in research and at the time of launch of a new drug or a new indication for use of a previously authorized product.

A press release or information disseminated at a press conference concerning a drug may considered not a promotional activity in the following circumstances:
the announcement is directed to shareholders or potential shareholders,

- The announcement is limited to the name of the drug and its authorized or proposed therapeutic use,
- No statement is made regarding the degree of safety or efficacy expected,
- No comparison is drawn with other treatments,
- in the case of unauthorized drugs, or unauthorized indications, the message cautions that the safety and efficacy are still under investigation and that market authorization has not yet been obtained
- There is no attempt to influence the placement or emphasis given in subsequent publication or broadcast, e.g., no payment is made by the manufacturer to influence the visibility (e.g., section) in the press.

- In contrast, a press release or information disseminated at a press conference may be advertising where any of the aforementioned conditions are not met, or where other factors indicate that the primary purpose of the message is to promote the sale of a drug.
- Undue emphasis is placed on the drug being a 'breakthrough'
- The press release is subsequently sent or provided to another audience, e.g., mailed to physicians,
- A fee is paid by the sponsor to have the message published or broadcast, or
- In the case of an unauthorised drug, it is indicated that the drug is available through the Special Access Programme.

Invitations to media events and clinical events are not treated differently. A journalist cannot be paid/compensated for their attendance, including travel, accommodation, and so on.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
No.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
In Canada, the regulations forbid sponsoring media to attend congresses and scientific meetings.
In the context of an international conference, display of a drug product prior to market authorisation in Canada, or a product that is labelled for a use that has not been authorised in Canada, may be considered not a promotional activity in the following circumstances:

- the conference must clearly be an international event, e.g., a significant proportion of the conference delegates are from other jurisdictions,
- the material must emanate from the parent company of the manufacturer,
- the material must only be for use within the confines of the conference, and
- the material is prominently identified as not being authorised for sale in Canada

If a company sponsors a journalist at a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
Pharmaceutical manufacturers are not allowed to sponsor journalists at scientific meetings. This is considered advertising since the manufacturer is paying the reporter's travel expenses, which could potentially to influence the journalist's story.

Do regulations cover the use of case studies or other third-party advocacy in the media?
No.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
No. They are not differentiated.

What levels of web security are required?
N/A

Do the regulations cover funding of, or provision of information to, non-company owned websites?
If funding for a website is provided by a pharmaceutical company, the website is subject to the regulations that govern pharmaceutical marketing. The Food and Drugs Act, The Distinction Between Advertising and Other Activities, and so on.

What are the most popular social networks in your region?
Facebook, YouTube, Twitter, Facebook Messenger and Instagram.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
In January 2013, the PAAB introduced a 'Guidance document for online activities.' There are four types of messages that may be posted (1.1):

1. Drug advertising
   - Must adhere to the same requirements as traditional drug advertisements.
2. Medical and disease information
3. Corporate information and promotion
   - Materials such as press releases, price lists and development pipeline information are not considered promotional. When a drug is mentioned, sponsors must 'align their discussions to the limits of drug advertising,' (1c).
4. Education and learning programmes
   - These are events or materials whose primary purpose is to better healthcare to Canadian patients (1d).

Are there any self-imposed regulations form social media companies?
No. The only social media regulations are the PAAB's.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
According to the PAAB's 'Guidance document for online activities':

- Terms and Conditions: The sponsor should provide in a clear and accessible manner the terms and conditions for users to engage in user generated content (UGC) on a sponsored site with clear

statements about what types of comments will be removed or modified. For example, a site may forbid any discussion of drug therapy and will remove any posts that include them.

- Monitoring the Conversations: Sponsors must monitor the UGC to ensure that compliance is maintained. An effective monitoring strategy can also assist in managing the risk to the sponsor that is inherent when the content is opened to users. To improve the effectiveness of the monitoring it is recommended that sponsors use a semantic, automatic filtering mechanism (e.g. brand key words, side effects) if the social technology supports it. Specifically, monitoring, and correction on the same site, is recommended for the following:
  1. Correcting misinformation: Users might post inaccurate information about a disease state or its treatment, the sponsor should monitor the UGC to correct any misinformation. Given the need for such corrections to occur in a timely manner, they may be made without PAAB pre-clearance provided content is limited to that which is required to address the misinformation. Caution should be exercised when correcting such misinformation as to ensure compliance with the regulations.
  2. Adverse event monitoring: As a complement to providing a statement referring reporters to the pharmacovigilance / medical department of the sponsor, it is recommended to include a reference for the reporting of adverse events directly to Health Canada and provide the relevant Health Canada web-site address and toll-free number.
  3. Off-label discussions: Discussions of a treatment that fall outside of the terms of marketing authorisation (TMA) can occur in UGC. As the sponsor is fully responsible for the content of the site (including the content created by the community) failure to address off-label discussions will render the site non-compliant. Off-label discussions must be removed outright.
- Ongoing Management of Interactive Content: All postings by users must be monitored as per the directives set out in corporate policies to that effect. Postings on company sites should be promptly triaged in accordance with the applicable corporate policy for determination of an appropriate response. Additionally, it is recommended that those individuals responding on behalf of the company receive specific training in the areas of adverse event monitoring and drug advertising.

As part of monitoring, online discussions postings that contain potential adverse event reports will need to be addressed according to established corporate policies and procedures for handling and reporting spontaneous adverse event reports. The Health Canada requirements, including follow up to obtain the necessary elements needed to report an adverse event, will need to be addressed when appropriate.

- Removal and Correction of Misinformation (including off-label discussions) When visitors post comments that are in direct violation with the site's Terms of Use (such as posts mentioning specific products) it is recommended that the sponsor develop a process for removing these posts should these contravene the rules for drug advertising. It is recommended that sponsors develop standard responses for when a post needs to be removed.
- Responding to Requests from Individual Users: Any product-related question from a user on a site not intended for product discussion must be responded to in a manner that is visible to the requestor only. In other words, the reply should not be made public. One-on-one correspondence is exempt from the rules of advertising. If a sponsor elects to respond to an individual user in a public forum such that all users can view the response, the drug advertising rules may be triggered.

Moreover, any request for information from a user for an unapproved product or for a use of a marketed product that is inconsistent with the TMA should be handled by the sponsor's medical information department.

What is mobile adoption like in your region? Are there separate regulations for it?
There are more than 20 million social media users that access social media via their mobile device. This makes up 55% of Canada's population. In total, more than 30 million Canadians have a cell phone. However, there are not distinct regulations for mobile phones and social media.

What are the disclosure laws like in your region for non-branded websites?
The websites sponsor is required to be disclosed on the site.

What is the response level needed for adverse event reporting?
According to CWTA, social media use is 23 million, with 63% active users, and 20 million social users accessing data through mobile application. More than 55% of the total population uses social media.

Manufacturers, healthcare professionals, and consumers can report adverse reactions to Health Canada and its partners. Depending on the product, reporting is either voluntary or mandatory.

STAKEHOLDERS /ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
There are no regulations around this. Each pharmaceutical company has their own policies and procedures which they follow.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Yes, it is possible to provide HCPs with honoraria to compensate them for their expertise and time away from their office. Many Canadian pharmaceutical companies have rules and have established monetary rates around how much HCPs can be compensated based on their specialty and level of experience. They can also be compensated for their travel and other expenses, however, companies also have individual rules around this as well.

For advocacy organisations, companies normally provide a grant. Yes, they can cover travel.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Yes, through an unrestricted grant.

What is possible in terms of media or message training for health professionals or advocacy organisations?
Media / message training is allowed for HCPs and advocacy organisations. However, it must be made clear that the messages/training are simply a guide, and they are not expected to say or do anything that makes them uncomfortable, or that would put them in a compromising situation.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisation?
According to The Distinction Between Advertising and Other Activities, patient support groups often publish information in the form of brochures/leaflets that are intended to promote a better understanding of a disease

and its treatment among members and potential members. It can be difficult to distinguish between advertising and educational information in this context.
Declaration of sponsorship of the brochure by a drug manufacturer does not in itself render the brochure promotional. Patient support group publications that include information on drugs may be an educational activity in the following circumstances:

- the content is disease related rather than product related, and the various treatment options (drug and nondrug) and their respective risks and benefits are discussed in an objective manner,
- no emphasis is placed on one drug product, e.g., excessive use of a brand name or description as a 'breakthrough', and no emphasis is accorded to the merits of one drug product,
- no reference is made to an unauthorised drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained), and
- no reference is made to the availability of unauthorised drugs through the Special Access Programme.

Patient support group publications may be advertising where any of the aforementioned conditions are not met, and where other factors indicate that the primary purpose of the publication is to promote the sale of a drug.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

There are no regulations that cover this.

KEY TAKEAWAYS/ SUMMARY

- If a message regarding a drug is not considered to promote sale or disposal, it is not subject to the advertising provisions of the Food and Drugs Act and Regulations.
- Promotion of a drug prior to market authorisation is not permitted. The promotion of a prescription drug (Schedule F) to the general public is limited to name, price and quantity (Section C.01.044 of the Regulations).
- Pharmaceutical manufacturers are not allowed to sponsor journalists to attend scientific meetings. This is considered advertising since the manufacturer is paying the reporter's travel expenses therefore, this could potentially to influence the journalist's story.
- If a website is funded by a pharmaceutical company it is subjected to the rules and regulations of The Food and Drugs Act /The Distinction between Advertising and Other Activities.
- Adverse Drug reporting is to be submitted to Health Canada and its partners. Depending on the product, this may be considered mandatory or voluntary.

MEXICO

Mexico does not have an official regulatory code for public relations in the health sector. Therefore, public relations activities must abide by the regulations that are in place for advertising. In recent years, there were changes were made to the Regulation of General Health Law in matters of advertising to create tools to avoid and discourage the proliferation of advertisements of the so-called 'miracle products', which offer fast or definitive cures without any scientific support, and irregular advertising in general.

These regulatory changes have contributed to decreasing the excess of publicity of products offering miracle cures with little or no scientific support for diseases with high prevalence rates in the country such as diabetes, obesity and pain. On the other hand, it also has contributed to regulating digital communication campaigns in the healthcare field, which had no appropriate regulation in the past.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The promotion of drugs is regulated by the COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios), which is part of the Health Ministry. COFEPRIS has specific regulations depending on the audience. There are rules for communications directed towards physicians, and other more strict regulations that address communication with consumers. Unlike countries such as the United States, it is forbidden to mention the brand name of any prescription medication, along with an explanation of what the product is for.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

All communication efforts are integrated under the umbrella of 'advertising' in Mexican law, without specific regulations for other marketing disciplines, such as public relations (PR). Generally speaking, this is what makes the use of PR in the pharmaceutical industry essential. The use of editorial coverage for the communication of messages (when advertising is so harshly restricted) is not against the law and can be undertaken within the advertising rules. In addition to general advertising rules, PR efforts for healthcare have strong ethics codes to which most pharmaceutical companies and PR professionals adhere. These codes dictate that disease awareness campaigns should be based on approved information and scientific data without promoting self-medication or encouraging physician consultation. Codes include the Mexican Association of Pharmaceutical Investigation's (AMIIF) code of intellectual property rights and the Code of the Federación Internacional de la Industria del Medicamento, de Normas de Comercialización de Productos Farmacéuticos (FIIM).

Who is responsible for the enforcement of these rules?

The Health Ministry is responsible—through the COFEPRIS for the enforcement of rules.

What are the regulations regarding healthcare engagement by pharmaceutical companies? How are these regulations enforced?

The regulations doesn't come from government or Health Minister, but from the Ethics and Transparency Council for the Pharmaceutical Industry (CETIFARMA).

It is acceptable to pay reasonable fees according to: local market indicators for that purpose, the curriculum of the health professional, time invested, reimbursement of travel expenses to moderators and speakers at meetings and congresses, symposia and similar professional or scientific events.

Payments to health professionals for such services shall be based on local market criteria; be commensurate with the time spent, the work performed and the responsibilities assumed; and shall be adequately documented. The contracting of health professionals will not be used as an incentive to induce, recommend, acquire, supply or manage the products of the contracting company.

Who receives concerns and complaints? How does this process operate?

COFEPRIS is responsible for receiving complaints regarding breaches in the promotional code. Typically, these complaints are submitted to the agency via rival companies, rather than consumers.

What promotional or media materials must be pre-approved by authorities?

Advertising and promotional materials are always submitted to the relevant authorities. In the case of press releases and other PR communication tools, authorisation and approval usually come from the pharmaceutical company's medical department, which is responsible for content. There's no need to submit information that will appear in editorial media sections for approval.

What are the most recent significant developments and are there planned changes to codes of conduct and regulations in the next few years?

In February 2005, an important step was taken with the approval of Article 376 of the General Law of Health. Before that, registration of drugs had an undetermined expiration date. With the approval of this reform, laboratories now have to revisit their registries every five years.

Drugs have to comply with bioequivalence and bioavailability tests in order to be placed on the market. In 1997 the application for these tests was approved for generic drugs. Since then, tests are made voluntarily, but they will now become compulsory. From 2010 onwards, only original and generic drugs exist and similar drugs are disappearing.

An important change was made regarding imports. Pharmaceutical laboratories that sell drugs in Mexico were forced to have a plant locally to be able to import products into the country. This requirement is being abolished. The first group of medications that are free from this requirement are the HIV drugs, which can now be imported from many more countries and companies than before. Others will follow and soon, anyone will be able to import medications. The polemic issue is that the authorities will not easily be able to verify the quality of every company wanting to export to Mexico. There are still many things to be determined around these new import rules. The change was announced by President Felipe Calderón at the VXII International AIDS Conference held in Mexico in August of 2008.

Finally, there is a proposal to ban the distribution of drug samples among physicians to prevent what is known as a grey or black market. This could create important commercial limitations for pharmaceutical companies, but is seriously being considered by health authorities. The latest law update, made in March 2012:

- Media advertisement departments to request the COFEPRIS a registration number for the product and also for the campaign—advertisement permission—as part of the advertisement requirement to buy an ad of any health related product.

The main changes contemplated by the Regulation project 2011–2012 for advertisement include:

a) In general

- The definition of mass media is extended and now includes containers, labels, promotional items and other technological media.
- Limit the claims or recommendations of product use made by public figures and celebrities that have the capacity to influence the health decisions of the population.
- Granting more weight to health messages (messages with greater impact than the health legends established by the Health Law) is proposed.
- Media will be co-responsible for the advertising campaigns, requesting previously from the advertiser the related COFEPRIS advertising permission as well as the product number registration.

b) In health inputs (supplies)

- In order to prevent self-medication promotion, the ability to use indirect advertising of medications that require a medical prescription for their sale is not allowed.
- Use of any type of cartoon is restricted.
- Regarding health services and beauty procedures, more accurate copies are required to avoid deceitful advertising concerning them (liposculpture, mesotherapy, lifting, etc.) when they are advertised as an alternative for obesity control.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

In the pharmaceutical arena, promotional activity is defined as all actions organised or sponsored by a company or by persons under their control, destined to favor the prescription, supply, sale and acquisition of drugs.

According to the code of ethics of the AMIIF, no promotional activity should hide its objective or nature. Any promotional materials related to drugs and their indications that are sponsored by a pharmaceutical laboratory should clearly identify that a specific company has sponsored them:

- Promotional articles are not subjected to previous authorisation when the name, generic denomination or the firm name are included.
- Free samples with the objective of promotion that comply with the requirements of the original products to be sold to the public and that only contain units do not require authorisation.
- Samples of drugs that are not over-the-counter (OTC) cannot be distributed to the general public. These, as well as OTC drugs cannot be provided to minors.

How is a media event defined?

This is not defined in the regulations.

Do the regulations differentiate between consumer and clinical publications?

Advertising for health professionals can only be included in media directed at them, including dictionaries with pharmaceutical specialties and drug guides. Advertisements should be based on a drug's prescribing information. The registry of advertised drugs should always be stated.

Information about prescription drugs should only be directed at health professionals and will be authorised at the moment the drug is registered. It should include: the brand name, generic name, formula, uses, therapeutic directions and other information such as warnings, general precautions and/or restrictions during pregnancy. Prescribing information will be authorised when the registry of the drug is approved. Advertising of drugs, including the commercial brand and information regarding the effect of medications, is not allowed in media available for general audiences or consumer media.

Do regulations differentiate between print and broadcast media?

In general terms, rules apply for both types of media the same way. However, there are some specifications that have slight differences in each case. For instance, the law points out that media must include the disclaimer, 'Ask your Doctor' and should mention the corresponding precautions the patient must take when the drug represents a danger in the case of a special condition.

Printed media must have the text printed, while for radio shows it must be auditory and for TV and cinema visual as well as auditory. In this last case, the written text should last a minimum time equivalent to a fourth of the total duration of the ad. It should be placed horizontally in contrasting colors, in 40 points per letter in proportion to a 40" screen. The auditory legends should be pronounced at the same rhythm and volume as the ad, clearly and understandably.

It is now also mandatory to include both the number of each advertising authorization as well as the number of the product approved by COFEPRIS.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?

According to the Good Practices Code of the pharmaceutical industry, the medical information department in each company must assure that the information provided by their professionals must be accurate, balanced, honest, objective and sufficiently complete to allow its addressees to judge for themselves the therapeutic value of the drug. A company should commit itself scientifically and morally to the content of the information it provides.

If external service companies participate in the preparation of the information, it is the responsibility of the laboratory to assure that these companies comply with the Ethics Code.

When promoting medical information in consumer media or to general audiences, it has to be undertaken by authorised third parties, such as physicians. There are no restrictions about communicating information from medical seminars or congresses, other than the general rules for drug promotion already discussed. According to the Ethics Code of the AMIIF, the results of a study should be the object of a complete report by the designated coordinator and be transmitted to all investigators as soon as it is available. If the results of the study are published, that is considered appropriate information for researchers. Clinical studies should not be used as disguised promotions.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

There are no restrictions from the Health Ministry for the distribution of press releases. Although no materials of this kind are submitted for authorisation, it is common practice to observe the codes of ethics that promote honesty in the information and it is important to have the approval of a physician or a specialist in the matter. As a rule, no information is released to the media without the written approval of the medical department in the pharmaceutical company behind the information. Also, the use of a product's commercial brand name should be avoided. Regarding printed materials for the consumer, the text required by the authorities is usually included. For example, in the promotion of cosmetics-related products it must read: 'Health is Beauty'; for alcoholic beverages: 'Avoid excess'; in the case of medications: 'Ask your Doctor' and for edibles: 'Eat Healthy'.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

No methods of distribution are covered in advance.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
No regulation on this matter exists.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
If a company sponsors a journalist to attend a scientific meeting, the copy that results from the journalist's attendance is completely independent of the company and is the property of the organisation the journalist represents. In the case of a freelance journalist, he or she is responsible for and owns the material.

Do regulations cover the use of case studies or other third-party advocacy in the media?
There is no regulation in this area.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
In the case of prescription drugs, all online content must be previously approved by COFEPRIS. Online disease information provided by pharmaceutical companies cannot mention commercial names or active ingredients.

What levels of web security are required?
In the case of prescription drugs, online information cannot detail illnesses with drug commercial names or active ingredients.

All website content additionally must be approved by COFEPRIS.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
External websites are not regulated, but if links takes users to a corporate web page it should comply with the rules of all other media.

What are the most popular social networks in your region?
According to digital media consumption surveys, at least 85 percent of internet users in Mexico are part of a social network, with Facebook and Twitter being the front-runners.

These networks have sophisticated usage regulations and are self-supervised. Some of these regulations involve their participation in advertising activities and bestow the content responsibility to the user, under the terms applied by international regulation and local laws.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
In 2014 COFEPRIS issued Trade No. CAS/1/OR/22/2014, which establishes digital advertising concepts, as well as administrative guidelines for procedures and requirements for the authorisation of digital advertising campaigns. These include: the regulation of owned content as well as variable digital content (generated by responses within the conversation). Community manager's responsibilities regarding both, owned and organic content include the process required to submit digital campaigns for authorisation, as well as the creation of websites, social media profiles and contents, and the way that authorisation codes should be displayed in digital ads.

Are there any self-imposed regulations from social media companies?
Facebook is the most popular social media platform in Mexico. To date, they have not provided any specific guidance relating to the marketing and promotion of pharmaceutical products independent of the regulations mandated by COFEPRIS. The same holds true for most other major social media platforms. The burden to ensure content on social media meets regulatory standards falls to the pharmaceutical company, not the social network.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
As with social media platforms, COFEPRIS now regulates consumer interaction on forums under Trade No. CAS/1/OR/22/2014.

What is mobile adoption like in your region? Are there separate regulations for it?
No, there are no separate regulations for mobile applications; the same advertising law applies to mobile devices.

What are the disclosure laws like in your region for non-branded websites?
In the field of health and medications, the same legislation applies, including non-branded websites. All the contents and communication issued by a pharmaceutical corporation must be submitted before and authorised by COFEPRIS.

In addition to the official regulations issued by the authorities, the pharmaceutical industry in Mexico—the same as for the rest of the world—has self-regulation mechanisms, based on its own ethics and compliance codes.

What is the response level needed for adverse event reporting?

The legislation on pharmaceutical surveillance is extremely severe. The responsibility of the companies, as well as everyone who work in them, including business partners, advertising and public relations agencies, must be trained on adverse event reporting, so that they know what to do as soon as one occurs. The companies, physicians, health professionals, and employees that are part of the pharmaceutical industry as well as health affairs (government institutions) are compelled to report to the National Pharmaceutical Surveillance Center (CNV) any sign of adverse effects in medications, vaccines and medical devices.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

The hospitality at events and meetings should be appropriate, in good taste and secondary to the original purpose. The pharmaceutical code promotes that the purpose of all events or meetings should be scientific or medical education.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

COFEPRIS does not have a specific law to regulate the honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events. These are self-regulated by each pharmaceutical company's compliance codes.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

There is no specific regulation in this matter. By compliance of each company, there are never honoraria to attend these sort of events. However, given the scientific profile of these meetings it is generally accepted to cover the travel expenses of physicians so they can attend medical events.

What is possible in terms of media or message training for health professionals or advocacy organisations?

With PR campaigns or earned media, health professionals or advocacy organisations are allowed to speak on their own behalf or on behalf of their institution or organisation. In this regard, the common practice is to train healthcare professionals on media management and efficient message transmission, but without imposing a particular guideline regarding the content of the information they will provide the media. If they are endorsing a product, campaign, etc., they must believe their messages to maintain an ethical behavior.

In advertising campaigns, when a physician endorses a campaign in a paid ad (TV or print), COFEPRIS requests by law the insertion of the professional licence number of the speaker in order to ensure the credibility of the content.

What rules govern materials written on behalf of third parties, such as clinical or advocacy s?

The same regulations for advertisement govern materials written on behalf of third parties and also the internal compliance codes of each company.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

In order to prevent self-medication promotion, the possibility to make indirect advertising of medications that require a medical prescription for their purchase is not allowed.

KEY TAKEAWAYS/ SUMMARY

- The top authority that regulates the pharmaceutical industry is the COFEPRIS.
- The Regulation of the Advertising-Related Health Act applies completely to online and offline communication media.
- In recent years, this law has been applied in an increasingly strict way and pressure has been put on communications related to nutritional supplements and the so-called 'miracle products'. One example of this is the latest law update, made in March 2012: media advertisement departments need to request from COFEPRIS, registration numbers of products and also of the campaigns—advertisement permission—as part of the advertisement requirement to buy an ad of any health-related product.

UNITED STATES

As direct-to-consumer promotion of prescription drugs is permitted, the boundaries between promotional activities and the provision of information are much less distinct than in the majority of the world's markets. Promotional activities are carried out under the aegis of providing information necessary for patient care, which empowers them to contribute to and make decisions about their healthcare and medicines. A wide variety of promotional activities is carried out by pharmaceutical manufacturers within published Food and Drug Administration (FDA) guidance. Guidance documents posted on the Office of Prescription Drug Promotion (OPDP) website include DTC Television Advertisements, Responding to Unsolicited Requests for Off-Label Information and Presenting Risk Information in Drug and Device Promotion.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The FDA consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods, Global Regulatory Operations and Policy, and Operations. The Center for Drug Evaluation and Research (CDER) is part of the Office of Medical and Tobacco Products, as is the Center for Biological Evaluation and Research which focuses on vaccines and other biologics. Within CDER, the OPDP provides extensive guidance to ensure that all prescription and over-the-counter (OTC) drug communications in journals, publications, newspapers, broadcast media and even social media comply with approved product labelling. OPDP protects the public through separate groups that focus on prescription and consumer drug promotion.

The Pharmaceutical Research and Manufacturers' Association (PhRMA) also provides a Code on Interactions with Healthcare Professionals (HCPs) and has issued Guiding Principles to Direct to Consumer Advertisements about Prescription Medicines. The principles were published in 2002 and last updated in March 2009. Both PhRMA guidelines are non-binding and depend on companies to self-regulate.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

The activities traditionally associated with public relations, including media relations, are all categorised as promotional activities. The FDA defines advertising very broadly, including all types of communications activity such as materials printed in journals, stand-alone publications, newspapers and Internet advertising. The FDA does make a distinction between product labelling and drug information as defined by written, printed or graphic elements found on drug wrappers or containers.

The United States has some of the most lenient drug-promotion regulations in the world, being one of just a few countries to allow direct-to-consumer branded advertisements and communications in media. Product communications and advertisements, including social media posts, may make statements about a drug's potential benefits, though they must also contain the drug's full important safety information (ISI) description, a principle known as 'fair balance'.

Who is responsible for the enforcement of these rules?

The FDA uses broad discretion in addressing promotional activities that it considers to be in breach of its regulations.

For advertisers who violate the FDA's regulations, including the 'fair balance' rule, the FDA will issue a formal warning letter requesting details on how to remedy the alleged violation, which may be disputed by the manufacturer. If these issues are not adequately addressed, FDA has the authority to initiate judicial proceedings, impose Federal Food Drug and Cosmetic Act (FDCA) violations and relevant penalties. PhRMA and other third-party organisations have no power over and above ethical guidance.

What are the regulations regarding HCP engagement by pharma companies? How are these regulations enforced?

Promotional materials provided to healthcare professionals by or on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other FDA requirements governing such communications.

In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as well as members of their staff attending presentations,

so long as the presentations provide scientific or educational value. Any such meals offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings. Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate.

Companies should not provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company.

Financial support from companies for Continuing Medical Education (CME) and for third-party scientific and educational conferences or professional meetings is appropriate. A company should separate its grant-making functions from its sales and marketing departments. In addition, a company should develop objective criteria for making CME grant decisions to ensure that the programme funded by the company is a bona fide educational programme and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment. Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending the event, either directly to the individuals participating in the event or indirectly to the event's sponsor (except as set out in Section 9 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals participating in the event.

Any compensation or reimbursement made to a healthcare professional in conjunction with a speaking arrangement should be reasonable and based on fair market value. Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements. While speaker programmes offer important educational opportunities to healthcare professionals, they are distinct from CME programmes, and companies and speakers should be clear about this distinction. Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution.

Non-educational items should not be offered to healthcare professionals or members of their staff, even if they are accompanied by patient or physician educational materials. Items designed primarily for the education of patients or healthcare professionals should not be offered on more than an occasional basis, even if each individual item is appropriate.

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. All companies that interact with healthcare professionals about pharmaceuticals should adopt procedures to assure adherence to this code.

Companies that choose to use non-patient identified prescriber data to facilitate communication with healthcare professionals should use this data responsibly. For example, companies should (a) respect the confidential nature of prescriber data; (b) develop policies regarding the use of the data; (c) educate employees and agents about those policies; (d) maintain an internal contact person to handle inquiries regarding the use of the data; and (e) identify appropriate disciplinary actions for misuse of this data.
In addition, companies should respect and abide by the wishes of any healthcare professional who asks that his

or her prescriber data not be made available to company sales representatives.

Companies should ensure that all representatives who are employed by or acting on behalf of the companies and who visit healthcare professionals receive training about the applicable laws, regulations and industry codes of practice, including this Code, that govern the representatives' interactions with healthcare professionals. In addition, companies should train their representatives to ensure that they have sufficient knowledge of general science and product-specific information to provide accurate, up-to-date information, consistent with FDA requirements.

Who receives concerns and complaints? How does this process operate?

Members of the general public can report a problem to the FDA online, via phone, or via mail. When emergencies have occurred, patients or healthcare professionals can report problems to the FDA's emergency line at 1-866-300-4374 or 301-796-8240 24 hours a day. In non-emergencies, the FDA Consumer Complaint Coordinator handles various problems via online forms available on the FDA website.

What promotional or media materials must be approved by authorities?

Pre-approval of all promotional materials is required by the FDA for products being considered for accelerated approval and those where patient safety issues exist. Preapproval submission may be required of manufacturers with a history of promotional violations. Companies may also voluntarily submit materials for OPDP advice and comment prior to product approval.

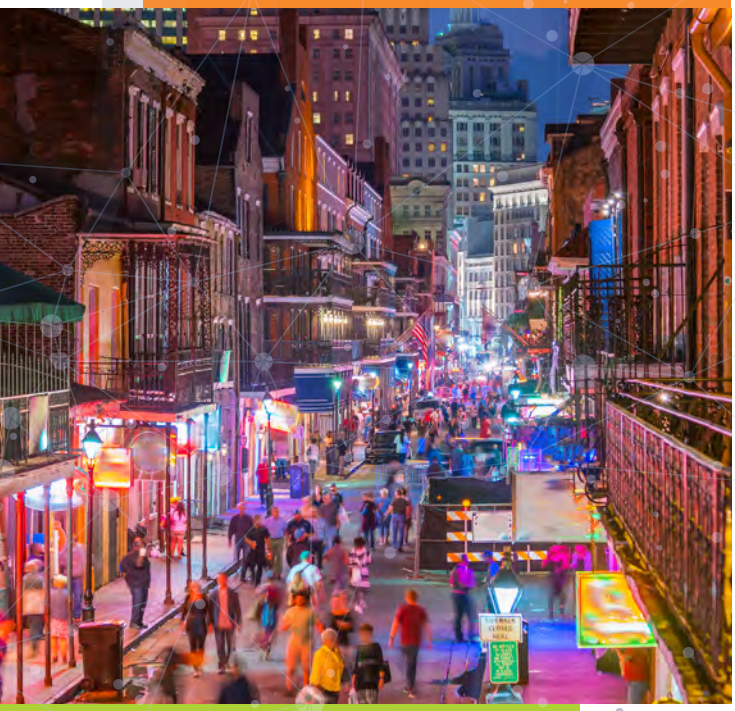
All other promotional materials must be submitted to OPDP at the time of initial dissemination. This requirement applies to all companies that market food, drug, device or biologic products in the United States. It is the responsibility of the manufacturer, distributor, packer or any party acting on behalf of the manufacturer to assure that all promotional materials, including advertisements, exhibits, videos, brochures, booklets, mailing pieces, slides and electronically disseminated materials, are submitted.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

In 2014, following five years of study, the FDA issued its first draft guidance on the use of social media in medical marketing communications. Though as of 2017 this remains in 'draft' form, subsequent, final guidance is hotly anticipated by industry.

The FDA's social media guidance refers to how organisations should present risk and benefit information within character limitations, stating that companies need to adequately represent the risk and benefits within the same communication message.

The draft industry guide for Correcting Independent Third-Party Information about Prescription Drugs and Medical Devices gives advice on appropriate corrective information and appropriate actions to correct misinformation.



Additionally, in 2015 the FDA issued its first guidance on medical apps that allow people to monitor and manage medical therapy.

In terms of interactive promotional media, the FDA issued a draft guidance with suggestions for submitting post-marketing materials that appear online. These promotional materials include anything owned or operated by the organisation or on its behalf, and promotion materials on third party sites. This also applies to real-time communications. Companies should also submit a monthly list of third party sited (restricted and non-restricted) of which they are active participants.

Further plans for the division include guidance documents on healthcare economic information/formularies, medical practice guidelines, comparative claims, and scientific exchange.

Addressing 'off-label' use of prescription drugs, has also been a growing focus of the FDA, along with a trend of prosecuting company executives in the case of egregious violations. In December 2011, the FDA issued draft guidance on Unsolicited Requests for Off- Label Information about Prescription Drugs and Medical Devices. This document provided more detail on how drug and device manufacturers should reply to unsolicited consumer enquiries for off-label usages, through either direct private enquiry or through online or in-person public forums.

The Physician Payment Sunshine Act provision of the Patient Protection and Affordable Health Care Act ('Obamacare') requires pharmaceutical and medical device companies to track any payments or 'transfers of value' to physicians and teaching hospitals as of 1 August 2013. The Sunshine Act industry has dramatically changed how the pharmaceutical industry conducts marketing activities. The list of payments covered is extensive and includes fees, gifts, food, beverage, travel/lodging, entertainment, charitable contributions, and royalty or licence fees. Companies began submitting the data to the Centers for Medicare and Medicaid Services (CMS) on 31 March 2014. CMS publicly began publicly reporting the data as of 30 September 2014. Even though companies are prohibited from offering any entertainment or gifts that do not advance disease or treatment education under the voluntary PHRMA Code on Interactions with Healthcare Professionals—a practice that is also banned by law in several states—many physicians report still accepting free tickets or gifts.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

As DTC promotion of prescription drugs is permitted, the boundaries between the two are much less distinct than in the majority of the world's markets. Promotional activities are carried out under the provision of necessary information to patients, which empowers them to contribute to decisions about their healthcare and medicines. A wide variety of promotion is carried out by

pharmaceutical manufacturers within the guidance of the FDA, largely dependent on public knowledge of a particular disease or condition, or how specialised a treatment.

The FDCA requires that all drug advertisements contain information in a Brief Summary, relating to side effects, contraindications and effectiveness. The Brief Summary includes only the risk- related sections of the product's labelling and effectiveness information by giving the product's indication. The current advertising regulations specify that this information disclosure needs to include all the risk information in a product's approval labelling. Advertisements cannot be false, misleading or omit material facts. In the case of DTC advertising versus materials focused on the medical professionals, the FDA encourages companies to use 'consumer-friendly' language to make any contradictions, warnings, and frequently occurring side-effects easier to understand by the general public.

How is a media event defined?

There is no distinction between a media and a public event in the FDA regulations or the PhRMA Code.

Do the regulations differentiate between consumer and clinical publications?

Consumer or clinical/trade publications are categorised as 'reference publications' under the FDCA. A reference publication is defined as a publication that has not been written, edited, excerpted or published specifically for, or at the request of, a manufacturer of a drug or device; has not been edited or significantly influenced by such a manufacturer; is not solely distributed through such a manufacturer but is generally available in bookstores or other distribution channels where medical textbooks are sold; does not focus on any particular drug or device of a manufacturer that disseminates information under Section 551 and does not have a primary focus on new uses of drugs or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and does not present materials that are false or misleading.

In 2014, the FDA released a draft guide for the distribution of scientific and medical publications on unapproved new uses. Manufacturers can distribute this information if it is first published by a third-party organisation with a review board and include approved labelling and a comprehensive reference list. This material must be distributed separately from promotional materials.

With regard to the consumer audience, in addition to requiring 'fair balance' of the risks and benefits of a product, the FDA advises that information be written in a way that is simple to understand by the average individual.

Do regulations differentiate between print and broadcast media?

Current regulations specify two requirements that all prescription drug broadcast advertisements must meet. Firstly, broadcast advertisements must include the product's most important risk-related information, known as the 'major statement' in the audio or audio and visual parts of the advertisement. Secondly, broadcast advertisements must contain either a brief summary of the advertised product's risk information, or alternatively, make adequate provision for disseminating the product's approval labelling in connection with the ad. Thus, the regulations for broadcast advertisements recognise broadcast's inherent limitations by providing an alternative mechanism for meeting the Act's information disclosure requirement. In 2007, the FDA updated the regulations, mandating that the major statement be neutral, conspicuous and presented in a clear manner.

All broadcast ads are also required to satisfy the 'adequate provision' laid forth in the FDA's 1999 'Guidance for Industry: Consumer-Directed Broadcast Advertisements', which call for:

- Providing a toll-free phone number for consumers to call to have the approved labelling sent to them;
- Referencing a printed advertisement or brochure that can be accessed with limited technology;
- Providing the address of an Internet website that contains the requisite labelling; and
- Advising consumers to ask doctors or pharmacists for more information.

In 2010, the FDA proposed guidelines that would require manufacturers to present a drug's major side effects and warnings in broadcast advertisements, regardless of how the drug's benefits might be presented. (Please note, these guidelines were not in effect at the time this document went to print).

A March 2012 guidance on the FDA DTC Television Ad Pre-Dissemination Review Programme states: These categories (products requiring pre-dissemination review) reflect a risk-based approach that will enable the Agency to leverage its limited resources to best protect the public health by ensuring that certain high risk and high impact TV ads accurately and effectively communicate key information about advertised products, including their major risks and indications. Specifically, these categories allow the Agency to review and provide comments on TV ads for prescription drugs with particularly serious risks, and to review and provide comments on TV ads at times when feedback on the risk and indication communication in the ad is particularly critical, including when a product is first advertised on TV and after a product has received a significant safety labeling update or a new or expanded indication.

In the case of print advertisements, the FDA encourages product sponsors to provide consumers with non-promotional, consumer-friendly information consistent with product labelling, along with the information required by the Act and the regulations. Print ads are required to inclue a Brief Summary which includes all risks listed in its prescribing information.

The advertisement or labelling piece may include the phrase 'FDA approved' if the manufacturer or sponsor has received a letter stating that the product has been approved. The word 'new' may be used in promotional labelling and advertisement for a newly approved product, indication or dosage form for six months from the time a product is initially marketed.

In accordance with FDA regulations, all DTC information should be accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA approved labelling. The FDA mandates that DTC advertising direct consumers to report negative side effects to MedWatch, the FDA adverse event reporting programme, by incorporating the following language into print ads: 'You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088'.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

Under FDA rules, there is no general restriction on publishing research around pre-licenced uses, or discussing it at scientific events. However, manufacturers are prohibited from DTC advertising or promotion of a drug prior to FDA marketing approval. The FDA also forbids any promotion or representation that a drug is safe or effective for use outside of the specific purpose for which it has been approved. This area of 'off-label' marketing has been a focus of the FDA in recent years.

With regard to specific rules around congresses and scientific meetings, each medical society implements a set of policies to be followed by all participants. Most medical societies have regulating committees that are responsible for establishing and enforcing the policies governing all media-related activities. Societies adopt embargo policies for all abstracts presented at their meetings to abide by any agreements made with publishers and to maintain authenticity of study results.

Medical meetings take embargoes very seriously, similar to a publication, because if the information is presented in advance for public consumption, it reduces the significance to present to colleagues on-site. Furthermore, advance distribution may unfairly affect stock prices by sharing one company's information prior to competitors. Materials distributed should include a prominent display of the words 'EMBARGOED UNTIL' with the date and time of presentation to avoid any possible negative ramifications.

In December 2011, the FDA issued draft guidance on how industry should respond to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices. The draft guidance clarifies the fact that manufacturers are able to provide information to unsolicited requests on off-label drug or device uses without violating regulations. However, any information provided could potentially be introduced as evidence of a new intended use.

Unsolicited requests are defined as both non-public, as in a call, email or direct request via a website from a consumer to the manufacturer, or public request sought in an open forum, either in-person or via an online source, such as message board, website or social media platform. Not covered are solicited requests which are defined in a number of ways, including requests received following company-affiliated presentations, speeches, business reply solicitation, calls for online videos or other comments, pre-formatted website responses or online and offline distribution of information. Responses to solicited requests for off-label information may be considered evidence of a firm's intent that a drug or device is intended for use other than specifically approved by the FDA. If a firm chooses to respond to an unsolicited request for off-label information, it must do so directly to the individual posing the question—regardless of whether the request is public or non-public—and in a way that is tailored only to the specific question or questions asked, meaning that follow-up may be required to secure additional information on the question asked. Responses should, to the greatest extent possible, be scientific, fair and balanced, published in peer-reviewed articles and should come from the company's scientific or medical personnel, not marketing or sales representatives. Responses must also include approved FDA labelling, a prominent statement indicating that off-label uses are not approved by the FDA, safety warnings and a complete list of scientific references.

The draft guidance specifically recommends against using digital or social media to publically follow up to unsolicited requests for off-label uses. Specifically, the FDA is concerned that this public discussion may lead to promotion of off-label uses by those not asking the questions, may cause confusion among consumers or medical professionals and may generate future problems, as outdated information can be accessed online for many years.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

FDA restrictions on press releases are informal and developed on a case-by-case basis. To determine whether a release is illegal promotion, the FDA looks at the phrasing of the release, its manner and its scope of distribution. Such materials should be fair, objective and must be directed at an audience whose interest in the content of the materials would be assumed to be reasonable to ensure messages can be understood. The PhRMA Code states that, as a general rule, interactions should be focused on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education.

According to policies implemented by medical societies, press releases may be issued in the months prior to the meetings to announce that a study will be presented, but the release must not in any way reveal the data or

study results. If the study results are reported prior to the embargo date and time, the abstract is subject to removal from the meeting. Most medical societies do not endorse corporate and institutional press materials, and will display such materials strictly as non-affiliated literature.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

The distribution of materials to any media or clinical outlet is reasonable, whereas unsolicited faxing or text messaging to other numbers would not be. No reference is made to the codes of other countries in any of the regulations, although International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) guidance says that promotional material should comply with the regulations in the country of release and distribution, as well as the source. As only the United States and New Zealand permit DTC communication, those sending United States press materials outside the U.S. should take particular care to ensure that their content does not contravene the regulations of the countries where distribution or publication is intended.

A manufacturer may disseminate information, under Section 551 of the FDCA, on a new use only if the manufacturer prepares and submits a list of materials for distribution to the Secretary of Health and Human Services. A list containing the titles of the articles and reference publications relating to the new use of drugs or devices by the manufacturer, along with a list of any clinical trial information used to promote the drug or medical device, must be provided to the Secretary sixty days prior to dissemination.

Companies exhibiting at medical meetings are encouraged to distribute meeting-relevant press releases and backgrounders on-site at the meeting; while there are exceptions, most meetings will allow some space for exhibitor news, given that the documents are approved in advance by the communications staff. Approved materials should have appropriate embargo information, time and date of the presentation, as well as a reference to the meeting presentation. Materials to be distributed must relate to data being presented at the meeting; other background and general company information will not be accepted. In some cases, material may be distributed, but only if it is unbranded (product and company) and aids understanding of the release information.

According to the draft guidance document, as of July 2014, the FDA has issued some regulations in terms of presenting risk/benefit information as well as other product information on internet/social media platforms with character space limitations. In doing so it seems that the FDA has differentiated to some extent between online, print and broadcast media - the FDA considers Interactive promotional media (which it clearly states includes- microblogs like Twitter and social networking sites like Facebook) as a separate entity. However as of now, these are only draft guidelines.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

Under FDA rules, there is no general restriction on publishing research around off-label or pre-licenced uses or discussing it at scientific events. However, if the manufacturing company is paying for or dictating the content of any publication, then it violates FDA regulations and may be subject to sanctions.

As communication to lay audiences is permissible under the regulations, no specific rules govern press activity at congresses and scientific meetings. Scientific organisations, such as the American Medical Association (AMA), do have strict guidelines as to events being held

at their own major meetings, and the various committees should be consulted in advance of planning.

Press briefings, news conferences, press reception and other media events—other than those sponsored by the host institution or manufacturer—are not permitted on-site. Organisations planning any off-site media activities, such as press conferences, satellite media tours and/or social events, are usually required to coordinate with the appropriate communications department. All events are bound by the rules of the meeting and are generally restricted to before or after the hours of the meeting, or on either end of the start or completion of the meeting.

Company events are very common at medical meetings; most events are Continuing Medical Education (CME) and focused on doctors only, and media are not typically invited to attend such events. Other satellite symposia and receptions are open to members of the media. In addition, those holding U.S. events in scientific meetings outside of the United States should take particular care with the content and format of materials and their intended audiences.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through ha company's regulatory procedure? Is it different for a freelance journalist?

This type of communication and subsequent editorial is permissible under regulations in the United States. However, according to the FDA, if the manufacturing company is paying for or dictating the content of any publication, it falls under FDCA regulations and, with any violations, could potentially result in sanctions. Journalists are in no way obligated to write and publish content in favour of the sponsoring company. Both sponsored and freelance journalists are free to publish independent reports, and it is unnecessary to go through a company's regulatory procedure for approval on copy.

Do regulations cover the use of case studies or other third-party advocacy in the media?

Regulatory information does not specify the use of case studies or other third-party advocacy in the media.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

An overview of the FDA's guidance around social media promotion and regulation is included above. In general, advertisements for prescription drugs presented through online venues are regulated under the same FDA regulations as print or broadcast media. Advancements in online advertising options have drawn question over the scope or feasibility of the FDA to regulate these digital advertisements; however the FDA remains committed to enforcement of its regulations through online channels.

In the United States, companies are permitted to sell some approved medicines over the internet, leading to a growth in internet pharmacies. These pharmacies are bound by the same regulations as conventional drugstores and the sites are regularly monitored by the Drug Enforcement Agency to ensure compliance. The FDA's Buying Medicines and Medical Products Online Web page and Buying Prescription Medicines Online: A Consumer Safety Guide gives guidance to consumers shopping for healthcare products online.

The use of patient Electronic Health Records (EHR) in clinical trials has also become a hot-button issue. In 2016, the FDA issued draft industry guidance on Use of Electronic Health Record Data in Clinical Investigations.

The guidance covers patient data such as use of medical records, radiology results, immunization history and lab results. The draft guidance sets best practices around EHR interoperability, data quality, certifications, privacy and security.

What levels of web security are required?

Patient records are protected through the Health Insurance Portability and Accountability (HIPAA) Act of 1996. Under this law, all websites are required to ensure that inputted patient medical information is kept confidential through site security.

The Office of the National Coordinator for Health Information Technology, under the Department of Health and Human Services (HHS), oversees privacy and security of online health information. The Coordinator's office in 2015 published a comprehensive guide governing best practices around provider websites in 2015.

Consumer websites, including disease-awareness websites, must comply with all United States Federal Trade Commission regulations and federal laws regarding privacy and security.

Any website asking users for personal information or using cookies to track metadata should explain exactly what the site will and will not do with the information as part of its Privacy Statement.

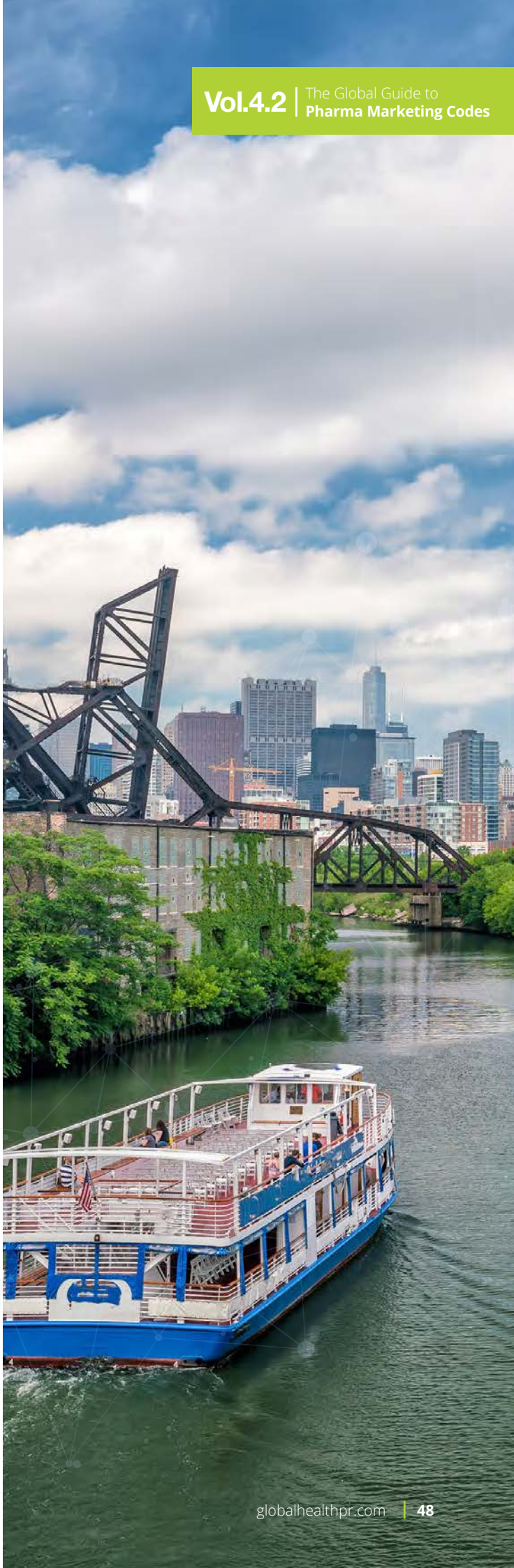
Do the regulations cover funding of, or provision of information to, non-company owned websites?

It is very common in the United States for pharmaceutical manufacturers to engage in legitimate funding of patient groups and other not-for-profit organisations, which may include sponsorship of websites, although, sponsorship should be openly declared. For the provision of information, typical copyright protection and plagiarism laws apply. Information is usually allowed to be reproduced for non-commercial individual reference with all copyright or other proprietary notices retained, and thereafter the contents may not be re-copied, re-produced or otherwise re-distributed.

A draft guidance issued in December 2011, Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices, includes response to unsolicited responses to off-label uses identified through public forums on non-company-owned websites. The FDA advises that companies can respond to these requests, but must do so in line with draft guidance, including direct response to the individual posing the question, specific response only to the questions asked and response from scientific representatives with transparent, fair and balanced information that includes approved labelling and adverse effect information.

What are the most popular social networks in your region?

As of 2017, more than seven in ten Americans use social media platforms regularly.



Around 68% of all U.S. adults are Facebook users, while 28% use Instagram, 26% use Pinterest, 25% use LinkedIn and 21% use Twitter. Youtube is also a top social media site.

Among teens and young adults who use social media, Snapchat is the most popular platform (7% of users), followed by Facebook (7%), Instagram (73%) and Twitter (4%).

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

In 2014-15 proposed two draft guidances for the industry with recommendations to help manufacturers and their representatives accurately communicate online about prescription drugs and medical devices.

The first guidance provides recommendations for the presentation of risk and benefit information for prescription drugs or medical devices using internet/social media sources with character space limitations, such as Twitter and the paid search results links on Google and Yahoo. No matter the internet source used, benefit claims in product promotions should be balanced with risk information. And companies should provide a way for consumers to gain direct access to a more complete discussion of risks associated with their products.

The second guidance provides recommendations to companies that choose to correct third-party information related to their own prescription drugs and medical devices. This draft guidance provides FDA's recommendations on the correction of misinformation from independent third parties on the internet and through social media sites -- any corrections should address all misinformation in a clearly defined portion of a forum on the internet or social media, whether the misinformation is positive or negative.

Are there any self-imposed regulations from social media companies?

In recent years, social media companies have developed extensive guidelines pertaining to pharmaceutical promoted posts; organic content is more of a gray area and may be subject to removal if it is found to be in violation of the platform's overall community guidelines.

In addition to complying with each platform's guidelines, FDA rules also apply.

Twitter:
Twitter provides extensive, country-by-country guidelines as part of its policy on Health and Pharmaceutical Products and Services (https://support.twitter.com/articles/20170441). This policy applies to Twitter's paid products, which are tweets, trends and accounts.

Facebook:
Facebook's advertising policy explicitly prohibits ads that promote prescription drugs and online pharmacies. Facebook also prohibits ads with content that "asserts or implies certain attributes", including medical conditions. Personal health (including before/after photos) are also

covered under this policy. Supplement advertisements are permitted as long as they are targeted to audiences over the age of 18.

Instagram:
Because Facebook owns Instagram and a Facebook ads account is required to run ads on the platform, Facebook's policies on pharmaceutical advertising content are understood to apply to Instagram, as well.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Forums and blogs fall under FDA's guidance on social media.

For forums, the FDCA regulations apply across promotional materials online, including the need to clearly cite warnings and side effects, as well as the necessity to capture and report adverse effects.

Any online channels or areas presenting or discussion medical information that are sponsored by the prescription drug manufacturer are currently regulated in the same manner as other promotional materials and are subject to the same conditions and potential penalties for non- compliance.

What is mobile adoption like in your region? Are there separate regulations for it?
According to CTIA, The Wireless Association, as of December 2015 there were 377.9 million wireless subscriber connections in the United States. About 49% of U.S. households are wireless-only. As of 2016, 78% of American adults have smart phones. The annual wireless revenue incurred was $191.9 billion as of December 2015.

In February 2015 the FDA issued guidelines regarding mobile medical apps. The FDA has already reviewed and approved apps that support medical professionals, such as a smartphone-based ultrasound and an app that allows doctors to view medical images and X-rays.

What are the disclosure laws like in your region for non-branded websites?
A 2009 study coordinated by Manhattan Research found that 35% of online pharmaceutical consumers use a non-branded website to find information. Experts note that non-branded resources, developed by prescription drug manufacturers, can be very useful in promoting disease awareness, educating diagnosis, introducing rare conditions and navigating compliance issues. There are, however, important compliance steps which are enforced by the FDA.

While the FDA has not issued specific guidelines on the regulation of non-branded websites, they are scrutinized by the agency as with any other promotional material paid for by a prescription drug manufacturer. In February 2015, the FDA issued a warning letter to manufacturer citing claims and presentations in the website about the safety and efficacy of an investigational new drug that is yet to be approved by the FDA

Under section 502(f)(1) of the FDCA the above drug was considered to be misbranded.

The agency has made a clear statement that all websites paid for by prescription drug manufacturers, even if they contain no direct branding or promotional information, will be regulated as with other promotional materials under FDCA. Without providing full disclosure and, whenever relevant information on labelling, warnings and adverse effect reporting, manufacturers may be subject to penalties.

What is the response level needed for adverse event reporting?
In December 2016, updates were made to the rules for reporting adverse effects to the FDA for consumers. According to the FDA, product related problems (including adverse events) can be reported online via MedWatch; the FDA Safety Information and Adverse Event Reporting Programme; The Vaccine Adverse Event Reporting System (VAERS); or the Safety Reporting Portal depending on the product. The document no longer mentions the 15 days' time interval between the occurrence of the event and time of reporting.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
There are no specific regulations covering hospitality to advocacy or patient groups mandated by the FDA or other government agencies. Legitimate funding of varied patient group activities is allowed and common in the United States. However, the PhRMA Code states that it would be ethically fair to restrict funding to modest expenses and travel, and that the meeting should occur in a scientific or academic venue and manner. While adherence to the PhRMA Code is voluntary, some U.S. states do require manufacturers to adhere to the Code while coordinating promotion in their state.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
It is acceptable for those participating in meetings or events, for example as speakers, to receive honoraria. The PhRMA Code states that no recreational or

entertainment events may be offered, meals must be judged as 'modest by local standards', and that meals are provided in a manner conducive to informational communication. Any meals offered in connection with informational presentations should be limited to in-office or in-hospital settings, not as part of an entertainment or recreational event. Inclusion of a healthcare professional's spouse or other guest is inappropriate, as is offering 'take-out' meals or meals to be eaten without a company representative.

The AMA's ethical guidelines state that the teaching faculty and other service providers (i.e., moderators) may be offered reasonable honoraria and reimbursement for travel, lodging and meal expenses. The amount received must be commensurate with the services they provide. Regarding advocacy groups, there are no legal restrictions on funding specifically relating to the healthcare sector. Pharmaceutical companies routinely provide funding for groups interested in the conditions that their products treat.

It should be noted that the Sunshine Act requires all payments to health professionals be reported to the CMS beginning in August 2013. Payments were made public beginning in September 2014.

The act requires manufacturers to report payments and transfers of value made to 'Covered Recipients' which refers to U.S. physicians and teaching hospitals but excludes Medical residents, nurse practitioners and office staff.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

The PhRMA Code categorically states that financial support should not be offered for the costs of travel, lodging or other personal expenses of any non-faculty healthcare professionals. Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the meeting, including attendees of interactive sessions. Modest, occasional meals are permitted as long as they are offered in the appropriate circumstances and venues as described in relevant sections of the Code.

Implemented in 2013, the Physician Payment Sunshine Act requires all payments to health professionals be reported to the CMS.

What is possible in terms of media or message training for health professionals or advocacy organisations?

Regulators acknowledge that speaker training is an essential activity to enable healthcare professionals to educate and inform their colleagues and peers about benefits, risks and appropriate uses of prescription drugs. The FDA holds companies accountable for the presentations of their speakers, so appropriate training and education is necessary. Section 7 of the PhRMA Code specifically states that 'it is appropriate for healthcare professionals who participate in programmes intended to recruit and train speakers for company-sponsored speaker bureaus to be offered reasonable compensation for their time…and reasonable expenses'. The PhRMA Code additionally recommends that when participants receive extensive training on the company's drug products, they should also receive training on compliance with FDA regulatory requirements for communication about such products. Payments for participation in media training must be reported to the CMS beginning in August 2013. Payments will be made public beginning in September 2014.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

As consistent with all aspects of prescription drug promotion, full and transparent disclosure of sponsorship by a manufacturer as related to any written materials by third parties is required for compliance with FDA and industry regulations.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

There are no legal restrictions that cover advocacy groups specifically in the healthcare sector.

KEY TAKEAWAYS/ SUMMARY

- The FDA has only recently begun to actively provide guidance and warnings to pharmaceutical companies regarding social media use. Despite this, enforcement has been inconsistent and social media still presents challenges for manufacturers.
- Marketing of 'off-label' uses of prescription medication has been a focus of FDA regulatory scrutiny recently. Strict adherence to the approved uses and dosing is important for manufacturers' marketing programmes to avoid penalty. This applies to non-branded materials and websites.
- Full open and transparent presentation of major statements of prescription drug labelling, such as warnings, approved dosing and possible side effects, along with clarification of financial support of physicians and third parties, remains vital in adhering to pharmaceutical marketing regulations in the United States.


EUROPE
& AFRICA

DENMARK

Promotion of medicines are governed by the Danish Medicines Act (DMA), the Executive Order No. 1154 of 22 October 2014 and the Advertising Order Etc. of Medicinal Products (the Advertising Order). The Danish Health and Medicines Authority (DHMA) has issued guidance note No. 10356 of 29 December 2014 on the advertising of pharmaceuticals (the DHMA Guide). Additionally, members of the Danish Association of the Pharmaceutical Industry (Lif) shall, in accordance with the Articles of Association, comply with decisions made by the Ethical Committee for the Pharmaceutical Industry (ENLI), which includes an ethical code regarding promotion of medical products and an ethical code regarding collaboration with health professionals. Although not legally binding, these ethical codes from ENLI are widely recognised by the pharmaceutical industry. The Danish national regulatory framework for promotion of medicinal products is largely based on European Union (EU) legislation. Similar to EU legislation it is prohibited to aim advertisement of medical products at children. Furthermore, the Danish legislation on advertisement on prescription medicinal products, and the rules on design and content of advertisements in general, is similar to EU legislation.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

Information distribution on pharmaceuticals is governed by the DMA, the Executive Order No. 1154 of 22 October 2014, the Advertising Order, the Marketing Act, DHMA guidelines and ethical codes from Lif and the ENLI.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Advertisements or promotional activities of medicines is defined as any form of informational activity or influencing customers with the purpose of enhancing sales and increasing the demand for a product. However, information and communication on general disease and health are allowed. For example: disease awareness public relations (PR) campaigns are legal. Exceptions that are subject to the rules of the Advertising Order include informative material on health and disease, provided that no direct or indirect reference is made to specific products. Patient information folders distributed by either a prescriber when prescribing a medicinal product or a pharmacy when dispensing a product are allowed, provided that the folder contains only factual information of significance. Press releases that give factual and concise details about a medicinal product, are newsworthy, have the press as the target audience and are distributed to a range of reporters or media to obtain journalistic review and comment prior to publication are also allowed.

Who is responsible for the enforcement of these rules?

The Medicines Act, the Orders, the DHMA Guide and the Marketing Act are enforced by the DHMA and the Consumer Ombudsman. Pursuant to the Advertising Order, §68 (2 and 4) the marketing authorisation holder must keep a copy of, or other documentation on, the advertisement for two years and on request be available to the DHMA, who subsequently controls whether the procedures have been done according to the rules.

Furthermore, if a company violates the rules of the DMA, they can be reported to the DHMA, who will decide if a violation has taken place.

All members of the LiF shall, in accordance with the Articles of Association, comply with decisions made by the ENLI, which includes an ethical code regarding promotion of product and an ethical code regarding collaboration with healthcare providers (HCPs). Although not legally binding, these ethical codes from ENLI are widely recognised by the pharmaceutical industry. There are no specific standard operating procedures (SOPs) for the government of promotional activities; however, according to ENLI's Codes on Advertisement, Article 20(2), every member company is obliged to select at least one person in charge to ensure that the company along with its subsidiaries comply with rules and regulations. The person shall approve all material before distribution. If a company violates the ethical codes, ENLI can sanction the company with a fine. At the beginning of each month the rulings are published by ENLI on their website.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

The obligation to report association between pharmaceutical companies and HCPs who prescribe medicine follows from the Danish Health Act, Part 61a, and the DMA, sections 18(1) and 43 b-c, and is further described in the Executive Order No. 1154 of 22 October 2014 and the DHMA's guidelines. All engagement between pharma and HCPs who prescribe medicine, financial or non-financial, must be reported to the DHMA. According to the Executive Order No. 1154 of 22 October 2014, Article 7, a HCP is not allowed to be affiliated with pharmaceutical companies, medical device manufacturers or special stores for medical equipment unless the HCP has reported this to the DHMA or after the application has been approved by the DHMA.

Furthermore, ENLI provides ethical codes on pharmaceutical companies' collaboration with patient associations and the Danish hospital service, with the objective of securing high ethical standards for pharmaceutical companies' collaboration with HCPs.

Who receives concerns and complaints? How does this process operate?

The supervisory activities on advertising are made by the DMA supplemented by trade specific self-regulatory bodies that monitor the legitimacy of advertising activities in parallel and collaboration with the DMA. There are five self-regulating bodies: the ENLI, the Marketing Board of the Danish Association of the Veterinary Pharmaceutical Industry, the Danish Pharmacy Committee, the DMA Ethical Council, and the Ethical Board of the Danish Association of Suppliers to the Health Industry. Even though a complaint about an advertisement falls under the activities of one of the self-regulatory bodies, a complainant can also complain directly to the DHMA. If a company violates the rules of the DMA, they can be reported specifically to the DHMA, who decides whether a violation has taken place. The report is made by means of an e-form available on DHMA's website. When the authority reviews a complaint, it may obtain an opinion from the relevant self-regulatory body. According to section 68(1) and (2) of the DMA, the holder of a marketing authorisation for a medicinal product must keep a copy of or other documentation of any form of advertising for a medicinal product for at least two years. In this period, the marketing authorisation holder must keep a copy of all advertising material regardless of form. The material must be made available to the DHMA on request.

What promotional or media materials must be approved by authorities?

A new medicinal product cannot be marketed until it has been approved by means of a marketing authorisation. An application must be submitted to DHMA, who assess the application and conclude the assessment by either an approval or a denial to get the marketing authorisation. As stated earlier, the holder of the marketing authorisation must keep a copy of or other documentation of any form of advertising for a medical product for at least two years. The material must be made available to the DHMA on request. According to section 17(2) of the Advertising Order, the advertising material must be stored in print or similar form, or electronically in a generally available format. In addition to the advertisement itself, the person advertising the medicinal product must keep information about how the advertisement was used in practice, cf. section 17(3) of the Advertising Order: 1) The advertisement's target audience, i.e. the group that the advertisement is targeted to 2) Distribution method 3) A list of media in which the advertisement was placed 4) The period when the advertisement was running.

With regards to HCPs association with pharmaceutical companies, in the event of a promotional activity, with or without payment, the HCP must notify the DHMA first. Notification must be submitted electronically using a form on the DHMA's website.

Member companies of LiF are obliged to inform ENLI about events where HCPs attend. The member companies are also obliged to inform ENLI about all printed advertisements and electronic texts targeted to HCPs. The member companies must send in the report online at www.enli.dk. It is possible for the company to apply for a pre-approval on ENLI's aforementioned website. In such cases ENLI will charge an extra fee for the service. ENLI states in section 21(1) and (5) of the Promotion Code that pharmaceutical companies are obliged to report activities to ENLI 1) which are organised or co-organised by a pharmaceutical company, and the event is fully or partially directed towards Danish HCPs, 2) where a pharmaceutical company, without organising or co-organising the event, provides financial (sponsor) support to a so-called third party event, fully or partially directed towards Danish HCPs, 3) where a pharmaceutical company buys an exhibition stand at a congress in Denmark. The report concerning those

activities must be filed within 10 working days prior to the opening day of the event. Reports concerning sponsorships must be filed no later than 10 working days after a binding promise to provide financial support has been made or, in case of exhibition, at least 10 working days prior to the opening day of the event. Reports on promotion material must be filed at least on the same day as the printed promotion material is distributed.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

The most recent development has been the legislation concerning HCPs and patient organisations association with pharmaceutical companies that was written into Danish law in October 2014. The rules can be found in the DMA § 202(a-c) and in the Advertising Order §24-28.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

The term advertising in the context of the pharmaceutical legislation is defined in section 1(1) of the Advertising Order: Advertising of medicinal products means any form of door-to-door information or canvassing activity designed to promote the prescription, supply, sale or consumption of medicinal products.

Necessary and specific information or documentation, which serves safety purposes and not promotional purposes, e.g. information about changes to the packaging, or new adverse reactions or manufacturing defects is not considered as promotional activity.

All promotion targeted to a public audience must clearly state that it is an advertisement about a pharmaceutical product so that it is easily recognised as such by the audience. Furthermore, the information must meet the criteria for minimum information listed in the Advertising Order §5-§9.

How is a media event defined?

This is not specifically defined. However, the Advertising Order §6-9 clarifies the rules on advertising in movies, the radio, television and on the internet, respectively. Media relations, i.e. a media event, should comply with the rules in the Advertising Order on press releases: they must give factual and concise details about a medicinal product, be generally newsworthy, have the press as the target audience and be distributed to a range of reporters or media to obtain journalistic review and comment prior to publication.

Do the regulations differentiate between consumer and clinical publications?

It is possible to advertise in clinical publications for prescription medicines. In public media it is only possible to advertise for over-the-counter (OTC) medicine.

Do regulations differentiate between print and broadcast media?

The regulations on print and broadcast media is defined in the Advertising Order §5-§9. There is some variation in regards to the criteria for information, however, they are mostly very similar to each other whether it is in print or broadcasting. There is no difference in PR media relations.

What is permitted in relation off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?

The rules do not specifically address this in regards to media. The company must have a marketing authorisation and pre-launch activities and commercials on off-label use are prohibited. Press releases are an exception and can be issued and journalists can be invited in i.e. medical conferences where phase 3 data are published. This, however, does not apply to off-licence.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

According to the Advertising Order §2, the rules on medicine advertising do not apply to press releases that give factual and concise details about a medicinal product, are generally newsworthy, have the press as the target audience and are distributed or made available to a range of reporters or media.

However, a press release which appears as an advertisement because of subjective content, misleading information or exaggeration will not be considered a press release. It will be considered an advertisement for a medicinal product. If a press release is paid for and placed in a media channel, it will also be considered advertising. A pharmaceutical company can make a press release available to the press in a press area on its website for three weeks. After that, it will no longer be generally newsworthy and could be considered advertising. This will be based on an individual assessment.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

Method of distribution is not regulated. Material from other countries also needs to comply with Danish rules and regulations.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

All media contact has to comply with the criteria for press releases, cf. §2(7) of the Advertising Order. Journalists can be invited in i.e. medical conferences where phase 3 data are published. This does not apply to off-licence.

If a company sponsors a journalist at a scientific meeting, is the resulting copy independent or does

it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
There are no general rules on this. Each pharmaceutical company has its own rules that may require that the copy go through regulatory procedures. Therefore, it depends on the case and company. However, it is not advisable to make the copy go through the company's regulatory, as it can be regarded as advertising

Do regulations cover the use of case studies or other third-party advocacy in the media?
Third parties, such as HCP and patient testimonials, can be used in the media if the association has been reported to and accepted by the DHMA. This is only allowed for OTC medicine and not prescription medicine. Patient testimonials must not mention prescription medicines, as it will be regarded as advertisement. According to the Advertising Order, §10(7) it is prohibited to make public advertisements, which contain any recommendation from a HCP or a third-party that because of its standing is in the position to encourage the use of medical products.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
There is no difference.

What levels of web security are required?
Log-ins are required for websites with information on prescription medicine. Patient information on specific prescription medicine must only be available for the patient via a password provided by the doctor. The regulation distinguishes between advertising aimed at the public and HCPs. Regarding advertising on the internet, article 9(2-3) of the Advertising Order states that advertising on the internet is generally considered as public advertising. However, if access to the online information is limited to HCPs, for instance by the use of personal login with password, this will be treated as advertisement targeting HCPs.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Regulation only applies to company owned and/or hosted websites. However, the company is held responsible if the company-owned website links to other pages with prescription medicine.

What are the most popular social networks in your region?
Facebook, Twitter, Youtube, LinkedIn, Snapchat and Instagram.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Yes, the Nordic Consumer Ombudsmen has published a position on social media marketing on 3 May 2012 stating that traders who use social media marketing must comply with the general rules applicable to internet marketing. Furthermore, ENLI has a guide to pharmaceutical companies use of social media for advertising.

Are there any self-imposed regulations from social media companies?
Social media platforms have their own codes of conduct. Facebook's Advertising Policies provide guidelines about which ads are acceptable and unacceptable on the site. The Facebook guidelines prohibit the promotion or sale of prescription pharmaceuticals. The guidelines can be found here: https://en-gb.facebook.com/business/help/223106797811279

Limitations to what may be published in these channels regarding pharmaceuticals are also governed by local laws and ethical guidelines for the pharmaceutical industry. Since the regulations distinguish between advertising to the public and to HCPs, advertising to HCPs on social media must be separated from the public. In such case, the party responsible for the advertisement on Facebook can create a page that is closed to the public and give health professionals access on an individual basis.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Yes, this is described in ENLI's guide to the use of social media for advertising.

What is mobile adoption like in your region? Are there separate regulations for it?
Access to social media through mobile devices is widespread in Denmark. In May 2015, 81% of internet users in Denmark owned a smartphone. Smartphone usage is predicted to continue to grow in the short term. There is no regulation addressing mobile devices separately.

What are the disclosure laws like in your region for non-branded websites?
The host of the website should not be more than one click away. On non-branded websites the owner or host of the site must be clearly stated. Pursuant to the Advertising Order Article 2(2), informative material on health and disease are not covered by the regulation, provided that no reference, direct nor indirect, is made to specific medical products. This could be anything from conventional leaflets to comprehensive internet websites. On the contrary, if the medical product is mentioned on a website accessible to the public, it is regarded as advertisement to the public and thus must

comply with the requirements for advertising to the public, cf. Article 9 of the Advertising Order.

What is the response level needed for adverse event reporting?

In pursuant to the DMA Part 5, Article 53, the holder of the marketing authorisation for a medicinal product must operate a pharmacovigilance system to monitor the safety of the medicinal products, assess the possibilities for risk minimisation and, if necessary, take appropriate measures. The company is obliged to keep records of suspected adverse reactions and make such records available to the Danish Medicines Agency. Furthermore, the company holding the marketing authorisation must report information on suspected adverse reactions to the Danish Medicines Agency or the European Medicines Agency. Doctors, dentists and veterinarians must report all serious adverse drug reactions to the Danish Medicines Agency no later than 15 days after they have come to their attention.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

Patient organisations do not fall under the Advertising Order's provisions on hospitality and congresses or meetings abroad, since they are aimed at HCPs only. However, ENLI's Ethical Rules for Collaboration between Patient Organisations and the pharmaceutical Industry state that support, in principle, may be granted for all activities, projects and purposes within the sphere of the organisation's work. Professional activities should always be the main intention of the collaboration and services must be proportionate to the compensatory measures. Events organised or sponsored by or on behalf of pharmaceutical companies must be held at a suitable location that contribute to the main purpose of event and which is not too extravagant or renowned for their entertainment facilities.

For congresses or meetings held abroad, the general ENLI rule is that a company must not organise or sponsor an event abroad, except when the majority of attendees are from abroad or when the location of the relevant resources or expertise involved in the event means that holding it in another country makes better logistical sense. Patient organisations can be invited or sponsored to attend congresses or meetings abroad, however it requires a report of association to the DHMA

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

It is not allowed to offer honoraria for HCPs and advocacy organisations for their participation in media activities. According to section 22(1) of the Advertising Order, economic advantages must not be offered or given to HCPs for advertising purposes or otherwise to promote the sale of a medicinal product. This does not extend to the remuneration of the services of HCPs or pharmacies when such remuneration is proportionate to the service offered. Both the giver and recipient of remuneration must, on request, present the basis for determining the size of remuneration to the DHMA, cf. section 24(1). Consequently, a HCP may receive payment for a service offered to a pharmaceutical company if the service is a natural element in an ordinary, mutually-binding agreement between the HCP and the company and if the service offered and consideration received in return are proportionate. Section 26(1) of the Advertising Order gives HCPs the opportunity of sponsorship of direct expenses for meals, travel, accommodation, etc. in connection with advertising of or professional information about medicinal products. This also applies to hospitality in connection with participation in courses and other professional activities involving pharmaceuticals and pharmacy matters. Furthermore, it gives HCPs the opportunity of sponsorship of direct expenses for courses and other professional activities, e.g. fees paid to external speakers, course fee expenses, or expenses to buy course material.

According to the Advertising Order, section 21(1), a patient organisation must publish on its website any economic advantages, including financial sponsorships (moneys) and payments in kind that the organisation has received from pharmaceutical companies. The information must be published on the website in such a way that the value of economic advantages is specified for each pharmaceutical company, cf. section 21(2) of the Advertising Order.

According to ENLI, all forms of hospitality offered to healthcare professionals must be kept at a reasonable level and be strictly limited to the main purpose of the promotional or professional event. As a general rule, the hospitality provided must not exceed the amount that recipients employed in the health sector would normally be prepared to pay for themselves. Companies must not provide or offer meals (food and beverages) to HCPs, except in those cases where the value of such meal does not exceed one of the following monetary thresholds: Danish Krone (DKK) 400 for lunch, DKK 700 for dinner or DKK 1,200 covering all meals at all-day meetings/ conferences, etc. The monetary thresholds apply to meals in Denmark. When providing meals in other European countries, the monetary thresholds laid down by the pharmaceutical industry associations in these countries must be complied with.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

No. it is not allowed to pay a HCP or patient organisation to attend a scientific meeting and funding must not be offered to compensate the time spent by healthcare professionals in attending the events.
According to the Advertising Order, Article 26, pharmaceutical companies can give or offer a HCP training and professional information in the form of payment of direct expenses in connection with professional relevant courses, conferences, training, etc., in which the HCP participates or arranges. The provision in section 26(1) gives health professionals the opportunity of sponsorship of direct expenses for meals, travel, accommodation, etc. in connection with advertising of or professional information about medicinal products. This also applies to hospitality in connection with participation in courses and other professional activities involving pharmaceuticals and pharmacy matters. The provision in section 26(2) gives the opportunity of sponsorship of direct expenses for courses and other professional activities, e.g. fees paid to external speakers, course fee expenses or expenses to buy course material. These services must be reasonable in level and must be strictly limited to the main purpose of the promotional or professional activity, cf. section 26(2) of the Advertising Order.

What is possible in terms of media or message training for health professionals or advocacy organisations?

Pharmaceutical companies are not allowed to give media or message training for HCPs. According to the Pharmaceutical Industry's Code of Practice on Promotion, Etc., of Medicinal Products aimed at Healthcare Professionals, the transmission of informational or educational materials to HCPs is permitted, provided it is inexpensive and directly relevant to the practice of medicine or pharmacy business and directly beneficial to the care of patients. Message alignment with HCPs and advocacy organisations are used.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

ENLI rules also apply to third parties operating on behalf of these companies, such as consultancies, including for example advertising agencies, communication agencies, etc.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

It is regulated by the Danish law on HCPs association with the pharmaceutical industry. Meetings and relations between pharmaceutical companies and patient organisations and other organisations are regulated by Article 2 in ENLI's Ethical Rules for Collaboration between Patient Organisations, Etc., and the Pharmaceutical Industry. Patient organisations are advised to write their own material.

KEY TAKEAWAYS/ SUMMARY

- Regardless of being a member of the trade association for the research-based pharmaceutical industry in Denmark's LiF or not, the best way to avoid any breach of law or regulations is to ensure that your company adhere to their ethical guidelines.
- The Danish market is highly regulated, but PR, public affairs and communication activities on disease awareness are still possible when correctly performed.
- It is important to remain in compliance with all updates to regulation and ethical standards.
- There is a high need for transparency.

FRANCE

In France, the health regulations are changing to avoid repeating major health crises. The National Agency for the Safety of Medicines and Health Products (ANSM) took over the French Agency for the Health Security of Medicines and Health Products (AFSSAPS) and implemented new responsibilities and missions to strengthen the safety of medicines and health products throughout the country. The ANSM has also created stricter legal constraints regarding publicity within the healthcare industry.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The French Public Health Code mainly governs the promotion of medicines, and it defines health products in Part 5. Articles L 511-1 to L511-4 define medication. To address dietary products that contain chemical or biological substances not classified as food, Article L 511-4 was created by the LAW n ° 2016-41 of 26 January 2016, Article 151, which redefines:

- drugs or classes of drugs for areas of major therapeutic interest;
- classes of drugs for which a break in treatment is likely to involve the vital prognosis of patients in the short or medium term; and
- drugs that represent a significant reduction in disease severity for patients.

The following details various parts of the code:

- Articles R-5122-1 to 5122-47 specify the rules for different classes of medicine.
- Articles L 5122-1 to L5122-17 define 'publicity' and explain the legal aspects—what's permitted, how publicity is controlled and what sanctions may be imposed.
- Articles L.5122-6 to L.5122-8-1 and Articles R.5122-3 to R.5122-7 –list the rules for advertising to the general public.
- Articles L.5122-9 and L.5122-12 and Articles R.5122-8 to R.5122-17 cover advertising for health professionals.
- Articles L4113-5, L4113-6, L4113-8 explain the independence of all physicians or pharmacists prescribing medicine and define the special situations in which a company can offer a subvention to a healthcare professional.
- Articles L-4163-1 to 4163-4 refer to the sanction that may be imposed if the rules are not abided by.

The rules for advertising drugs are strict. Such advertising is subject to control by the National Agency for the Safety of Medicines and Health Products (ANSM).

The term 'advertising' covers advertisements in the press or on television, brochures, scientific or medical publications, mailings and posters. This advertising is subject to an a priori control for advertising intended for the general public and for advertising intended for healthcare professionals.

Additionally, the French Drug Agency (formerly called AFSSAPS/Agence Francaise de Sécurité Sanitaire des Produits de Santé) issued guidelines that have been replaced since May 2012 by the ANSM's guidelines. Although they are not legally binding, French courts assert that pharmaceutical companies must take the guidelines into account. The ASNM receives mandatory application forms that it reviews before a product may be advertised to the public, and a commission checks all material prior to every advertisement or 'propaganda' piece's release. If the ANSM approves an application, it issues a visa (GP or PM.

Last, the code of practice issued by Les Entreprises du Médicament (LEEM), the French Pharmaceutical Industry Association, proposes guidelines of good practice in its Charte de la Visite Medicale and Référentiel des Bonnes Pratiques de la Visite Médicale des Entreprises du Médicament.

LEEM and The Comité Economique des Produits de Santé (CEPS) also signed the charter for communication of pharmaceutical companies in 2004, and it was updated in 2014 and renamed a 'promotional information charter' (concerning the certification of promotional information activity). The Haute Autorité de Santé (HAS) proposed a new procedure (using a repository) in two stages:

1. A first section published in 2016 dedicated to pharmaceutical companies
2. A second component in 2017 for subcontractors (with part 1 being taken over)

This repository makes it possible to audit the quality management system of companies in the following areas: policy for promotional information, training and evaluation of people responsible for promotional information activity through canvassing or prospecting and rules of professional conduct applicable to these people and their careers.

These materials may be amended shortly after this guide's publication. No official translations of the documentation currently exist, and any dispute must adhere to the original French material.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

There is little differentiation. The Public Health Code defines promotion of pharmaceutical products as 'any form of information, including the door-to-door selling, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'.

Who is responsible for the enforcement of these rules?

The ANSM approves all publicity material. The French Drug Agency is helped by the Commission de Contrôle de la Publicité et de la Diffusion de Recommendations sur le Bon Usage du Dédicament. The commission publishes recommendations about how publicity campaigns should be held, how media can be used in a promotional context and how to properly use medicines. The ANSM can withdraw a commercial that doesn't conform with French law.

The pharmacists and physicians' independence (as defined in the French Public Health Code, L-4163-1 to 4163-4) is controlled by public health inspectors (from the French Ministry of Health), the ANSM's inspectors, agents from the French Ministry of Finance Direction against Fraud or tax agents. A pharmacist, a physician or a dentist who makes a profit from illegal promotional activity may receive a €75,000 fine, be subject to a two-year prison punishment and be deprived of his or her professional duties for 10 years.

What are the regulations regarding healthcare provider engagement by pharma companies? How are these regulations enforced?

Publicity directed to healthcare professionals is subject to the ANSM's approval (it used to be controlled *a posterior*, it's now controlled *a priori*).

Who receives concerns and complaints? How does this process operate?

Concerns are brought to the ANSM by competitors, who may take direct legal action on the grounds of unfair competition if they are able to prove that they have suffered as a result. The penalties are among the toughest in Europe. The most serious punishment would result in a product being taken off the list of reimbursed medicines or a fine that could be anything from up to 10% of the turnover a company made from the medicine. Further criminal sanctions may also be applicable.

What promotional or media materials must be pre-approved by authorities?

Direct-to-consumer advertising is permissible for medicines that are not reimbursed by French social security schemes, on condition:

- No presentation of the medicine is reimbursable.
- Mandatory mentions are respected.

Any promotional material of these products intended for the general public or directed to healthcare professionals is subject to pre-approval by the ANSM (via the Commission de Contrôle de la Publicité).

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

Since 2012, the former agency AFSSAPS has been the new ANSM.

The control over conflicts of interest is tightened – agencies seek experts with no conflicts of interest. Publicity directed to healthcare professionals is subject to the ANSM's approval (it used to be controlled a posterior, it's now controlled a priori).

The device 'Transparency of the links of interests' introduced by the drug security law (Law n ° 2011–2012 of 29 December 2011) was widened by the health law (Law of modernization of our health system n ° 2016-41 of 26 January 2016). Drug companies are required to publish on the public database (www.transparence.gouv.fr) financial information on the remuneration paid to the various players, with the intent to further strengthen the transparency of the links.

The publication of information relating to each link of interest (convention, remuneration and benefits) is done twice a year and remains online for five years.

The HAS has extended the Drug Promotion Charter to all the people and situations potentially concerned by promotional activity. The regulation must thus apply 'whatever its form (by telephone or email[,] for example, and no longer only face to face), or the place (wherever an exchange can be made and not only on the place of practice of the professional)'.

To hold a promotional activity, manufacturers must respect the HAS charter and its reference system (updated in 2016 and March 2017). The new standard reinforces the quality of information communicated to healthcare professionals; communications about drug safety data must be systematically offered to them, and at least one approved communication by the ANSM must be submitted. Scientific and medical information must not be promotional.

The new reference framework also strengthens the conditions for organizing promotional visits to healthcare institutions. Visits must now be organized formally and tracked, and contacts with professionals in training (interns, students, etc.) are subject to prior agreement or support by experienced professionals.

In parallel, the HAS recalls that it provides independent and reference information for health products, in particular via the public drug database, the opinions and summaries of opinions of its evaluation committees and fact sheets. good use of the drug published on its website.

Other news encompassed in this charter includes the LEEM and CEPS deciding to create the National Observatory of Promotional Information to measure the quality of promotional practices based on objective, verifiable and transparent criteria.

The agency is able to trace the practices of companies and report to the LEEM and CEPS, via a trusted third party, the noticeable discrepancies. On this basis, the CEPS can

sanction companies whose practices do not comply with the charter's principles.

This new reporting process will not replace the control and audit certification already exercised by the High Health Authority, which will still be completed.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

The French Public Health Code categorises anything designed with the 'intention of promoting the sale or prescription of a medicinal product' as promotional. This is sometimes difficult to assess, as in the case of scientific data. However, as a general rule, the authorities will deem material issued by a pharmaceutical company promotional, whatever the context. The regulation is applicable regardless of the context, form (phone, email, etc.) and place (wherever an exchange may be done and not only at the professional's place of practice).

When a healthcare professional receives audio, video or interactive media, it must be accompanied by documents, as defined in the LEEM code, including but not limited to a summary of the product characteristics mentioned, the maximum price for its sale to the public and the situation of the product with regard to reimbursement by health insurance organisations or public authorities.

How is a media event defined?

There are no legal provisions defining media events for medicinal promotion, but a priori, it depends by default on advertising rules and constraints for the general public.

Do the regulations differentiate between consumer and clinical publications?

Yes, relating to the audience. Publications targeting consumers can insert commercials for medical products, provided:

- the medical products do not have to be prescribed by a physician and are not reimbursed by French social security schemes or do not belong to a promotional campaign in favour of vaccination;
- the advertisement includes all mandatory mentions (as defined in Public Health Code Article L5122-6); and
- publications targeting a professional audience can insert commercials for medical products if –
  - » the advertisement includes all mandatory mentions (as defined in Public Health Code Article R5122-8) and
  - » the commercials have a visa from the ANSM.

Do regulations differentiate between print and broadcast media?

No.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?

Direct promotion of products without marketing authorisation is not permitted. Unlicenced products may

be discussed at scientific meetings if the manufacturing company has not organised or directly or indirectly sponsored the meeting. Providing promotional information or data during a congress organised by a healthcare professional or advocacy body is fine.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
Generally, promotional material must be objective and consistent with a product's 'bon usage' (appropriate use). The Public Health Code further details that the following information must appear on a medicine's advertisement: its price (if determined by the French authorities), the daily cost of the treatment and its reimbursement by French social security schemes. The ANSM has advised that all press materials should mention the sources of scientific references. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion about the therapeutic value of a medicinal product. The product's claims should be based on an up-to-date-evaluation of all relevant evidence and reflect that evidence clearly. Claims must not mislead by distortion, exaggeration or undue emphasis and omission, or in any other way.

As a general rule, information must promote the rational use of medicines with objective presentation.

A pharmaceutical company or one of its agencies may invite a journalist to a congress if the discussions and presentations will deal with clinical studies in a scientific perspective. Journalists' articles may not mention a medicine by its commercial name, but may include the chemical name.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
No. Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) regulations, the materials must conform to both the issuing and receiving country's codes of practice. When the codes conflict, the stricter code prevails.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
See answer to the following question.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
The French regulations do not cover this consideration, because expenses and travel costs for third parties are permitted under EFPIA regulations if the journalist's time wasn't paid for or the nature of his or her outputs would not be deemed as promotional. However, under the regulations on transparency, EFPIA states that, where a company pays for or otherwise secures or arranges the publication of promotional material in journals, the material must not resemble independent editorial matter (LEEM guidelines 7.03). Under EFPIA regulations, material relating to medicines and their uses, whether promotional in nature or not, that is sponsored by a company must also clearly indicate that it has been sponsored by that company (LEEM guidelines 7.04).

Do regulations cover the use of case studies or other third-party advocacy in the media?
Again, because this is not covered, the wider regulations apply. The EFPIA Code states that quotations must be faithfully reproduced (4.01) and that when a company pays for or otherwise secures or arranges for promotional material to be published in journals, the material must not resemble independent editorial matter (7.03).

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
In 2006, the LEEM and AFSSAPS signed the Charte pour la Communication sur Internet des Entreprises Pharmaceutiques, which presents guidelines for web communication.

Among the guidelines:

- A website must present the information required by Article 6 of Law No. 2004-575 of 21 June 2004 on confidence in the digital economy and must identify the operator and recipients targeted and the type of information disseminated.
- Advertising must be clearly identified, which can be done by any means clearly perceptible to make unequivocal to the public a message's advertising nature.
- The corporate part of a company's website must be clearly separated from the commercial part; product promotion must be clearly distinguished from the general information about the company.
- Advertising must conform with the French Public Health Code restrictions regarding audience. Banners targeting healthcare professionals must not be accessible to consumers but available on pages accessible to registered healthcare professionals only; mentions that ought to be included in an advertisement (according to Public Health Code Articles R 5122-3 and R5122-8) have to be accessible via a link to a special page (which must be registered by the ANSM as well as the commercial itself).

- Depending on the type of product presented, the promotional pages could be subject to a request for prior authorization to the ANSM (drugs and DM/DMDIV, according to the lists fixed by orders) before allowed online, or they could be the subject of a posteriori control without deposit (DM/DMDIV outside the aforementioned lists).

- A printed copy of the promotional materials used for email campaigns has to be registered by the ANSM, and the French Drug Agency must receive a copy at celluleinternet@ansm.sante.fr.

What levels of web security are required?

An advertisement must be adapted to its recipients. Advertisements intended for healthcare professionals must appear on pages reserved for them only. In addition, the the CHMP or the Centre Spécialités Pharmaceutiques (CSP) imposes restrictions on how certain advertisements are distributed and prohibits including any public advertising for class IIb and III refundable DMs, DMIAs and breast implants and for medicines subject to compulsory medical prescription, refundable or under advertising restrictions to the general public mentioned in the AMM.

Other media, like internet headers or pop-ups, may have lighter requirements only if all the mandatory information that the CSP provided appears clearly in the hyperlinked pages. At a minimum, these supports must show the name of the health product; its destination or indication; its status (medical device or medication); and, where appropriate, an age limit.

Do the regulations cover funding of, or provision of information to, non-company owned websites?

Guidelines for websites under the new EFPIA Code, which supplements the French regulations, describe to what extent non-promotional product information may be published on websites that patients and the general public access. Although the information must be factual, balanced and consistent with the summary of product characteristics, the guidelines seem to expand the scope for the kind of information that companies are allowed to make available to the general public, which meets an industry need. How these will be interpreted remains to be seen.

What are the most popular social networks in your region?

Facebook remains the most popular, with 61% of French internet users active on it and 44% active on Facebook Messenger, but France is experiencing growth with other platforms, like YouTube (31%), WhatsApp (24%) and Instagram (20%).

YouTube channels are increasingly used as 'video directories' that then relay to other sites, such as LinkedIn or Twitter.

The number of followers for pharma companies on Twitter is increasing more slowly – by 15%, to 2 million internet users.

Communities following the pharmaceutical industry on YouTube and Instagram are smaller, with respectively 106,000 and 77,000 subscriber accounts at one of the 20 largest laboratories, but both platforms recorded strong increases in 2017 (+50% for YouTube and +67% for Instagram).

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

Yes, the ASNM Charter for communicating about and promoting health products (medicines and medical devices) on the internet and in electronic media. The functionalities inherent to open social networks (like Facebook, Twitter, YouTube, etc.) lead to linking to pages with comments and messages whose content is free and uncontrollable (through sharing functions, in particular). In addition, the '[x] people like' feature displays the number of people who liked a page, and can be interpreted, if it is devoted to a health product, as a certificate of cure by the public or a surety if a healthcare professional likes it, and this is, therefore, contrary to the public health code. Consequently, promoting health products to the general public in the form of a page like this is not permitted, except if these engagement functions can be disabled by the page's owner. Likewise, sharing a website's promotional page to an open social network is not allowed.

Are there any self-imposed regulations from social media companies?

No.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

No.

No publicity for healthcare professionals can be published. The French Agency for the Web Normalization is currently working on an authenticity norm that would fight against fake testimonies about products or services. It's not specific to health and healthcare communications.

An operator setting up this type of service must achieve a real moderation of discussions held in order not to jeopardize the proper use of health products that would be mentioned. A posteriori moderation must at least be carried out under the operator's responsibility, who must put in place sufficient means to ensure that remarks that do not respect the regulations in force cannot last more than 24 working hours. Setting up a charter or leaving users to report an abuse is not acceptable because it risks allowing comments that do not respect the current regulations.

Regarding discussion forums and personal contribution spaces hosted on a third-party site, the operator can occasionally intervene in a discussion about one of his or her products to rectify erroneous information, in particular by providing links to the summary of product characteristics (RCP) or the notice. However, the answer should not promote the drug or medical device concerned.

What is mobile adoption like in your region? Are there separate regulations for it?
Of the French population, 77% of which owned a smartphone as of 2017, smartphone usage continues to increase, especially among people with higher incomes:

- 83% of French people between 12 and 17 years old have a smartphone.
- 98% between 18 and 24 years old have a smartphone.
- 92% between 25 and 39 years old have a smartphone.
- 81% between 40 and 59 years old have a smartphone.
- 55% between 60 and 69 years old have a smartphone.
- 35% 70 years old and older have a smartphone.

There are no separate regulations for mobile adoption.

What are the disclosure laws like in your region for non-branded websites?
For health information, there are no disclosure laws. Experts' interviews are considered reliable information. Experts don't have to disclose their conflicts of interest or information about specific diseases that do not mention commercial brands or include any symbol that could identify the brand, because this is considered disclosure of scientific or technical information.

What is the response level needed for adverse event reporting?
Adverse events have to be reported to the ANSM.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

The regulations allow pharmaceutical companies to provide various funding to patient groups, such as reimbursement for expenses. The reasonableness of the hospitality is assessed according to the main purpose of the event, which must remain exclusively professional and cannot be quantified, with its appreciation being multifactorial. Thus the following is taken into account: the medical interest of the event, qualification of invited health professionals, type and level of benefits provided and partially or totally paid for (transport, hotels, restaurants, etc.), the timetable provided by the program during the event, the topics covered and the medical content and participating scientist(s).

The duration of the hospitality is strictly limited to that of the scientific event. The reimbursements for these events are limited to all or part of the expenses relating to transportation, meals, accommodations and registration fees. Care can only be offered to healthcare professionals who are qualified to be full participants. The level of care offered to healthcare professionals must be 'reasonable' and strictly related to the main purpose of the event. It should not exceed what healthcare professionals would normally pay for themselves if they had borne the cost. Meals, including drinks, offered in this context cannot exceed €60, including tax.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Yes, it is possible to pay a healthcare professional reasonable compensation for professional services rendered (such as giving a presentation), but not simply for attending such an event. It is also possible to pay or reimburse reasonable expenses incurred by attendees.

On this matter, the Public Health Code (L4113-5 and L 4113-6) details that specific requests from healthcare

professionals to have all or part of their travel and accommodation expenses paid for must be submitted to the Conseil National de l'Ordre des Médecins (national medical board) for a national/international congress or to the Conseil Départemental de l'Ordre des Médecins (regional medical board) for congresses at the regional level. A request for an opinion file (paired with a letter of request written by the healthcare professional, congress programme and total expenses to be covered) must be submitted to the board authorities within a reasonable timeframe before the event takes place (clause 11 of the LEEM guidelines suggests one month). The levels of travel and accommodation must be 'reasonable and suited to the occasion and the expenses incurred must not exceed what the participants would have paid for themselves' (Public Health Code L4113-6). Expenses must not include family members' or friends' accommodations.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

See the answer to the previous question. Additionally, the EFPIA Code specifically states that 'funding must not be offered to compensate merely for the time spent by healthcare professionals in attending events' (LEEM guidelines 11.01).

Legal and regulatory framework was strengthened by the health law of 26 January 2016. Companies are obligated to declare the amount of remuneration they paid to stakeholders on the transparency site hosted by the Ministry of Social Affairs and Health.

All of the following are considered health actors working with companies:

- healthcare professionals and their associations;
- students aiming for health professions and their associations;
- the associations of users of the health system (including patient associations);
- health establishments;
- academies, foundations, learned societies and consulting companies or organisations involved in the health products or services sector;
- legal entities publishing press, radio or television services and online public communication services;
- software publishers that help with prescriptions and dispensing; and
- legal entities providing initial or ongoing training for healthcare professionals or participating in this training.

The French Anti-kickback Law has been the subject of several amendments, the last of which is the health law of 26 January 2016.

The text first clarifies the nature of prohibited transactions; authorized transactions are not considered benefits (such as the employment contracts of healthcare professionals employed in companies) and transactions that may be subject to derogations (service contracts, grants or subsidies that encourage research or associations, hospitality or funding training). The law also sets up a new control regime – from now on, all transactions that exceed the financial thresholds (set by decree) must be authorized

by the professional orders or by an administrative authority (which remains to be designated).

Below the thresholds, transactions must be reported to the professional orders or the administrative authority. An order was issued on 19 January 2017 to clarify the framework for this reform. It was scheduled to take effect no later than 1 July 2018, but implementation has been delayed and a new date has not been set.

What is possible in terms of media or message training for health professionals or advocacy organisations?

There are no specific rules.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

Under EFPIA regulations, material relating to medicines and their uses, whether promotional in nature or not, that a company sponsors must clearly indicate that it has been sponsored by that company (LEEM guidelines 7.04). Under the regulations on transparency, EFPIA states that when a company pays for or otherwise secures or arranges promotional material to be published in journals, the material must not resemble independent editorial matter (LEEM guidelines 7.03).

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

The regulations allow the provision of non-promotional information, including factual information relating to human health or diseases, provided that there is no reference, even indirect, to specific, branded medicinal products.

KEY TAKEAWAYS/ SUMMARY

Because of major health crises, French regulation is changing; all the actors, such as agencies, industry and healthcare professionals, are cautious not to reproduce the old schemes that led to the crises. Key takeaways include the following:

- There is a new agency for the medicines and health product security (ANSM).
- The publicity legal constraints are stricter
- The fight against conflicts of interests has been tightened.

GERMANY

In Germany, several constituents make up the overall Freiwillige Selbstkontrolle für die Arzneimittelindustrie (FSA) Code of Conduct, the governing agency responsible for regulating and stipulating the rules for all promotional activities surrounding medicines. Federal guidelines are still undergoing alterations, the most recent of which addresses pharmaceutical companies' ability to objectively promote any type of medicine to the public.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

In Germany, the FSA Code of Conduct (the Code) governs the promotion of medicines. This code was recently amended to take into account the Professional Rules for German Physicians issued by the German Federal Chamber Physicians and the Common Position of the Assessment in Criminal Law of the Co-operation between Industry, Medical Institutions and their Employees, which was published in 2000 by the trade associations and other organisations in the healthcare sector.

The content of the Code is also based on the Conduct Recommendations for the Cooperation between the Pharmaceutical Industry and Physicians issued July 2003 by the Verband Forschender Arzneimittelhersteller (VFA), also known as the German Association of Research-based Pharmaceutical Companies, the German Association of Pharmaceutica Manufacturers (BAH) and the German Association of the Pharmaceutical Industry (BPI). Laws include the German Drugs Act (AMG), German Advertising in the Health Care System Act, Law on Advertising in the Field of Healthcare, the German Fair Trade Practices Act (EWG) and the German Penal Code (StGB).

In early June 2016 the anti-corruption law came into force. This new regulation listed 'corruption within the healthcare sector' among the offenses in the criminal code: consequently, doctors found to have corrupt business practices, as well as pharmaceutical and medicine technology companies, can be sentenced to pay fines or go to prison.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

All promotional activities, including public relations and advertising, are defined as the same for the purposes of the Code itself. More specific regulations, as outlined above, govern the rules for advertising. The German Public Relations Association has also developed its own ethical guidelines. In general, advertising and public relations are considered as separate activities.

Who is responsible for the enforcement of these rules?

The conduct requirements of the Code are binding to member companies and monitored and sanctioned by the FSA's arbitrators. They can impose fines of €5,000 to €250,000.

What are the regulations regarding healthcare provider engagement by pharma companies? How are these regulations enforced?

Due to the implementation of the FSA Transparency Code 30 June 2016, all pharmaceutical companies in Germany were required to publish all monetary contributions they have paid to medical institutions, doctors and other partners throughout the previous year.

Who receives concerns and complaints? How does this process operate?

Concerns are mainly submitted by competitors who try to stop public relations activities via legal channels.

The German Public Relations Council can also make complaints. Complaints regarding advertisements are more common and are usually a result of direct action through the civil courts using the laws of unfair competition. Furthermore, INTEGRITAS, the association for fair drug advertising, is a self-controlled body of the pharmaceutical industry, that executes advertising controls and combats unfair advertising.

What promotional or media materials must be pre-approved by authorities?

No relevant authorities need to be contacted for pre-approval of promotional or media materials. Companies generally submit materials for internal review by their legal and medical-scientific departments to make sure that wording or any graphics used are correct.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

In June 2016, the anti-corruption law came into force. This new regulation listed 'corruption within the healthcare sector' among the offenses in the Criminal Code: consequently, corrupt doctors, as well as pharmaceutical and medicine technology companies, can be sentenced to pay fines or go to prison.

The FSA Code of Conduct was revised to reflect the latest requirements issued by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and came into enforcement law in March 2006. On 5 May 2011 the European Court of Justice decided that pharmaceutical companies are allowed to neutrally share the packaging and the unchanged package leaflet on the internet, provided that non-experts have to click actively on the information. The German government is discussing amendments of the health insurance system. However, it is not yet known how this will impact the promotion of medicines.

Furthermore, there were some important changes in the Law on Advertising in the Field of Healthcare (HWG) in 2012. Under specific submissions, it is allowed to communicate scientific outcomes (e.g., studies or expert reports) to the public press. Now, advertisement or public relations can use stories of illness as long as they are not abusive or repulsive or mislead to a wrong self-diagnosis due to an exact description. The same applies for 'before and after' photos. 'Before and after' photos are allowed if they don't show changes from illness or effect of medicine and are not abusive or misleading. 'Before and after' photos from plastic surgery and in connection with medical devices are not allowed.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

All communication regarding medicines issued by pharmaceutical companies is defined as promotional activity with the following exceptions: labelling of medicines and leaflets; correspondence and documents of a non-promotional nature intended to answer a specific question about a particular medicinal product; factual information, such as announcements relating to labelling changes, adverse warnings, as well as reference material; factual information relating to diseases or human health; and corporate information directed to investors or potential employees.

How is a media event defined?

The regulations contain no definitions of a media event, or any meetings with non-medically qualified personnel.

Do the regulations differentiate between consumer and clinical publications?

The German code on promoting medicines does not provide definitions of, or differentiation between, types of media.

Do regulations differentiate between print and broadcast media?

The German code on promoting medicines does not provide definitions of, or differentiation between, types of media.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?

The provision of medical and scientific information to the media during the development or marketing authorisation phases of a product is permitted, provided that this is not part of product-related advertising. This would generally mean that the outcomes of clinical

studies or scientific speeches and publications might be made available at scientific meetings or conferences using the generic but not the brand name of the product. Press releases are usually deemed to be unlawful when the anticipated product name is mentioned. In general, it is important to use the generic name and not the brand name prior to product approval. Advertising is prohibited during this stage.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

The German code on promoting medicines does not provide for any specific regulations regarding press relations or other materials. Therefore, they would be subject to the same general principles as all promotional material. Promotion must be based upon sufficient scientific evidence and must be consistent with the information addressed to healthcare professionals. This rule applies in particular to claims referring to specific benefits, qualities or properties of a product or substance.

Promotional materials regarding side effects must also reflect all available findings or be capable of substantiation by clinical experience. They must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties. They must also be balanced, fair, objective and based on a current evaluation of all relevant evidence, as well as reflect that evidence clearly. The word 'safe' must not be used without robust evidence, and the word 'new' must not be used to describe any product generally available, or any indication that has been generally promoted, for more than one year.

All materials must contain the following: company name and domicile of manufacturer; name of product; composition of product; therapeutic indication; contraindications; side-effects warnings, if and to the extent required for the labelling of receptacles and outer packages; the indication 'verschreibungspflichtig' (prescription-only); and the date on which the information was generated or last revised.

Section 11 covers clear guidance on the admissibility of references, which must all indicate whether the publication concerns the product in question, its method or treatment as well as the author name, date and source. Materials must also clearly state that they have been sponsored by that company. These regulations are especially important for advertising.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

The Code states several times that, where there is a conflict of codes, the stricter code is said to apply, making it important to be acquainted with both the german code on promotional materials (see above) and that of the country of distribution. This is also consistent with the wider international guidelines.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

For the purposes of the Code, these events would be viewed in the same way as scientific events. It is permissible to organise them at international scientific meetings, such as recognised medical congresses, because the relevant resource or expertise is on-site. For the purposes of hospitality, media should be treated as doctors, so it is not permissible to pay for their time, but 'reasonable' expenses for travel and accommodation may be covered. Regarding licensing, the same rules apply, so the outcomes of clinical studies or scientific speeches and publications could be made available at scientific meetings or conferences using the generic but not the brand name of the product. Please check the detailed rules before any media event, as the rules are very diverse (www.fs-arzneimittelindustrie.de).

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?

If a company has invited the journalist with the express intention of creating and approving publishable copy, then the rules on promotional material will apply. Where a company sponsors the publication of promotional material in journals, it must make sure that such promotional material cannot be confused with independent editorial matter. In the case of any publications made by third parties about medicinal products and their use, which are either wholly or partially sponsored by a company, particular care must be taken to ensure that such publications clearly indicate that the company has sponsored them.

Do regulations cover the use of case studies or other third-party advocacy in the media?

Section 8 of the Code covers transparency and the prohibition of disguised promotion and is quite specific in that any arrangement of publication, whether direct or indirect, that concerns a product or its disease area must be clearly indicated as sponsored. Regarding expert quotations, it is very important that healthcare professionals must not be unfairly influenced and, although it is not specifically addressed, it would seem clear that payment for media work and quotations would not be acceptable.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

There is no specification in the regulations.

What levels of web security are required?
There are no specific regulations on the level of security required to restrict healthcare professionals-only websites. However, disclaimer statements are not deemed to be sufficient, and 'safe access systems' are recommended, which basically means that websites must be password protected. Websites of pharmaceutical companies should have password-protected areas for healthcare professionals where detailed information about the medication and its indication is published.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Not specifically.

What are the most popular social networks in your region?
Facebook is the most popular social network in Germany, followed by Instagram, LinkedIn, Pinterest, Xing and Snapchat. Twitter use has also increased recently.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Regarding social media activities, it is crucial to react promptly, to synchronise the community and process management and undertake a close monitoring process. All social media communication towards patients or the general public must comply with the pharmacovigilance criteria and German law on the advertising of medicinal products.

Are there any self-imposed regulations from social media companies?
Facebook's terms of use within Germany require companies in the pharma industry to permit comments on their pages. Otherwise, general regulations for promotional activities apply.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
In general, there is no requirement to observe or to evaluate online interactions concerning drugs. In individual cases, a product observation exists when there are concrete indications. The admission board prohibits pharmaceutical companies from answering customer questions concerning prescription drugs. A pharmaceutical company can only delete questions from their platform or ask the provider to delete the question.

What is mobile adoption like in your region? Are there separate regulations for it?
Nearly 80% of the population has a smartphone in Germany, and the percentage is increasing. Nevertheless, the pharmaceutical industry is still reserved when communicating via mobile channels. Also, within mobile adoption, the general rules take effect.

What are the disclosure laws like in your region for non-branded websites?
Non-branded websites have to show who initiated and supports them.

What is the response level needed for adverse event reporting?
If a customer/patient posts about adverse reactions to a drug on a pharmaceutical company's forum or on a Facebook page, the company must pass the information to the authorising authority. This rule is why many pharmaceutical companies do not use the platform for patient feedback.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
The regulations do not specify this information.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
The section of the Code that addresses this is not very specific. It says, 'Physicians or third parties must not be granted payment of any fees for their willingness to meet with or receive information from a pharmaceutical company'.

The legal provisions of the Professional Rules for German Physicians differentiate between 'active' and 'passive' participation in scientific meetings. 'Active' includes giving a presentation, acting as a moderator or rendering another reasonable service. Fees are allowed for this so long as they conform to the guidance outlined above. 'Passive' participants, who are not participating in the activities outlined above, may not be paid. It is acknowledged that a pharmaceutical company may reimburse conference fees as well as reasonable travel and accommodation costs. As with active participants, passive participants need the written approval of their superior or administrator. Accommodation and hospitality must not exceed 'reasonable limits'.

'Reasonable' costs are only permissible if the job-related, scientific nature of the event takes center stage. In 2010, the FSA added the following amendment: 'It is not allowed to reimburse attendance fees of entertainment programmes directly or indirectly to healthcare professionals or other members of medical body of experts by FSA member companies'. It is thus ensured that the financing of entertainment or leisure mes by companies does not take place.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

While there is no specific regulation in this matter, any honoria on travel expenses provided by the pharmaceutical company must be disclosed per the anti-corruption act and fit within the abovementioned regulations.

What is possible in terms of media or message training for health professionals or advocacy organisations?

Member companies may invite healthcare professionals who are particularly concerned with the companies research areas, pharmaceuticals and/or their therapeutic indications to their own job-related training events. It would seem fair to surmise that, provided the scientific content was robust and deemed as necessary knowledge for the physicians, then 'message' training would be allowed. Media training without scientific content would not be permissible. The rules of moderate hospitality also apply and the venue must be chosen on the basis of factual criteria, such as geographical location, rather than the leisure facilities offered. In the case of media training, it is important to sustain the expert's independence in front of the media.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

Any materials that have been written or organised by a pharmaceutical company, whether directly or indirectly, are subject to the above-mentioned rules on promotional material, unless they are factual information on diseases. It is clear that the pharmaceutical company must abide by the Code even if it commissions others to design or implement any activities on its behalf.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

As with meetings with healthcare professionals, there must be a reasonable need for the meeting before it can take place. Again, factual information relating to diseases or human health would be nonpromotional and not subject to the Code.

KEY TAKEAWAYS/ SUMMARY

The German code outlines how pharmaceutical companies must act with regard to print and online communication.

- Laws harness the pharmaceutical industry, but not always in ways that benefit needs of customers or pharmaceutical companies, especially in regards to interactive social media.
- Patients and customers are looking for information and exchange, but the possibilities for pharmaceutical companies to interact are limited.

ITALY

In Italy, pharmaceutical regulation is governed by The Italian Medicines Agency (AIFA), a division of the Ministry of Health (MoH). Members of the Italian Association of the Pharmaceutical Industries abide by the Code of Professional Conduct of Farmindustria. In addition to the decrees set forth by these organisations, pharmaceutical marketers must adhere to the code issued by the Institute of Advertising Self-Regulation (IAP). Promotional material includes any scientific information provided by pharmaceutical companies direct-to-consumer. promotion of prescription-only medicines is not permitted.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

In Italy, Title VIII (Articles 113-128) of Legislative Decree No. 219 of 24 April 2006 (the Decree) is the most relevant for the regulation of the advertisement of medicinal products to the general public and healthcare professionals. The Decree implements under Italian legislation Directive 2001/83/EC (and subsequent modifications) on the community code on medical products for human use and Directive 2003/94/EC. Other relevant provisions on advertising of medical products and the activities of pharmaceutical companies are set out in Legislative Decree 229/99 regarding CME principles and in Legislative Decree 74/1992, as amended by Legislative Decree 67/2000 on unfair advertising, implementing Directive 97/55/EC. Additional regulations regarding advertisements to the general public include: the Legislative Decree No. 205 of 6 September 2006, (the Consumer Code); the Guidelines of the MoH of 17 February 2010 concerning advertising, of medicinal products via the internet and telephone, including MMS and SMS (the MoH Guidelines); and the code issued by the IAP

The Decree defines the advertising of medical products, as 'every informative action, search for clients or exhortation aimed to promote prescription, sales or consumption of medical products'. Any scientific information provided directly or indirectly by pharmaceutical companies (supply of samples, sponsorship of meetings and events, activities of sales representatives) is considered as advertising (to health professionals or to the general public) and should be carried out in accordance with the provisions set forth in the Decree. Public relations activities include 'informative actions to different targets', and are also subject to this legislation. The Decree regulates advertising to the general public, advertising to health operators (physicians and hospital pharmacists) and advertising to chemists/ drugstores. The Decree does not regulate general information about public health when it does not mention (either directly or indirectly) a particular drug (e.g., health campaigns or disease information).

Regarding advertising to healthcare professionals, the regional Guidelines of the State-Regions Conference of 20 April 2006 (the State-Regions Conference Guidelines) and Article 2598 of the Civil Code are also relevant. The State-Regions Conference Guidelines concern scientific information provided by medical sales representatives, while the latter regards misleading advertisement contrary to fair business practice.

The main principles concerning the advertising of medicinal products are:

- Advertising of medical products that have not been authorised by European Union (EU) law is prohibited;
- Advertising of medicinal products must always comply with all the requirements listed in the relevant authorised summary of product characteristics (SmPC)
- Advertisements must not be misleading and must promote correct use of the products being advertised.

General press articles are the responsibility of the journalists, authors of the articles and of the publisher/ owner of the journal/media, as regulated by the codes of journalism, e.g., the Charter on Information and Publicity and the Charter on the Duties of Journalists. In general:

- A journalist is not allowed to accept any payment causing a conflict of interest to his/ her professional role
- Articles should be written in a way that enables the reader to easily distinguish between information and advertising
- The brand name of a medicine should not be mentioned in the lay press with the intent of increasing its use

Specific to Italy, the 20 regional governments in Italy

can also regulate promotional activities to doctors and pharmacists within their own territory.

Another important code is the Code of Professional Conduct of Farmindustria, the Italian Association of the Pharmaceutical Industries, as amended 23 October 2012. This is a voluntary agreement entered into by the pharmaceutical companies belonging to Farmindustria. The Code sets out to regulate relations not only between companies but also their relations with the scientific and health sectors. All member companies of Farmindustria must accept and comply with its provisions. Recently, most of the pharmaceutical companies have adopted their own Corporate Code of Conduct, which is a compendium of the Government Decree and the Farmindustria Code.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

As far as the different decrees and the Farmindustria Code are concerned, no special rules apply to public relations activities as distinct from advertising. Because public relations activities include 'informative actions to different targets', they are subject to the same legislation. For more details, see the answer to the first question.

Who is responsible for the enforcement of these rules?

The Italian Medicines Agency (AIFA) is the division of the MoH which deals with all drug-related issues , including research support, licensing, control of distribution and all communication activities directed at patients and doctors. AIFA has the authority to regulate information and activities about drugs and diagnostics. With the sole exception of authorised SmPC, promotional material disseminated to healthcare professionals must be submitted to AIFA at least 10 days prior to its dissemination.

In the case of no reply from AIFA, dissemination of promotional material shall be considered authorised (the 10-day tacit consent procedure). Reference to the date of submission to AIFA shall be placed on the authorised promotional material. In case of failure to comply with its guidelines, AIFA can order termination or suspension of the advertising and can issue a corrective statement to be published. For example, AIFA has powers to stop a screening campaign that might encourage the general public to ask their health professionals to prescribe specific tests that would increase Ministry costs. Or, it may stop an advertising campaign which overemphasises the effects of a particular drug.

What are the regulations regarding healthcare provider engagement by pharma companies? How are these regulations enforced?

According to Farmindustria's Code, pharma companies may hire healthcare providers (HCPs) for scientific consultancy. Pharma companies must create a contract that specifically stipulates the nature of the service and the HCP's relationship with the company. The pharma company must keep the contract for at least three years.

These regulations are enforced by The Supervisory Committee.

Who receives concerns and complaints? How does this process operate?

The Supervisory Committee receives complaints. The committee carries out investigations into complaints, and upon an investigation's conclusion, proposes a specific sanction and notifies the company. This sanction is then sent to the single-judge tribunal.

The single-judge tribunal then notifies the company that official proceedings have begun, during which the company may file a defense brief. The company's legal representative then participates in discussions before the judge. Thirty days after the discussions, the judge will submit a ruling. The company may submit an appeal, or comply with the recommended sanctions.

What promotional or media materials must be pre-approved by authorities?

The difference between advertising and public relations activities is that for public relations activities there is no prior control, whereas both advertising messages to the general public and information provided to health professionals are subject to the prior approval of the Italian regulatory authority.

Advertising to the general public:

- Must be submitted to and authorised by the MoH 45 days before publication. No answer from the MoH within 45 days means implicit approval
- The authorisation is valid for 24 months, unless a shorter period is indicated in the authorisation
- In the case of implicit approval, the authorities can nevertheless order any time the suspension of the advertising; however the authorities need to justify its reasons

Advertising to health professionals (MDs and hospital pharmacists):

- Must be submitted to the AIFA and approved
- With the sole exception of an authorised SmPC, promotional material disseminated to healthcare professionals shall be submitted to AIFA at least 10 days prior to its dissemination.

It is possible to distribute a press release without prior involvement of AIFA, but the content must follow the same rules for the contents of advertising as defined in Article 117 of the Decree:

Art. 117 states tha publicity content to the public regarding a medicine that is not permitted advertising cannot contain any element that:

1. Makes a medical consultation or surgical intervention appear unnecessary, specifically by offering a diagnosis or proposing a corresponding therapy;
2. Leads a member of the public to believe that a medicine is free of undesirable side effect or superior or equal to another treatment or another medicine;
3. Leads a member of the public to believe that the medicine can improve the normal state of good health of the subject;
4. Leads a member of the public to believe that the non-use of the medicine can have a prejudicial effect on the normal state of good health of the subject;
5. Is directed exclusively or generally towards children;

6. Includes a recommendation of scientists, medical operators or persons well known to the public;
7. Compares the medicine to a food product, a cosmetic product or another consumer product;
8. Induces to believe that the safety or effectiveness of the medicine is owing to the fact that it is a 'natural' extract;
9. Can lead to a wrong self-diagnosis;
10. Refers in an inappropriate, impressive or false manner to evidence of cure;
11. Utilises in an inappropriate, impressive or misleading way visual representations of changes to the body caused by illness or lesions, or of the action of a medicine

What are the most recent significant developments and are there planned changes to codes of conduct and regulations in the next few years?

Farmindustria to comply with legal provisions of statute law and the Codes of Conduct of European and international federations of the pharmaceutical industry (EFPIA and IFPMA), amended its Code of Professional Conduct on 23 October 2012. No legal change is expected in the near future, although it is likely that the increase in availability of generic drugs will lead to tighter controls on promotional materials.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

All the material that the pharmaceutical industry provides to doctors is considered as promotional (advertising). Further limitations are set according to different categories of providers.

Advertising to healthcare professionals:

- Limited to those healthcare professionals who may prescribe or sell medicinal products, typically medical doctors and pharmacists
- Advertising to healthcare professionals during visits of sales representatives shall, in principle, always include presentation of the most recently authorised SmPC, supply classification and public price
- Advertising to medical doctors also includes visits to laboratories and centers of research aimed at improving scientific knowledge

Advertising to pharmacists (excluding those working in hospitals):

- Advertising of prescription medicinal products shall be limited to the sole information contained in the SmPC.
- Advertising of non-prescription medicinal products may include all information that may be relevant to the pharmacist for advising patients on their adequate use.

Advertising aimed at the general public:

- Limited to medicinal products that do not require the help of a medical doctor for diagnosis, prescription and monitoring of their use.

Advertising of medicinal products that are available on medical prescription only; that contain substances defined as psychotropic or narcotic, that are reimbursed, even in part, by the National Health Services (NHS) or that are intended for research and development trials, as well as distribution of medicinal products to the public by the industry for promotional purposes, is forbidden.

How is a media event defined?

This is not specifically defined.

Do the regulations differentiate between consumer and clinical publications?

Yes, regulators have separate requirements for advertisments targeted at HCPs and consumers. See the previous question for additional information.

Do regulations differentiate between print and broadcast media?

The same conditions apply. Advertising in newspapers with only the reproduction of the authorised medicinal product information and a picture or graphic of the product, or pictures, and graphic reproductions of a medicinal product that is available without prescription placed on price labels is acceptable.
Advertising of medicinal products aimed at the general public is subject to the prior authorisation of the competent committee of the MoH

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

In the specialist press for health professionals, it is possible to publish information regarding clinical trials of an unlicenced drug. When the scientific studies contain significant developments in a disease of general interest, it is possible to also publish information in the lay press or on radio/TV and the internet. The information is generally provided by print, radio and television journalists as part of their professional services. References to any treatment, research or launching of a product can be made provided that there is no contractual relationship between the pharmaceutical company and the publisher or the journalists. In any kind of press, either general or health professional and in TV and radio broadcasting, it is forbidden to use the brand name. Dissemination to the public in written publications, radio or television images or with a reference to the name of a medicinal product in a way that may cause its consumption is also forbidden.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

The Decree does not specifically mention press releases. It is common practice, however, to consider press releases permitted when they relate to a potential improvements in public health and do not contain the brand name of the product. It is important that the

message provides scientific information and that the information is factual, balanced and non-promotional.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
Clinical studies are also published on the internet and can be consulted by relevant journalists. In general, if a medical company is promoting in its own country, then its local country code is applied to the conduct of the promotional activities, plus the EFPIA code.

- For a non-European company promoting in a European country, the EFPIA code applies, along with the local code in the country in which the promotional activities are taking place.
- If a European company based in one country is promoting in a second European country, then the national codes of both countries and the EFPIA code apply.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
The Decree provides that advertising and promotion of medical products may relate only to products for which marketing authorisation has been issued. However, based on the Italian Constitution and the liberty of the press, it is possible in scientific meetings for independent scientific speakers to provide information regarding new active agents or new off-label indications and to discuss recent developments of clinical trials regarding unlicenced products or indications. The scientific secretary of the meeting may organise a press conference or distribute press releases. It is forbidden to use the brand name of the product. Scientists and journalists can only use a generic name.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
The general principle is that advertising should always be easily distinguished from educational information. Supplements and editorials to the general public are subject to the same regulations as advertising (i.e., the brand name of products cannot be mentioned) and cannot be paid for by the drug producer. However, if signed by a journalist, the liability is on the writer and/or the publisher. In practice, it is quite difficult to demonstrate that an article is a form of concealed advertising and the author/journalist/publisher can always appeal to the principle of the freedom of the press. For supplements and advertorials in the medical press, the same rules of Decree 219/2006 (Article 119) apply. Original scientific papers published in scientific journals and signed by their authors can be used and distributed by pharmaceutical industries or others with the permission of the publishing company. There are no specific limitations on the use of freelance journalists. Rules about content apply as stated above and are relevant to prior copy clearance.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Per questions 15 and 16, as long as the product name is used, general health information provided by a third party group can be included in the media. The burden to meet legal standards falls on the journalist writing the article, not on the original provider of information.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
Websites must comply with the legislative basis and the self-regulation codes. However, the Guidelines of the MoH of 17 February 2010 concerning advertising, and of medicinal products via the internet and telephone (including MMS and SMS) state that information directed to healthcare professionals and regulated by the Ministry must be accessible exclusively to these professionals, even when broadcasted via the internet. Therefore, companies should provide access only with an encrypted password given out to doctors, pharmacists and other health professionals after they are duly registered following the submission of their identification materials.

What levels of web security are required?
This is not yet fully specified; however, see answer to previous question.

Also, on 22 December 2010 the Italian Communications Authority (AGCOM) published a draft regulation, relating to AGCOM's powers in respect to the protection of copyright on electronic communications networks. In the first instance, AGCOM said it is competent to protect copyright on 'electronic communications networks', a term which includes television and telecommunications networks and the internet. This draft regulation provides an indication of a possible future regulating authority.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Guidelines for websites under the new EFPIA Code, which supplements the Italian regulations, describe to what extent non-promotional product information may be published on websites accessible by patients and the general public. Although the information must be factual, balanced and consistent with the SmPC, the guidelines seem to expand the scope for the kind of information that companies will be allowed to make available to the general public, which meets an industry need. How this will be interpreted remains unclear. The general rules and guidelines apply in this case as well.

What are the most popular social networks in your region?

More than half of the Italian population used social media regularly as of 2017. Facebook dominates the social landscape in Italy, with an 87% market share, while Twitter is a distant second, with a 4% share. YouTube and Google+ were also popular, as was Instagram.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

In March 2017 the MoH updated the guidelines regarding internet Advertising on over-the-counter products. The advertising message, authorised by the Ministry on the basis of the MOH' committee for advertising, has to be static and not editable by the promoter of the ADV or other subjects.

The use of the social network -- which in general allows the users to manifest their own opinions -- compromises this static requirement guaranteed by law. Therefore, the use of social networks is not allowed except for the following cases:

Facebook:
It is possible to use Facebook for advertising messages (image, script, video, audio) only on the right column of the "Social Wall/Timeline". This type of insertion allows attaching images and a short texts. Clicking on the insertion/banner you will be directed to an external site. Facebook business pages (e.g., pharma company pages on Facebook) cannot show posts of products. Advertising on other social networks (e.g., Twitter, Instagram, etc.) is not allowed.

Youtube:
It is allowed to use Youtube for advertising messages (image, script, video, audio) - that have obtained authorisation by the MoH - with full interactivity functions disabled (like, share, comments).

Mail, SMS and MMS Messages:
It is possible to distribute authorised advertising messages via mail, SMS or MMS on condition that the company declares that the messages will be disseminated exclusively with the consent of the person who will be free to revoke constent at any time the consent.

Links:
Links from sites, banners, and other promotional material authorised by the Ministry and addressed to the general public are allowed under the condition that the company warn the user with the following statement: 'You are abandoning the Company's XXXXXX site ... with content authorised by the current legislation on health advertising'. This statement is not required in case the link refers to the SPC or SmPC) or to an image/packaging of the product.

Are there any self-imposed regulations from social media companies?

There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

No specific rules exist. The general rules and guidelines apply.

What is mobile adoption like in your region? Are there separate regulations for it?

In 2017 there were an estimated 50 million mobile phone users in Italy, or 80% of the population. Regulations for mobile advertising and marketing follow the general social and digitla media guidelines.

What are the disclosure laws like in your region for non-branded websites?

Non-branded websites have to show who initiated and supports them. For example, it must be clear if the website of a patient organisation is funded by pharmaceutical companies. General regulations will apply as well.

What is the response level needed for adverse event reporting?

The AIFA states that reports of adverse reactions (ADRs) are an important source of information since they allow detecting of potential safety issues associated with the use of the medicines available on the national territory. The reporting form for healthcare professionals is a simple form to be filled in to report adverse events relating to any drug. Reports are entered into the RNF, allowing the instant monitoring of adverse reactions. However, pharmacovigilance according to AIFA involves the whole community and the report on the occurred ADRs can be provided not only by the healthcare professionals, but also by citizens through the completion of the proper citizen's reporting form. Although this dual reporting procedure exists, surveys show that not all incidents get reported.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

Patient associations are becoming increasingly important in Italy and form partnerships with both AIFA and the pharmaceutical industry to discuss research plans, compassionate use programmes, new drugs and improvements to existing products. Patient associations have an important role in public relations and lobbying activities and are often financially supported by the pharmaceutical industry to help distribute information on diseases and treatments. Constraints on payments to these groups are not detailed in existing regulations. Collaboration of the pharmaceutical industry with patient organisations is not expressly regulated by the law in Italy. There are a number of provisions, however, which are relevant, including Article 4.5 of the Farmindustria Code, which provides that:

- All forms of economic support, whether direct or indirect, by the pharmaceutical company towards a patients' association must be based on a specific and preliminary agreement aimed at regulating the amount of financing and the reasons for its disbursement, and need to be entered into in accordance with specific internal procedures
- Public use by a pharmaceutical company of the logo or material owned by a patients' association must be authorised in advance by the association
- Any form of sponsorship by the pharmaceutical companies regarding patients' associations must be transparent and without promotional objectives
- No company can request to be the sole financier of a patients' association
- Pharmaceutical companies must include a list of the patients' associations they support on their websites.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel not allowed?

The main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals include the following:

- Article 123 of Legislative Decree No. 219 states that when giving out scientific information before healthcare professionals, the granting, offer or promise of gifts, pecuniary advantages or benefits in kind is forbidden unless they are inexpensive and relevant to the practice of medicine or pharmacy; a similar provision is also contained in the State-

Regions Conference Guidelines, which specify that inexpensive gifts or gadgets shall be understood as goods having an economic value of no more than €20 per year
- Article 4.1 of Farmindustria Code, provides that collaboration with healthcare professionals (e.g., scientific consultancies, speeches at conferences, studies, scholarships) must be in the form of a written contract, clarifying the need for the service and specifying its nature; the consultant also needs to disclose the relationship with the pharmaceutical company whenever there is a public presentation about the results of this collaboration
- Finally, according to Article 53 of Legislative Decree No. 165 of 30 March 2001, civil servants (including healthcare professionals working for the NHS) may not perform any paid activities unless a prior authorisation has been obtained

Failure to comply with the rules above may cause criminal liability, for example for criminal corruption. Sanctions range from imprisonment to fines.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Italian law allows under certain conditions pharmaceutical companies to sponsor scientific meetings, congresses, courses, prizes and grants.

Sponsorship activities require prior authorisation or communication to health authorities. Farmindustria members are required to give prior notice to AIFA of any meeting and event that they sponsor. Journalists' hospitality, fees and expenses, including travel expenses, may be paid directly by pharmaceutical companies and no AIFA permission is needed.

What is possible in terms of media or message training for health professionals or advocacy organisations?

There are no limitations regarding participation in media training programmes.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

In general, it is not permitted to use a pharmaceutical product's brand name in media materials (only a generic reference can be mentioned) unless the name of the product is central to the news.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

Article 4.1 and 4.1 of the Farmaindustria Code apply to the provision of information to patient groups and healthcare professionals.

Any form of sponsorship and provision of information must be transparent and without promotional objectives.

KEY TAKEAWAYS/ SUMMARY

- The retail market for pharmaceuticals in Italy has been significantly affected by the overall economic climate, and no new legal regulations have been adopted in recent years.
- Any scientific information provided directly or indirectly by pharmaceutical companies (supply of samples, sponsorship of meetings and events, activities of sales representatives) is considered promotional (to health professionals or to the general public) and should be carried out in accordance with the Italian legislation.
- Advertising aimed at the general public shall be limited to medicinal products that do not require the help of a medical doctor for diagnosis, prescription and monitoring of their use.

NORWAY

Promotion of medicines in Norway is governed by the Pharmaceutical Laws, the regulations on Pharmaceuticals, Norway's Association of the Pharmaceutical Industry's (LMI) Guidelines and Rules for Cooperation and Advocacy Groups/Healthcare Providers (HCPs). Although not legally binding, LMI's guidelines are widely recognised by the pharmaceutical industry as an expression of fair and ethical marketing. The national regulatory framework for promotion of medicinal products specifically states that its legislated regulations do not stop the industry from having their own structure and process for marketing pharmaceuticals. The national regulatory framework for promotion of medicinal products is largely based on EU legislation. It is, for instance, prohibited to advertise medicinal products that are not authorised to sell in Norway or to aim advertisements of medicinal products at children. In addition, advertisements on prescription medicinal products may not be aimed at the general public, with the exception of vaccination campaigns against infectious diseases.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

Information distribution on pharmaceuticals is governed by the pharmaceutical laws, the regulations on pharmaceuticals, LMI's Rules for Pharmaceutical Marketing and the agreement between LMI and the Norwegian Doctors' Association (Dnlf) regarding guidelines and rules for cooperation between the pharmaceutical industry and patient advocacy groups.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Information designed to enhance sales and increase the demand for a product, which mainly focus on the benefits rather than the potential risks associated with the pharmaceutical product, might be considered advertising or promotional activity. Public relations is not defined separately.

Who is responsible for the enforcement of these rules?

The Council for Pharmaceutical Information, established by LMI and the Norwegian Medical Association (NMA), is responsible for controlling the adherence to the Rules for Pharmaceutical Marketing Every employee of a pharmaceutical company involved in production or approval of information directed towards HCPs must be fully familiar with the regulations in the Rules for Pharmaceutical Marketing. Every firm must have a scientific department handling all information. They must appoint a compliance officer who is responsible for approving all informative material for distribution. This person may be a doctor, pharmacist or a person of sufficient educational competence to assess the material.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

According to pharmaceutical laws, doctors, dentists, veterinarians, pharmacists or fish health biologists may not participate in marketing with recommendations and thereby encourage the use of pharmaceuticals. According to the Rules For Pharmaceutical Marketing, HCPs are allowed to be used as consultants by the industry given that there is a written contract, the actual need is clearly defined and that the compensation is reasonable in comparison to the service provided by the HCP.

Who receives concerns and complaints? How does this process operate?

According to the Pharmaceutical Law, § 13-10, the Norwegian Medicines Agency (SLV) is responsible for compliance of pharmaceutical marketing. Any company violating marketing regulations may be forced to stop that specific marketing activity and corrective actions may be administered. With repeated violations, all marketing measures for a medicine may be stopped for an unspecified amount of time, or permanently. Aside from these agency regulations, the industry may have their own control measures.

The industry's pharmaceutical information is subject to ongoing audit by the Council for Pharmaceutical Information, run by the LMI and NMA. All members of LMI are obliged to submit all information and marketing material to the Secretary of the Council.

Complaints regarding members of LMI or NMA may be submitted. The council's verdict on all matters is final and binding.

What promotional or media materials must be pre-approved by authorities?

SLV may pre-approve specific promotional material targeting users of a prescription drug, e.g. regarding advanced forms of administration, or other important user information.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?
The Rules for Pharmaceutical Marketing were last updated 14 November 2014.

1 January 2016, television commercials for over-the-counter (OTC) pharmaceuticals were legalised in Norway.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
This difference is not specifically defined.

How is a media event defined?
This term is not specifically defined.

Do the regulations differentiate between consumer and clinical publications?
No, the regulations are the same.

Do regulations differentiate between print and broadcast media?
No, the regulations are the same.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?
The rules do not specifically address this issue.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
In accordance with business practice, press releases are not considered marketing, even if this contradicts the view of the SLV. LMI disagrees with the authorities and urges their members to continue to issue relevant press releases that are balanced, leaving the decision to publish in the hands of media editors.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
The method of distribution is not regulated. Material from outside of the country also needs to fulfill Norwegian rules and regulations.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
Journalists may receive congress reports containing news on research, ongoing studies and preliminary research findings, given that the information is relevant and balanced.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
The resulting copy is independent, in all cases.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Third-party advocacy of medicinal products in media by HCPs or patients on behalf of pharmaceutical companies or their PR agencies is not allowed. However, an article regarding a patient, written by a journalist, is protected by the freedom of speech. Pharmaceutical companies are still not allowed to use these statements, or refer to them.

DIGITAL & SOCIAL MEDIA

Are online media channels treated differently from print and broadcast and, if so, how are they regulated and monitored?
There is no difference in the regulations between online media and print media.

What levels of web security are required?
This issue is not specified.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Cooperation with third parties, e.g. patient advocacy groups, is allowed but must be transparent. All pharmaceutical companies must publish an annual list of which patient advocacy groups to which they contribute economic or significant non-economic support to.

What are the most popular social networks in your region?
Facebook, Twitter, Youtube, LinkedIn, Snapchat, Google+, Pinterest and Instagram.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
No.

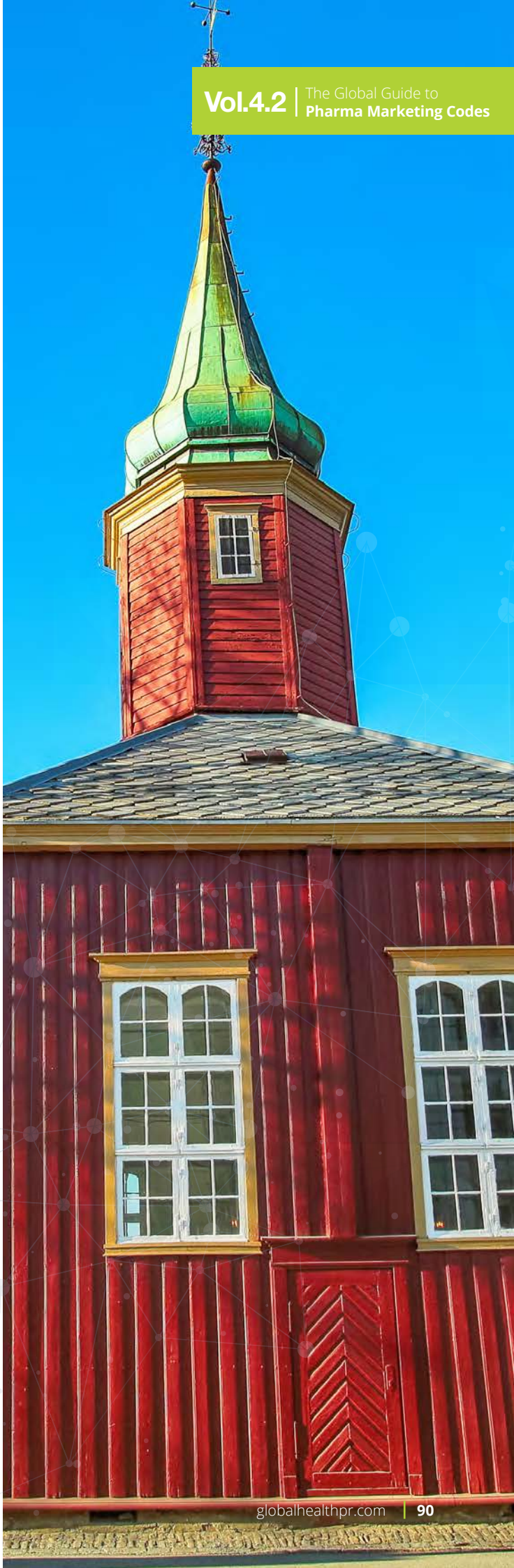
Are there any self-imposed regulations from social media companies?
Social media platforms have their own codes of conduct. Limitations to what may be published in these channels regarding pharmaceuticals are not governed by such codes of conduct, but by local laws and ethical guidelines for the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Any adverse events, including such reported through social media, shall be reported to the authorities within 24 hours by the pharmaceutical company.

What is mobile adoption like in your region? Are there separate regulations for it?
There are no separate regulations for mobile devices. Use of social media through mobile devices is widespread.

What are the disclosure laws like in your region for non-branded websites?
Information regarding the pharmaceutical company behind the information must be included. This information must include the name of the company or their Norwegian agent and contact information.

Pharmaceutical information on websites must clearly include information regarding target audience. This includes links to websites containing pharmaceutical information, e.g. from non-branded websites, where the information by the



link needs to clarify the target group for the information at the link. If the link leads to a page with HCP information, a disclaimer should be used that asks the visitor to confirm his or her category before accessing the information.

What is the response level needed for adverse event reporting?

According to the Regulation on Pharmaceuticals, § 10-5, pharmaceutical companies are obliged to report all severe adverse events within 15 days to EudraVigilance. Other suspected adverse events shall be reported within 90 days.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

According to the rules for cooperation between the pharmaceutical industry and patient advocacy groups, congresses or meetings arranged by a pharmaceutical company shall address their area of expertise and the major part of the programme must be scientific or profession-related. A company is not allowed to sponsor ordinary or internal activities of an advocacy/patient group. The meeting should be held in Norway, if possible. Destinations associated with leisure or entertainment are to be avoided. All forms of representation shall be at a reasonable level and shall be subordinate to the scientific purpose of the activity. Costs that may be covered by a pharmaceutical company are limited to travel, meals, accommodation and registry fees for participants as well as, in special cases, also for their personal assistant. It is allowed to travel to another country if a majority of the participants are from another country than Norway or due to certain experts being from that country.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

It is possible to offer honoraria if a HCP or advocacy/patient organisation representative is participating in a media activity targeting journalists. Honoraria is to be reasonable in regards to the time required to perform the activity. All cooperation shall be preceded by a written contract specifying the project, its purpose and the budget.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

According to the agreement between LMI and Dnlf

regarding guidelines for cooperation, Chapter 2, section 2.2, it is allowed to sponsor a HCP to attend a scientific meeting within the pharmaceutical company's own area of expertise. They may cover travel, meals and accommodation within reasonable limits.

According to the rules for cooperation between the pharmaceutical industry and patient advocacy groups, pharmaceutical companies may sponsor an advocacy/ patient group's participation at a conference, including travel, meals and accommodation expenses, within reasonable limits.

What is possible in terms of media or message training for health professionals or advocacy organisations?

There are no limitations in regards to message training.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

If pharmaceutical companies, or PR agencies operating on their behalf, produce written material on behalf of third parties, their support shall be announced for transparency. In accordance with the Rules for Cooperation Between the Pharmaceutical Industry and Patient Advocacy Groups, a company may not affect the text in a material from the patient advocacy group in such a way that it favors their own interests.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

Pharmaceutical companies' relations and meetings with advocacy groups are regulated by the Rules for Cooperation Between the Pharmaceutical Industry and Patient Advocacy Groups.

KEY TAKEAWAYS/ SUMMARY

- The distinction between PR and advertising in cases of promotion of medicinal products has become less relevant from a regulatory point of view. Promotion of prescription medicinal products may not be aimed directly at the general public, with the exception of vaccines.
- Even though it is not officially allowed to send press releases to media regarding pharmaceuticals, companies continue to do so in accordance with business practices. It is important, however, that the press releases are relevant and balanced.
- Regardless of being a member of LMI or not, the best way to avoid any breach of law or regulations is to ensure that your company adheres to its ethical guidelines.

POLAND

Any correspondence or materials produced by a pharmaceutical company about medicines or their use is promotional, whether or not it makes product-specific claims. All promotional information should be accurate, balanced, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicine. It must not be misleading and must reflect the most up-to-date evidence.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The relevant government regulation that has been enforced in Poland since September 2001 is the Pharmaceutical Law Act and its amendment, implemented in December 2008, concerning the advertising of prescription medicines.

In addition, self-regulation of the pharmaceutical industry is administered through the Employers' Association of Innovative Pharmaceutical Companies (INFARMA) under the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations (the Code).

the Code sets forth standards for promotional activities and refers to all forms and methods of medicinal product advertising, particularly advertising materials, press advertisements and the activity of medical representatives. The Code also regulates issues of interactions between the pharmaceutical industry, healthcare professionals and patient organisations and is binding for all of the INFARMA member companies and associations that do business in the European Union.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

There is no official definition of public relations (PR) in Poland, so there are no laws that specifically regulate the PR practice. The only national PR code is the Kodeks Dobrych Praktyk of the Polish Public Relations Consultancies Association (ZFPR).

However, the section of the Pharmaceutical Law Act that is dedicated to the advertising of medical products defines advertising broadly and is interpreted to cover all promotional activities and direct marketing. The law also differentiates what is not considered as advertising, and specifically describes those advertising practices that may be considered legal.

Who is responsible for the enforcement of these rules?

The ultimate power establishing and implementing pharmaceutical laws and regulations resides in the Polish Parliament (Sejm), acting through the Polish Ministry of Health (Ministerstwo Zdrowia or MZ). The agency within MZ that administers pharmaceutical law in Poland is the Main Pharmaceutical Directorate (Głowny Inspektorat Farmaceutyczny) and the officer who oversees advertising is the Main Pharmaceutical Inspector (Głowny Inspektora Farmaceutyczny).

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

The basis of HCP engagement by companies is outlined in the Pharmaceutical Law and specified in the Regulation of the Minister of Health of 21 November 2008 in the advertising of medicinal products. The bill specifies what is considered an advertisement, i.e. visiting doctors, sponsoring doctor's participation in a conference, distributing samples, and details processes and procedures for advertisements.

The representatives should be prepared to receive reports on adverse effects. It is enforced by the Chief Pharmaceutical Inspector, who can order illegal advertisments be stopped.

The Code also details standards for gifts, donations to healthcare organisations, sponsorship of healthcare professionals and services rendered by healthcare organisations to the signatories of the Code and employing consultants. Those activities should be carried out in accordance with the Code and documented.

Another regulation is the Disclosure Code, which states 'a self-regulation of the innovative pharmaceutical companies associated' in INFARMA. It defines the rules for providing information on cooperation between signatory companies and medical profession

representatives and healthcare organisations. The Disclosure Code is part of the European project which aims to increase transparency of innovative pharmaceutical companies' cooperation with the medical community. It was prepared by the European Federation of Pharmaceutical Industries and Associations (EFPIA), which is represented in Poland by INFARMA. The provisions of the Disclosure Code are implemented simultaneously by 33 affiliated associations and EFPIA member companies.

According to the Disclosure Code, all cooperation agreements of the signatory companies with the medical profession representatives and healthcare organisations, effective from 1 January 2015, shall include an additional consent form to share personal data. In June 2016, signatory companies published disclosure reports on their websites.

Who receives concerns and complaints? How does this process operate?

If the actions of one INFARMA Code signatory disrupts the interests of another signatory, they can lodge a complaint with the Disciplinary Court. Others can also complain if the company's actions are not in sync with the Code. The Court does not replace the enforcement and courts of general law, but rather looks into code infringement to the benefit of the whole pharmaceutical industry. The general law infringements are handled by general law courts.
Sanctions are specified in Article 57 1.

If any breach of the Code provisions is found, the Court may, considering the type and degree of harmfulness of the breach as well as the benefits gained by the defaulting party and whether or not the Court has declared a breach of the provisions of the Code by the same entity over the previous 12 months, rule as follows

1. A prohibition on the continuation of the challenged actions, in particular, the immediate withdrawal of the advertising materials breaching the provisions of the Code from all mass media
2. A reprimand or rebuke
3. An order to submit a single or repeated statement of particular wording to specified mass media or to specified addressees
4. A notice to the Main Pharmaceutical Inspector regarding the decision
5. A notice to The European Federation of Pharmaceutical Industries and the Associations for the International Federation of Pharmaceutical Manufacturers and Associations) regarding the decision that was issued;
6. a notice regarding the decision to affiliated entities of the party breaching the Code; the obligation to publish the decision or its parts in specified mass media once or multiple times; the suspension or expulsion from INFARMA in the case of gross breaches of the Code.

The sanctions may be imposed cumulatively. The Code is available in English on INFARMA website. Potentially, a complaint may also be sent to Chief Pharmaceutical Inspector, who can order arrest of advertisements activities

What promotional or media materials must be approved by authorities?

No, there is no approval process in place.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

The only significant change would be if the State Health Fund (Narodowy Fundusz Zdrowia or NFZ) is dismantled. If this happens, the reimbursement process will change. However, while there is discussion of the fund changing, this is only speculation.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

In the original Pharmaceutical Law Act, enforced in 2001, there is a distinction between advertising and information dissemination (see Question 11). Promotional activity is covered in the broad definition of advertising.

How is a media event defined?

There is no one, clear definition of a media event available. There are no legal provisions regarding media events for medicine promotions, as such. However, the role of companies in supporting media events and the contents of the materials that are disseminated in conjunction with such events are regulated within the context of advertising.

Do the regulations differentiate between consumer and clinical publications?

The regulations (especially amendment: Dz.U. 2008 nr 210 poz. 1327) do not differentiate between consumer and clinical publications. However, as in all European countries, product brand identification is not acceptable in consumer communications but is allowed in the advertising and promotion of pharmaceutical products to medical practitioners authorised to issue prescriptions or to those involved in the distribution (such as wholesalers or distributors) or dispensing (pharmacists) of pharmaceutical products.

Do regulations differentiate between print and broadcast media?

No, the regulations do not differentiate between print and broadcast media.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?

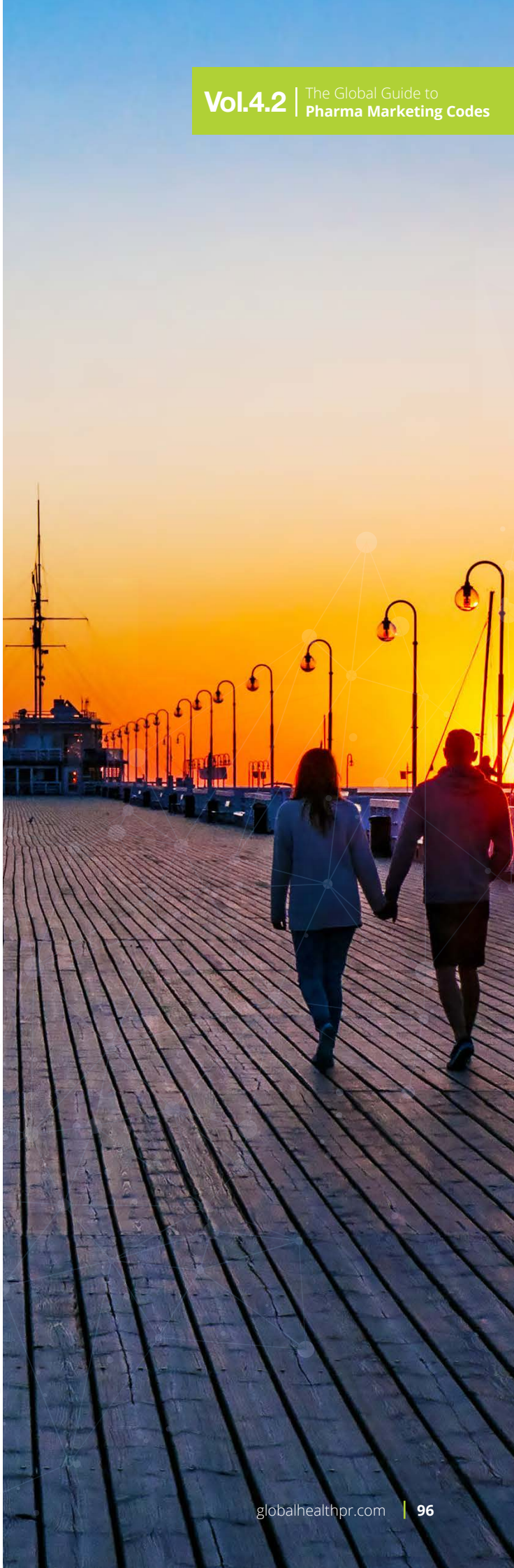
According to the Pharmaceutical Law Act, the permitted promotional activities are:

- Correspondence, including attached informational, non-promotional materials, sent by manufacturers in response to doctors' questions about the product (including its characteristics)
- Informational notices about changes in packaging, side effect warnings, prices
- Information about health or illnesses of people and animals, provided they do not mention, even indirectly, the medicinal product

The Pharmaceutical Law Act does not provide any specific information about congresses, scientific meetings or major publications and media relations.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

There are no specific regulations in the Pharmaceutical Law Act regarding these issues.



Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
Polish regulations do not extend beyond Poland. However, the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations states that any information delivered to professionals outside the country (such as at international congresses) should mention essential differences bewtween countries in the registration and indications for the medicine.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
There is no clear statement about the sponsoring of media attendance to congresses and scientific meetings. The Pharmaceutical Law Act does, however, state that it is illegal to offer such sponsorship to pharmacists and individuals authorised to issue prescriptions when the organisers' 'acts of generosity' go beyond the merits or purposes of the meeting or conference.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
There are no legal constraints controlling journalists' coverage of an organised congress or meeting, or their use of informational materials distributed at such events.

Do regulations cover the use of case studies or other third-party advocacy in the media?
There is no regulation of this area.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
There is no regulation of this area.

What levels of web security are required?
There is no regulation of this area.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
No, they do not cover this area.

What are the most popular social networks in your region?
Facebook is the most popular social network in Poland and Instagram is gaining increasing traction in the market. Twitter and YouTube are also among the top social media platforms.

NK, a native Polish social network established in 2006, has experienced a rapid decline in its user base and influence in recent years, replaced by the global networks.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
According to the Polish law, pharmaceutical companies must not share information on RX medicines with the general public -- only with the doctors.

This also means social media, which is why pharmaceutical companies who sell prescription medicines seldom run their own social media profiles on disease awareness. Most commonly patient organisations do this. Patients can talk about their prescription with other patients. Websites which can be fully controlled by the owner exist and are used to build awareness.

Are there any self-imposed regulations from social media companies?
There are no self-imposed regulations from social media companies.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
It depends on a particular site.

Each forum has its own policies. Most of them don't accept spam, and any information that looks like spam will be removed by the site administrator. If a company wants to communicate with users via forums, it has to first contact the site administrator, and ask for conditions. For instance, forums of goldenline.pl do not allow users to use brand or product names. Such comments are considered advertising and treated as spam. The only possible way to inform the customer is to talk about the problem or social issue addressed by the product.

What is mobile adoption like in your region? Are there separate regulations for it?
In Poland, there is minimal access to mobile applications that would provide medical information to physicians, medical students or interns, so there is little regulation surrounding mobile adoption in the health sector.

What are the disclosure laws like in your region for non-branded websites?
There are no official laws concerning non-branded websites. However, there is a section in the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations devoted to websites. The Code states that the site should include information about the sponsor of the website, contact details, the aim, and the addressees of the site.

What is the response level needed for adverse event reporting?
The amendment to the Pharmaceutical Law assumes that each person eligible to prescribe, dispense or administer a medicinal product should immediately report any suspected adverse event directly to the producer or to the Office for Registration of Medicinal Products, Medical Devices and Biological Products. Initially, this obligation concerned only doctors and pharmaceutical companies. A more recent amendment added two new professions: licenced nurses and midwifes.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
There are no clear distinctions in the Pharmaceutical Law Act. The Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations, however, states that the criteria used by the company to choose the advocacy/patient groups invited to an event should be objective and based on merit. The place chosen for such a meeting should not be extravagant in terms of entertainment offered. Acts of hospitality of the sponsors should not exceed the main aim of the meeting. The sponsor should cover the expense of no more than: the trip, accommodation, congress registration fee., and catering. These sponsorships should not cover any expenses of any accompanying persons (i.e., family, friends).

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Generally speaking, it is possible under certain conditions to offer honoraria to healthcare professionals and/or advocacy/patient group leaders (see Question 25). There are no special comments excluding any particular category of travel.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
According to the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations, it is prohibited to pay a health professional or advocacy/patient group

compensations for time spent going to a meeting/ congress, but it is acceptable to pay them for the costs of their presence at the specific event (see Question 25).

What is possible in terms of media or message training for health professionals or advocacy organisations?

There are no regulations on this subject.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

According to The Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations, the sponsor should always respect the independence of the third party and cannot expect an exclusive partnership.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

The only operative regulations can be found in the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations.

KEY TAKEAWAYS/ SUMMARY

- It must be kept in mind that Poland spends less money per capita on healthcare and medicines than almost every other country in Europe. The cost of medicines is controlled tightly and is generally quite low, although patients are subject to co-pays that are proportionately quite high relative to other European countries. One way that Poland controls the amount of money it spends on prescription medicines is to carefully ration the use of the newest products and often to delay their broad availability until an array of generic versions (branded or otherwise) can be added to the reimbursement list.
- If a company is suspected of abusing advertising and promotion, the MZ will not hesitate to use the mass media (which is generally negative towards the industry) to 'name and shame' that company. One notable instance was the publication of a photo of numerous women doctors enjoying a luxurious day spa during a company-sponsored medical education meeting.
- Polish professionals and lay audiences alike are avid consumers of health and medical information. The best medical writers, both for the trade and general media, are very good and very willing to let third-party medical information sources review their quotes and facts for accuracy. Social media is extremely popular. The Polish patient advocacy and support community are growing in size and sophistication.

PORTUGAL

In Portugal, as direct-to-consumer promotion of prescription drugs is not permitted, the boundaries between promotional information as opposed to educational information are more distinct than other countries, such as the United States.

Promotional activities are conducted by the National Authority of Medicines and Health Products (INFARMED) and the presented information must be scientific, accurate and objective and not misleading.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The promotion of medicines in Portugal—both over-the-counter (OTC) and prescription—is subject to two main standards: (1) Decree-Law n.º 176/2006 (Aug. 30 2006) (Code of Medicinal Products), which was amended by Decree-Law n.º 128/2013 (Sept. 5 2013), which require additional notification to INFARMED. (2) APIFARMA's (Portuguese Association of the Pharmaceutical Industry) Ethics Code of Marketing & Pharmaceuticals Practices form.

While the Drug Statute regulates the promotion of medicines and conducts censure if not followed, the Ethics Code has disciplinary sanctions attached. It also integrates some of the Drug Statute guidelines from both the International Federation of Pharmaceutical Manufacturers and Associations and European Federation of Pharmaceutical Industries and Associations Ethics Code.

The Code also details the EC Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use. The Advertising Code approved by Decree-Law n.º 330/90 of October 23 states that advertising in general, including all the aspects of the advertising of medicinal products not defined in the Code of Medicinal Products. Regarding medical devices, Decree-Law n.º 145/2009 of June 17 should be noted, as it establishes legal framework for advertising.

Gral - INFARMED Decree-Law No. 176/2006 includes articles and chapters such as Section IX, which states: 'It is considered drug advertising for the purposes of this document, any form of information, canvassing activity or inducement in order to promote the prescription sale, purchase or consumption of a specific treatment'.

Article No. 152 says:
1. The advertising of drugs that are not subject to a valid permit or registration for the national market or have been authorised according to Articles 92 and 93 is prohibited;
2. It is prohibited to advertise medicinal products to the general public that:

- Are subject to prescription;
- Contain substances defined as psychotropic or narcotic drugs under international conventions that bind the Portuguese State;
- Are distributed by (?) National Health Service;

3. The information presented in the previous number doesn't preclude:

- Vaccination campaigns carried out by the industry, if previously approved by INFARMED;
- Promotion campaigns for generic drugs developed by the industry and approved by INFARMED.

4. The distribution of medicines directly to the public by industry is forbidden.
5. It is forbidden to mention the name of the treatment even if it's related with a sponsorship initiative to the public, unless it has explicit legal approval.

In spite of this restriction regarding prescription drugs, Article No. 153 states that non-prescription drugs can be advertised and promoted to the public.

The sunshine rules were transposed into Portuguese law by means of an amendment made in February 2013 to the Portuguese Medicinal Products Act (Decree-Law 176/2006 of Aug. 30).
In 2013, the Code of Medicinal Products had two major changes. In February 2013, it was amended by Decree-Law n.º 20/2013 (Feb. 14, 2013), transposing Directive 2010/84/EU (15 December 2010) and including pharmacovigilance.

Subsequently, the Code was further amended in September 2013 by Decree-Law n.º 128/2013 (5 September 2013), detailing Directive 2009/35/EC (23 April 2009) on the colouring substances that may be

added to medicinal products, as well as Directive 2011/62/EU (June 8, 2011) as regards the prevention of the entry into the legal supply chain of falsified medicinal products and Directive 2012/26/EU (25 October 2012) as regards pharmacovigilance. Other substantial amendments introduced into the Code include those regarding the advertising of medicinal products.

According to the new legal provisions, entities covered by the Code of Medicinal Products must notify INFARMED within 30 days of any offer, sponsorship, grant, or any other amount, good or right assessable in cash terms, granted to any entity (regardless of its form or nature), individual, association, or representative of a certain patient group or medical company, association or corporation that is scientifically oriented or conducting clinical studies.

The other binding document—Ethics Code of Marketing & Pharmaceuticals Practices—presents a more generic approach regarding the promotion of medicines. Article No. 4 of the Code states: 'Information on the characteristics of the drug should not exceed the limits presented by the available scientific evidence and their preparation must be devoid of any ambiguous data'.

Article 9 states: 'The information related to a prescription medicine should only be addressed to the people for whom one can assume, with reasonable accuracy, that they need or have an interest in it'.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Currently there isn't any form of differentiation. The rules presented for advertising also apply to public relations and media relations. The communications professionals must carefully evaluate the content of the different materials. In these cases, the PR professionals have to implement self-regulation with a strict nondisclosure code.

Who is responsible for the enforcement of these rules?

INFARMED and the National Council on Drug Advertising are the main entities that are responsible for enforcing the Portuguese law and promotion rules. The Institute controls all drug-related processes from clinical studies, licensing and distribution to all communication activities directed at patients, nurses, pharmacists and doctors. In the last 10 years, INFARMED has become increasingly aware of the media issues, and it now has a specific department that monitors the enforcement of the communication rules.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

Article 20 of the APIFARMA Code states that:

a. Pharmaceutical Industry companies may provide support to institutions, organisations or associations of Health Professionals providing healthcare or are engaged in research if:

i. They are made with the purpose to support healthcare provision or research;

ii. They are preceded by a written request of the beneficiary entity, dated, signed and addressed to the donor;
iii. They are documented and recorded by the donor;
iv. They are not an incentive nor the contribution to the recommendation, prescription, purchase, supply, sale or administration of certain medicinal products, nor the use, prescription, dispensing, selling, purchase or the consumption of in vitro diagnosis medical devices.

b. The supports mentioned in the previous number may be financial or non-financial contributions.
c. When the support is benefits in kind they should not bear the name or the logo of a medicinal product.
d. No support should be granted to HCPs individually.

Pharmaceutical companies are also allowed to provide HCPs with informational/education materials as long as the materials are of low cash value and relevant to the health practice (Article 21). Pharmaceutical companies are also allowed to hire HCP consultants 'to participate, among others, in lectures, meetings, take part in medical/scientific studies, clinical trials, training programmes, follow up of counselling and market research committees,' as long as they are (Article 22). Specific limitations of this practice are also listed under Article 22 and include the following:

- The number of selected healthcare professionals should not exceed the reasonable number of professionals required to achieve the identified purpose
- The contracting company should keep all records related to the services provided by the healthcare professionals
- The obligation of the healthcare professional to identify himself/herself as a consultant of the company, whenever he/she writes or lectures in public on subjects which are the object of the contract or agreement
- Limited market studies, such as phone interviews or questionnaires sent by mail/email/internet, are excluded from the scope of this article if the healthcare professional is not consulted in a recurrent manner and the payment for the service is suitable and not excessive

The Council of Ethics of APIFARMA oversees the enforcement of these regulations.

Who receives concerns and complaints? How does this process operate?

The Council of Ethics of APIFARMA receives concerns and complaints. In the case of a violation, the 'Association should ask the offender to immediately put an end to the irregular activity and to undertake, in writing, the obligation to not relapse in that practice,' (Article 30). The applicable sanctions are listed in the APIFARMA Statutes, which include the following from Article 29 of the Statutes:

- Simple warning;
- Reprimand;
- Penalty up to the amount of five years membership fees;
- Suspension up to one year;
- Banishment

What promotional or media materials must be pre-approved by authorities?

Only the ones considered advertising pieces. INFARMED created the Drug Advertising Management System (GPUB)

with the Deliberation No.044/2008 that monitors, approves and controls the promotional pieces for the pharmaceutical market. Companies must present their materials before starting the marketing process. While the materials will be rejected if they don't comply with the rules, the analysis continues after the launch of the treatment and includes different channels such as television, radio, press and Internet. Complaints from the general population or healthcare stakeholders may also be considered. Before the GPUB submission, the submitted materials must be approved internally by the respective medical departments.

Currently there is a legislation gap regarding media relations and PR. News isn't considered advertising but companies (and journalists) can still receive INFARMED letters when a media outlet publishes information regarding a specific prescription treatment using the commercial name.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

INFARMED is currently evaluating the impact of social media in the process of sharing health information. New guidelines should be available soon.

Between 2011 and 2014, Portugal has been under an EU/IMF Financial Assistance Programme (FAP) which involved a set of initiatives including structural legal measures relating to public finances, financial stability and competitiveness. In relation to the health sector the FAP, which has not been used since 2014, involved:
Reorganisation and rationalisation of the public hospital network through specialisation, concentration and downsizing of hospital services, joint management and joint operation of hospitals;
Legal and administrative measures to control and decrease the price of medicines subject to medical prescription and of reimbursed medicines;
Reduction of debt due to suppliers of the NHS, including pharmaceutical companies (Sustainability of NHS Memorandum of Understanding);
Improvements in the billing and collection of revenues from NHS moderating fees (taxas moderadoras), insurance companies and fees for the treatment of cross-border/foreign patients;
Improvement of the monitoring and assessment system of doctors' prescription process regarding medicines and diagnostic in terms of volume and value and as against prescription guidelines and peers;

- Additional centralised public tenders for active substances and medical devices, and establishment of an observatory for prices and acquisitions.
- In 2016, the Ministerial Order, a Working Group for the Prevention of and the Fight against Fraud in the National Health Service;
- Rules for prescription, dispensing and accountability of medicines;
- Compulsory e-prescription and international non-proprietary name (INN) prescribing: mandatory INN prescribing for all active substances (06/2012);
- Stimulus to improve efficiency resulting from the use of generic medicines and biosimilar - access to truly innovative medicines;
- Changes in pharmacies' margins in the international reference price system and in the pricing of generics;

Despite the end of the FAP, part of the referred measures will continue to be adjusted and monitored during 2016 by national public authorities.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

All the material that the pharmaceutical industry provides to doctors such as brochures, newsletters, advertorials in medical journals and internet web pages for the medical profession are considered promotional.

How is a media event defined?

This is not defined in Portugal but National Entities consider the ones exclusively directed to media professionals.

Do the regulations differentiate between consumer and clinical publications?

Yes. In consumer publications, the promotion of prescription drugs is forbidden; specifically, the use of the commercial name for the treatment is not allowed. Any event or promotional action using the product's brand name can't be presented to the general public. Also, journalists of general publications are advised not to assist in particular scientific symposiums sponsored by the pharmaceutical industry. They can, however, interview physicians outside the room. Clinical publications don't have these specific limitations, but any products advertising page must include the drug's leaflet.

Do regulations differentiate between print and broadcast media?

There is no differentiation except for trade media.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

A medicine cannot be actively promoted prior to the marketing authorisation allowing its sale or medical supply (the formal authorisation is called Autorização de Introdução no Mercado (AIM). However, publication in clinical newspapers of scientific information prior to authorisation is acceptable if supported by scientific data. Usually that occurs after the presentation of international information from an independent medical source or from a press release—medical and general media—about a clinical trial.

In congresses, scientific meetings, and major publications, it is possible to distribute and share scientific information (not for the general media) as

long as there are sufficient scientific data that represent credible information and not promotion.

Pharmaceutical companies can sponsor medical meetings and scientific symposiums prior to the launch of a product but in accordance with Article No. 159 from INAFRMED's Drug Statute:

1. The sponsorship of congresses, symposiums or scientific events directly or indirectly should be documented as well as the promotional materials and the reports published after the completion of those actions and events
2. The marketing authorisation holder or the company responsible for the information or promotion of the product should keep the data for each of the events or activities sponsored or organised
3. The documentation referred includes, in a complete and faithful way, the following
   - Action and events programme
   - Main entity identification
   - Copy of the scientific and professional communication;
   - Expense maps, receipts and justification documents.
4. The documentation referred in the previous paragraphs should be retained for a minimum of five years from the date of the event and made available to entities with supervision powers such as INFARMED. Furthermore, the recipients of these benefits, which include certain patient groups or medical companies, associations or corporations that is scientifically oriented or conducting clinical studies, but also any entity or individual (specifically healthcare professionals), must notify INFARMED and register such benefit on INFARMED's website. Since 7 October 2014 these rules only apply to transfers of a value exceeding €60 (prior to 2014, these rules applied to transfers of a value exceeding €25). INFARMED further clarified that any hospital, service or medical society that organises a certain congress must be identified as the beneficiary of the event, and not the healthcare professionals

The main rule in this respect is aimed at preventing any type of prescription incentives; therefore, the holders of the marketing authorisation or of the registration of medicinal products, as well as companies responsible for the promotion of medicinal products and wholesale distributors, are not allowed to directly or indirectly give or promise to healthcare professionals or their patients prizes, offers, bonuses or precuniary benefits or benefits in kind unless they are insignificant and relevant for medical or pharmaceutical practice.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

The information of the drug characteristics should not exceed the limits backed by the available scientific evidence, and their preparation must be objective. The information presented in the promotional material or the intended information to promote a drug's good use must:

1. Be based on an updated assessment of all available scientific evidence in accordance with the summary of product characteristics;
2. Comply with the marketing authorisation;
3. Not lead to incorrect or wrong conclusions.
4. Scientific data that support claims about the product characteristics must be available.
5. Information about side effects should reflect the data available and the clinical experience.
6. Promotion should encourage the rational use of a drug, presenting it objectively and without exaggeration of its properties.
7. All promotional elements, including graphics, illustrations and tables from published studies and integrated promotional material must:
8. Clearly indicate the exact source or sources of the promotional elements;
9. Be faithfully reproduced. In case of need they may be adjusted, mentioning the introduced adjustment.
10. Also, the word "safe" should never be used to qualify a product. Likewise, the word "new" should not be used to describe a product or presentation that has been available for more than a year, or one that has been promoted or launched before. Finally, we write that a drug has no side effects, risks of toxicity, addiction or dependence.

It is not forbidden to invite the media to a clinical event, but if INFARMED receives a complaint about an article published in the trade media, they will analyze all the information provided by the pharmaceutical company that was responsible. This doesn't occur for trade media.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

This issue is not covered, but press materials intended for Portuguese distribution must comply with the local regulation.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

No specific indication is given, but press conferences or briefings can be held at congresses and scientific meetings outside the main rooms. Media, general and specialised, can attend. The events should not be dedicated to the presentation of products (except for specialized journalists) since the direct communication of unlicenced products or indications is prohibited. A disease awareness communication is often adopted.

The press conference materials (press releases and media backgrounders) must be approved by the medical department of the hosting organisation of the major event, and should include a quotation of an important key opinion leader (KOL) (to preserve the reputational focus). This serves for both licenced and unlicenced products equally.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?

If the invitation is directed to a journalist from the general media, the resulting copy is independent, but if the communication professional is from a specialized newspaper, then the text goes through the company's regulatory process. Journalists that work in general media (the company that sent the invitation is always referred at the end) receive a different kind of press kit with more scientific information about the disease and less about the treatment. A freelance journalist is seen in the same way as the specialised one, and the information shared depends on the final goal of that press material. If the information is supposed to impact patients and the general population, then the drug statute must be applied. If it is for internal use or to communicate with physicians, more commercial data can be presented.

Do regulations cover the use of case studies or other third-party advocacy in the media?

There are no specific regulations regarding this issue, but APIFARMA'S Ethics Code of Marketing & Pharmaceuticals Practices states that companies must follow the conduct code when endorsing a partnership with patients associations. These can speak to the media at company press events and, in pressing situations, case histories, but usually the patients talk with the media only during patient association press events.

The common media tactic is to use real-life case studies involving successful treatments shared by the patients and physicians. When using a quotation from a key opinion leader (KOL) in a product press release, it is important to know the product and the rationale for the reference.

There isn't any formal guidance, but case studies should not be promotional, and they should not be used to encourage use of a product.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

Online media are not different from print and broadcast, and the same rules apply; however, a difference is seen in the monitoring process. With the increase of internet access, more and more new media (especially locally) are starting to appear. INFARMED and the National Council on Drug Advertising try to analyse the digital information channels, but most of them are difficult to control on a daily basis.

What levels of web security are required?

Promotional material about prescription-only medicines can only be placed on a website owned or sponsored by a pharmaceutical company. These must be open only for the healthcare professionals and not be directed to the public. Companies can endorse websites that only talk about the disease. Again, INFARMED analyses and approves the information presented.

Do the regulations cover funding of, or provision of information to, non-company owned websites?

The Code of Conduct Governing the Relations between Pharmaceutical Industry and patients' organisations is always present during companies' and institutions relationship. According to the Code:

Article 3

Agreement

1. Companies that want to provide direct or indirect financial support and significant non-financial support to Patients' Organisations should put it in writing, by means

of an agreement signed by both parties, according to the form included in Appendix of this Code.
2. The agreement mentioned in the previous number should mention the express amount of the financing, as well as its purpose or a description of the significant nonfinancial support as the case may be.
3. Each company should establish internal proceedings of formal approval of the agreements mentioned in the previous numbers.

Article 4

Use of logo and materials subject to copyright
1. The public use by a Company, in the scope of the agreements mentioned in the previous article, of a logo and/or materials subject to copyright belonging to a Patients' Organisation is subject to a written authorization given by the latter.
2. The authorisation request mentioned in the previous number should clearly indicate the specific objective and the way the logo and/or materials subject to copyright are to be used by the company.

Article 5

1. Companies should not try to influence the contents of materials produced by patient organisations they sponsor.
2. Companies may correct evidence-based and/or scientific inaccuracies existing in produced materials.
3. Companies may contribute to the preparation of texts of scientific nature, if requested by patient organisations.

Article 6

Transparency
1. The list of patient organisations sponsored by each company in the scope of the agreements mentioned in article 3 should be disclosed, each year, with a short description of the nature of the provided support.
2. Companies should make sure that the information on the sponsorship of patient organisations is disclosed in a clear and transparent manner on request of any stakeholder or through the institutional website of the Company, until May 31 of each year.

Article 7

Financing
1. No company can impose itself as to being the exclusive sponsor of a patient organisation or of its main programmes.

INFARMED regulations aren't clear about the pyramid of influence, but it is important that companies comply with the general principles presented in the drug statute.

According to the above-mentioned new legal provisions, entities covered by the Code of Medicinal Products must notify INFARMED within 30 days of any offer, sponsorship, grant, or any other amount, good or right assessable in cash terms, granted to any entity (regardless of its form or nature), individual, association, or representative of a certain patient group or medical company, association or corporation that is scientifically oriented or conducting clinical studies.

What are the most popular social networks in your region?

Facebook is the largest social network in Portugal, with 5.9 million users as of 2017. Pharmaceutical companies remain cautious when using social media and have prepared internal guidelines around their usage, as INFARMED has yet to adopt specific regulations for these platforms.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

While there are no provisions on the use of social media for promotion, the APIFARMA Code of Ethics does provide guidance for promotion on the Internet in Article 11:

1. Internet promotion of medicinal products or in vitro medical devices should be based on technical, scientific and professional principles, and in compliance with the national legislation of force.
2. Companies should adopt such measures so as to guarantee that the promotion of prescription only medicinal products or in vitro medical devices requiring a healthcare professional's mediation or decision is accessed only by healthcare professionals.

Are there any self-imposed regulations from social media companies?

There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

Currently, there aren't any rules for digital platform engagement, but the general principles presented in the drug statute should be followed. Pharmaceutical companies shouldn't express their view about prescription medicines or try to directly engage patients since direct commercial contact is forbidden.

A company can start or endorse a forum to discuss a specific disease, but the management of that digital space must be made by an outside entity.

What is mobile adoption like in your region? Are there separate regulations for it?

65% of Portugal's population used smartphones as of 2017. Due to the relatively high adoption rate, pharmaceutical companies have begun to invest in apps for consumers and healthcare professionals. However, direct-to-consumer advertising of medical products is still prohibited on mobile devices, so many apps focus on disease awareness and management.

What are the disclosure laws like in your region for non-branded websites?

There are no specific laws regarding non-branded websites. As stated in the drug statute, it is not permitted to address the general population with commercial information regarding prescription medicines. The non-branded websites supported by the pharmaceutical companies need to respect Article No.152 from the Drug Statute.

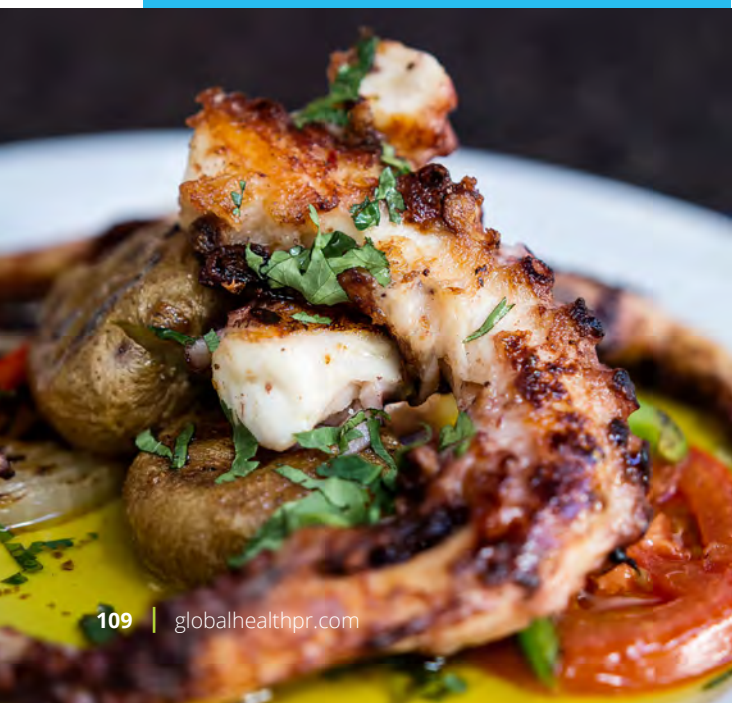
What is the response level needed for adverse event reporting?

Health professionals, inside and outside the National Health System, must inform the INFARMED pharmacovigilance as soon as possible about adverse reactions, suspected adverse reactions or serious unexpected situations that occur.

Article No.153 from the INFARMED's drug statute clearly states that it is forbidden to suggest that the drug effect is guaranteed with no adverse reactions or side effects. Article No.170 from the same document also says that the pharmaceutical companies must record and immediately report (through health professionals or other sources) to INFARMED all suspected serious adverse reactions that occur in Portugal.

After that INFARMED promptly reports the suspected serious adverse reactions to the other European Member States, and to the Agency, within a period not exceeding 15 days after the date of notification.

Recent amendments to the Medicinal Products Code, established by Decree-Law n.º 20/2013 (Feb. 14, 2013) and Decree-Law n.º 128/2013 (Sept. 5, 2013), concern medicine safety matters. Directive 2010/84 (15 December),



which amends Directive 2001/83/EU as regards pharmacovigilance, was transposed into national law in 2013. This reformulated the Portuguese National Pharmacovigilance System, and included new requirements to prevent, detect and assess adverse reactions to medicinal products placed on the EU market, as the full safety profile of medicinal products can only be known after they have been placed on the market. Directive 2012/26/EU (Oct. 15, 2012) also amended Directive 2001/83/EU as regards pharmacovigilance, and further strengthens the European rules respecting the safety and monitoring of medicinal products, and was transposed into national law in 2013.

All developments regarding the safety monitoring and, specifically, the pharmacovigilance of medicinal products that are placed on the Portuguese market, including those that are sent by EMA, are published on a daily basis on the INFARMED website.

Also, adverse event reporting must be detailed in the press materials for the healthcare media and/or medical material. When a media crisis situation presents itself, the commonly used strategy includes the following hierarchy: communicating with INFARMED—Ministry of Health—Physicians/Nurses/Pharmacists—Patient Associations—Media.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

In Portugal, pharmaceutical companies can provide funding to patient groups for travel and accommodations as long as the hotels are below four stars. This is possible for national and international events, and on more general grants, but according to the Drug Statute, pharmaceutical companies cannot give any commercial information directly to patients or patient groups.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

Companies can offer an honorarium to healthcare professionals to participate in meetings, press conferences, medical symposia or advisory boards, but a contract must be established with the physician with a description of the activity.

According to APIFARMA's Ethics Code of Marketing & Pharmaceuticals Practices, hospitality which includes travel, registration and subsistence expenses, must not exceed what the recipients would normally be prepared to pay for themselves in the same circumstances. The guests must travel in economy class, stay in four- or three-star hotels and cannot include family or friends in the global budget.

Also, the funding should not be provided as compensation for time spent in events by health professionals. In the case of international events for which a company sponsors the participation of a health professional, the financing is subject to legal rules from the health professional's country and not the local rules of the international event. Regarding patient group representatives, the honoraria must be given to the respective association.

Is it possible to pay a healthcare professional or advocacy/patient group to attend a scientific meeting?

No money can be offered to compensate the time used by healthcare professionals or patient groups to attend the event, and physicians can only be paid when participating.

What is possible in terms of media or message training for health professionals or advocacy organisations?

This is not reported in the Portuguese Drug Statute or in APIFARMA Code. In the last five years, Medical Media Trainings (MMT) have become quite popular, and we advise using a media training company that specialises in the healthcare area. The first goal of this type of formation is to prepare doctors and patient association representatives for media contacts. When a pharmaceutical company sponsors the media training, they must prepare the information depending on the targets and we must always consider the Portuguese Medicine Law. It is possible to present prescription medicine information for physicians, but not for patient associations. In both cases, all the material must have references regarding the sponsoring company.

If the media training occurs during weekends, the Ethics Code of Marketing & Pharmaceuticals Practices regarding hospitality must be taken into consideration.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

There aren't any specific rules regarding this issue, and third parties are responsible for the content presented. On an internal level, when sponsoring different types of materials, pharmaceutical companies always try to evaluate the information (through the medical department) that must be generic and non-commercial. Also, quotations from medical or scientific literature inserted in the different materials must be faithfully reproduced and properly referenced.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

According to the INFARMED and APIFARMA Statute and Ethic Code, pharmaceutical companies can interact with different patient advocacy groups. However, when working with any patient organisation they must present non-promotional information, such as disease information data without references, direct or indirect, to prescription medicine.

KEY TAKEAWAYS/ SUMMARY

- Portugal has an inflexible Drug Statute Law that prohibits DTC promotion of prescription medicines. The county is aligned with the European Medicines Agency (EMA), and when it comes to new medicine and advertising laws, some influence comes from other European countries.
- Pharmaceutical companies also need to be aware that non-scientific media relations programmes can contribute to official requests from the Portuguese Authorities for more information about the degree of influence and participation.
- The Portuguese Pharmaceutical Association Code of Marketing & Pharmaceuticals Practices also positively influences the conduct of the companies on different communication levels.
- Pursuant to paragraph 5 of Article 159 of the Medicinal Products Act, legal entities will also be required to declare to the Communications Platform - Transparency and Publicity of INFARMED any kind of sponsorship granted to individuals, including healthcare professionals.

ROMANIA

Generally, pharmaceutical marketing regulations in Romania are governed by the Ministry of Health through the National Agency for Medicines and Medical Devices (ANMDM), the Romanian Association of International Drug Manufacturers (ARPIM) Code and the Romanian Association for Generic Medicine Producers (APMGR). In addition, National AudioVisual Council oversees if commercials respect the law.

Romania does not allow pharmaceutical companies to promote prescription medicines to the general public. Companies with a prescription portfolio can only conduct disease-awareness campaigns, in which the only brand reference permitted is to the corporate brand. Over-the-counter drugs can be promoted to end-consumers through an advertising visa only.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

Romanian law no. 95 of 14 April 2006 (republished in the Official Monitor as no. 652 of 28 August 2015) governs the promotion of medicines. The most relevant chapters from this law are Chapter VIII, "Advertising", with Articles 811–814, and Chapter IX, "Informing the public", with Articles 815–826.

According to the law, advertising means:

...any kind of direct-door information (door-to-door system) as well as any form of promotion intended to stimulate the prescription, distribution, sale or consumption of medicines; advertising for medicines includes in particular:

- advertising of medicines for the general public;
- advertising of medicines for persons qualified to prescribe or distribute medicines;
- visits of medical representatives to persons qualified to prescribe medicines;
- providing samples;
- stimulating the prescription or distribution of medicines by offering, promising or granting cash or in kind benefits, unless they have a symbolic value;
- sponsoring promotional meetings attended by individuals qualified to prescribe or distribute medicines;
- the sponsorship of scientific congresses involving persons qualified to prescribe or distribute medicines and, in particular, the payment of transport and accommodation costs incurred by them.

Another local regulation that governs the promotion of medicine is Order No. 194, issued 23 February 2015 by the Ministry of Health about the norms for evaluating and approving advertising for medicine intended for human use.

Another two codes of practice apply only when their stipulations are more severe than the legislation in force. In such a case, the violation only imposes sanctions on behalf of these respective associations: the ARPIM Code and the APMGR Code.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

There is no differentiation. The rules that local authorities enforce for advertising also apply to public relations and other promotional activities.

Who is responsible for the enforcement of these rules?

ANMDM is the main entity responsible for enforcing Romanian law and promotion rules.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

Pharmaceutical companies are limited in terms of sponsorships for healthcare providers to attend events (for registration fees, travel fees and accommodation costs, etc.). Companies also have a standard fee for booking healthcare providers as speakers that ARPIM and ANMDM regulate. Companies can also hire healthcare providers for scientific consultancy or for clinical studies, for which the fees are greater. Companies must report such hires to the Ministry of Health.

Companies must annually disclose all such sponsorships and hires, with each reporting period covering the previous calendar year in full. For individual disclosures, companies must contact and disclose to ANMDM within three months following the end of the relevant reporting period. And on their own (public) website, they must disclose such sponsorships and hires within six months following the end of the relevant reporting period, in accordance with the provisions of Order No. 194/2015 of the Ministry of Health and the disclosed information must remain in the public domain for a minimum of three years following the disclosure date.

Who receives concerns and complaints? How does this process operate?

In the event that a company does not comply with the rules governing advertised medicines, ANMDM will apply sanctions in accordance with existing laws. All pharmaceutical companies that do not comply with these laws and regulations will be published on ANMDM's official website (www.anm.ro). ANMDM inspectors check these companies and their promotional activities to see if they are acting in accordance with Order No. 194 of 23 February 2015, which governs the norms for publicly advertising medicinal products intended for human use.

What promotional or media materials must be pre-approved by authorities?

All promotional or media materials not intended for a company's internal use must be pre-approved by authorities.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

At the time of this guide's publishing, the rules for promoting medicine were last updated in 2015. As a member of the EU, Romania is required to implement all the EU directives that refer to advertising medicine.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

This difference is not defined.

How is a media event defined?

This term is not defined.

Do the regulations differentiate between consumer and clinical publications?

Yes. Companies must first submit all advertising materials that reach consumers to ANMDM and place the materials on the market only after obtaining an advertising visa. ANMDM evaluates advertising materials for healthcare professionals after they're disseminated or as a result of complaints. The materials' design and presentation should be clear and easy to understand. If footnotes are used, they must be a legible size.

Do regulations differentiate between print and broadcast media?

No, the regulations for print and broadcast media are the same.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

The rules do not specifically address this issue.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

Media materials, including press releases, are not allowed to encourage the public to consume or purchase pharmaceutical drugs. Companies are also forbidden from promoting or communicating about medicine to the general public.

Clinical events are planned events with a scientific character that are addressed to healthcare professionals and initiated and organized at a local, regional, national or international level (e.g., congresses, symposiums, roundtables, workshops, courses, advisory board meetings, etc.). At such events, companies may offer small gifts or promotional materials to healthcare providers, but ANMDM should have previously approved the items. There are no specific regulations for media events.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

The method of distribution is not regulated.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

The same regulations that apply to all promotional activities apply to congresses and scientific meetings. There are no differences mentioned in Order No. 194 between licenced and non-licenced products.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?

When promotional materials are published in the press following services engaged by a pharmaceutical company, its subsidiary or a related company (i.e., the company's PR agency) should be clearly revealed as the company benefitting from the publication. Such articles must not resemble an independent editorial opinion.

Do regulations cover the use of case studies or other third-party advocacy in the media?

No specific regulations address this issue.

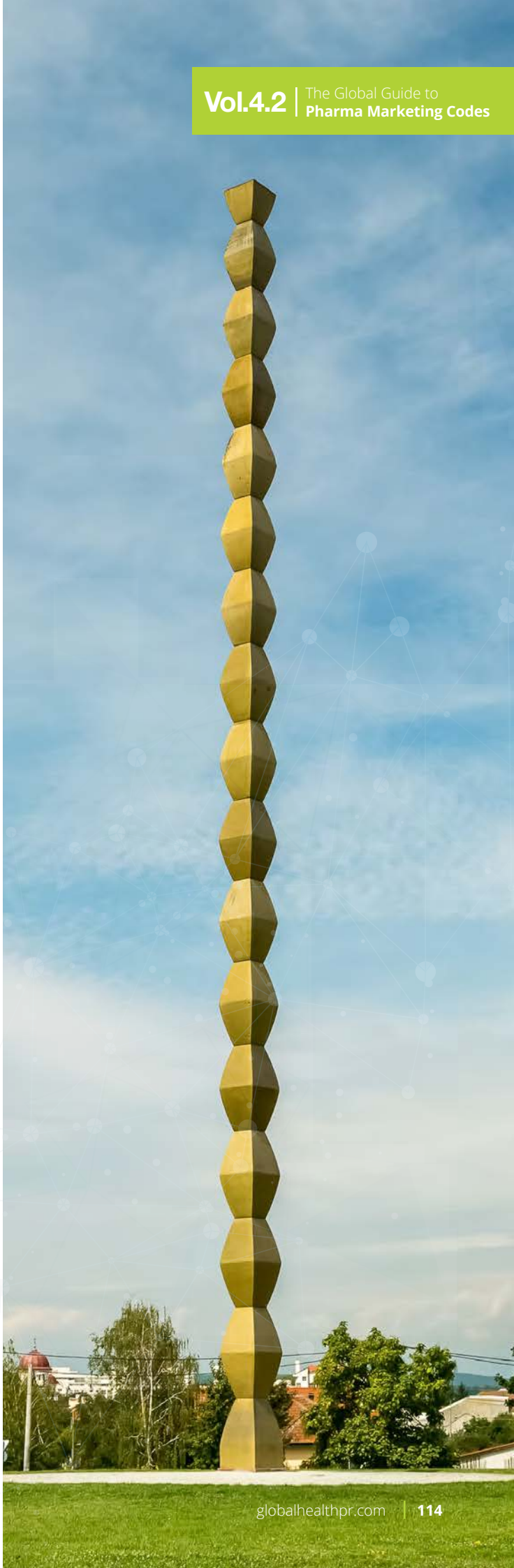
DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

- For prescription medicine, pharmaceutical companies must provide evidence that they have restricted access to online information from non-healthcare professionals through password protection. Companies must also include a summary of a product's characteristics with this information.
- All online medical information should be supported by scientific references compatible with the approved summary of a product's characteristics.
- Romanian users must be informed if certain websites include links that target users from other countries.
- Romanian users must be able to access drug information (the Patient Information Leaflet, or the approved summary of a product's characteristics) directly from any company's website.
- Websites must specify their target audience.
- Any information from websites that addresses healthcare professionals and is a form of promotion must comply with the regulations governing the content, the advertisement format and how to promote medicine.

What levels of web security are required?

Websites must conform to legislation and applicable codes of conduct governing the privacy, security and confidentiality of personal information. All websites should comply with the EU's General Data Protection Regulation.



Do the regulations cover funding of, or provision of information to non-company owned websites?
No, the regulations do not cover this area.

What are the most popular social networks in your region?
Facebook, Instagram, YouTube and LinkedIn.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Companies are not allowed to promote prescription or over-the-counter medicine on social media. They may, however, run disease-awareness campaigns/education programs on social media with no reference to specific medicine. The only reference allowed is to a medicine's corporate brand.

Are there any self-imposed regulations from social media companies?
Regarding social media, companies should follow the general regulations for promotional activities.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
This particular subject it is not addressed.

What is mobile adoption like in your region? Are there separate regulations for it?
More than 50% of Romanians used a smartphone at the end of 2016, and the percentage is growing quickly. There are no separate regulations for mobile devices, but because of their high adoption rate, pharmaceutical companies have begun to invest in mobile-friendly websites and apps designed for both consumers and healthcare professionals.

What are the disclosure laws like in your region for non-branded websites?
No specific laws exist addressing non-branded websites. However, each website must clearly identify a) the identity and physical and electronic addresses of the website's sponsor(s)/owner(s); b) full references related to the source(s) of all medical information included on the website; c) the website's target audience (e.g., healthcare professionals, patients and the general public); and d) the website's purpose or objective.

What is the response level needed for adverse event reporting?
Companies must report adverse reactions to ANMDM's website via an online form on a dedicated page. These same adverse event reports can be addressed directly to pharmaceutical companies, which should have a green line phone service, which can be dialled free of charge from any home or mobile phone, and a delegated person in charge to take such calls.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Hospitality extended in connection with company-organized events attended by healthcare professionals and with sponsored independent events must be limited to travel, meals, accommodation and genuine registration fees. Airline travel (both domestic and abroad) has to be economy (coach) class; business class or higher is not allowed. In "host countries" where local provisions do not set a limit for meals, the maximum limit is 150 EUR (or the relevant equivalent) per day.

All forms of hospitality offered to healthcare providers must be reasonable in level and strictly limited to an event's duration. As a general rule, any hospitality must not exceed what healthcare providers would normally pay for themselves.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Sponsorship, donations and/or grants (monetary, in-kind or otherwise) to public institutions, organisations or associations that are made up of healthcare professionals and/or that provide healthcare or conduct research are only allowed if a) the company's sole purpose is to support healthcare or research; b) the funds are documented and kept on record by the sponsor, donor or grantor; c) the funds do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products; and d) the respective organisation did not request or solicit the funds.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Yes, companies may pay healthcare providers (including residents) to attend scientific meetings, but in a limited capacity. Sponsoring independent events and/or healthcare providers to attend such events must not be conditional to any obligation to promote, prescribe, recommend or purchase products.

What is possible in terms of media or message training for health professionals or advocacy organisations?
Pharmaceutical companies may engage healthcare providers for services such as, but not limited to, lectures, consulting and/or advising (e.g., advisory board meetings), involvement in medical/scientific activities and studies, training services (e.g., medical training) and participation in individual or group-based market research.

Companies must comply with criteria governing how healthcare providers are selected and sponsored to attend training or events.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?
No specific regulations address this issue.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
Pharmaceutical companies may sponsor independent events organized by third parties to allow healthcare providers to further their professional development and clinical performance and to improve patient care and patient outcomes.

KEY TAKEAWAYS/ SUMMARY

- Promoting prescription medicine is restrictive in Romania; prescription drugs can be promoted to healthcare professionals only. It is prohibited to leave promotional materials in places accessible to the general public, such as pharmacies, waiting rooms, corridors of hospitals and clinics, etc.
- All advertising materials for the general public must be submitted to ANMDM and placed on the market only after obtaining an advertising visa.
- In terms of promotional activities, companies may run disease-awareness campaigns or educational programs for both prescription and over-the-counter medicine. The affiliated corporate brand may be mentioned, but no reference to specific medicinal products, whether direct or indirect, is permitted.
- Companies may sponsor healthcare professionals to attend events, take part in market research, attend lectures, be involved in scientific activities, etc., however, in a limited capacity only.
- Transparent promotion is a key part of Romania's pharmaceutical marketing regulations.

SOUTH AFRICA

The promotion and advertising of pharmaceutical products in South Africa is governed by legislation enforced by several organisations. Companies may not promote direct-to-consumer Schedule 2 and higher medicines. Medicines that fall under this scheduling status include all prescription drugs, as well as certain over-the-counter products sold in pharmacies. Healthcare professionals are the only ones authorised to advise, inform consumers about and prescribe those medicines.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The Medicines and Related Substances Act 101 of 1965 (Medicines Act), amended most recently in 2002, is the primary legislation under the Ministry of Health. Relevant provisions are located in Sections 18, 20 and 35(1)(x). These sections must be read with Regulation 42 of the General Regulations published under the Medicines Act (GN 859/25 August 2017). The act relates to health products' marketing, including Western medicines and homeopathic and alternative medicines.

The South African Code of Marketing Practice under the Marketing Code Authority (MCA), together with the associated guidelines to the MCA Code (MCA Guidelines, from February 2015), guide the marketing and promotion of all products, including medicines. The MCA Code and MCA Guidelines apply to industry associations, pharmaceutical manufacturers, distributors and wholesalers but are only binding to the members of the MCA Code, either directly or through industry associations.

The Health Professions Act 56 of 1974, published under the Health Professions Council of South Africa's (HPCSA's) Ethical Rules, along with the HPCSA Guidelines on Over-Servicing, Perverse Incentives and Related Matters (HPCSA Guidelines), are binding for all healthcare professionals. The Health Professions Act sets out the ethical rules for registered practitioners' conduct related to promoting, selling and prescribing medicines under Rule 23 of the HPCSA Ethical Rules and Rule 3.3 of the HPCSA Guidelines.

The Advertising Standards Authority's Code of Advertising Practice (ASA Code) is not a national law but a self-regulated code of conduct for telecommunications companies, marketers and advertisers that are ASA members.

The Consumer Protection Act 68 of 2008 is enforced by the National Consumer Commission (NCC) and also applies to the promotion of medicines in South Africa.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

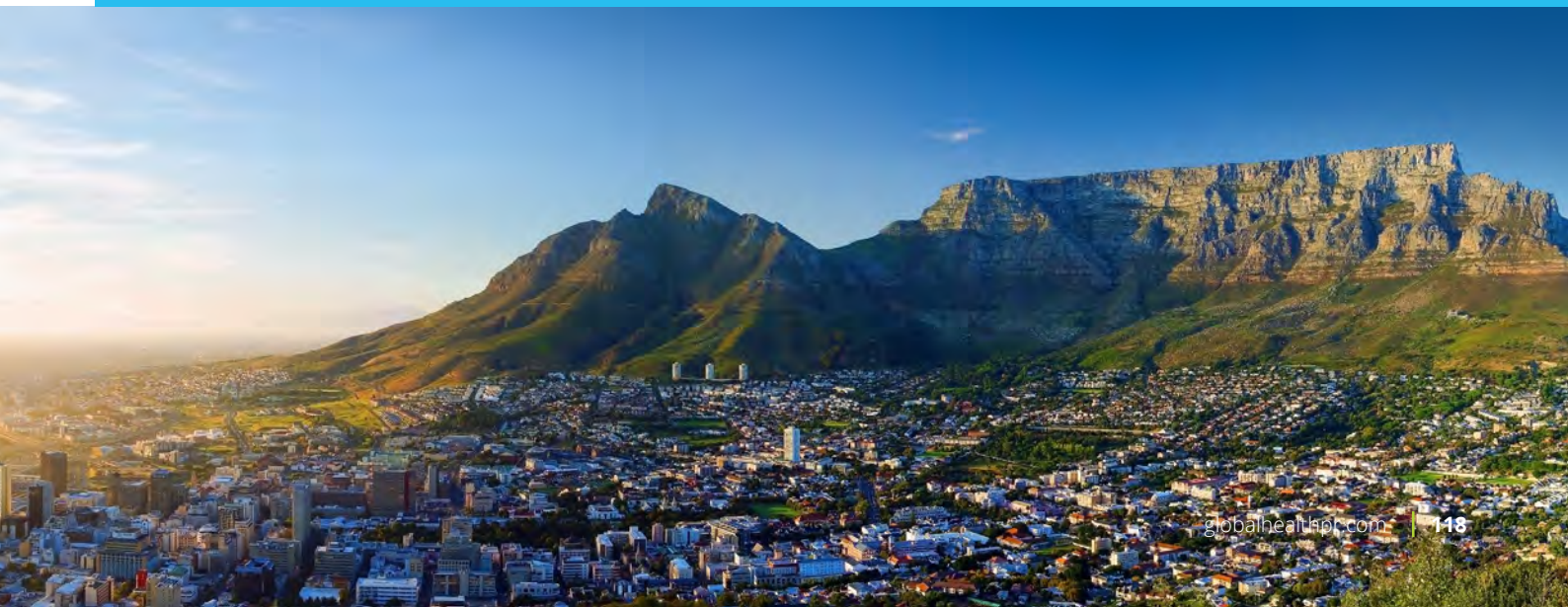
Public relations and advertising are not defined separately, and there are no special rules for public relations activities.

Who is responsible for the enforcement of these rules?

The Medicines Act, which forms the main legislation controlling medicine regulation, is enforced by the South African Health Products Regulatory Authority (SAHPRA). The NCC enforces the Consumer Protection Act, while the South African Code of Marketing Practice, the associated guideline to the MCA Code and the ASA Code are self-regulated by members and member organisations.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

The Medicines Act prohibits any person from supplying free medicines outside a clinical trial setting. No gift, benefit in kind, rebate, discount, kickback or other pecuniary advantage may be offered or given to healthcare professionals as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any health product. Healthcare professionals may receive occasional gifts and promotional items, provided that they are inexpensive and of minimal intrinsic value, are not for personal use, are of educational and/or scientific value, benefit the patient and/or are relevant to the practice. Inexpensive gifts not related to a professional's practice may be given only once per year in recognition of significant national, cultural or religious occasions.



Companies are permitted to organise or sponsor meetings and events, including Continued Professional Development (CPD, also known as Continuing Medical Education or CME), which are subject to some restrictions:

- The payment of reasonable honoraria and reimbursement of out-of-pocket expenses, including travel, are permitted if it is in terms of a written contract.
- No product promotion is allowed in a CPD meeting room.
- Payment for registration fees, travel and accommodations must be made to the professional associations/organisers.
- No standalone entertainment or other leisure, social or sporting activities may be planned or arranged.
- Healthcare professionals may not receive direct payment for any other services, apart from speaker engagements.

Who receives concerns and complaints? How does this process operate?

Complaints can be filed directly with the appropriate regulatory authority. Contravening the Medicines Act or the General Regulations constitutes an offence. If a complaint is brought to the South African Police Service (SAPS), SAHPRA enforces the offence with the office of the National Prosecuting Authority (NPA). Competitors may lodge a complaint with the ASA, MCA, SAHPRA, NCC or SAPS.

In the event that a company contravenes the ASA Code, the ASA has the power to order its members to withdraw the contravening advertisement. The ASA can indirectly enforce its code against non-members by requiring ASA members to refuse to publish or broadcast a contravening advertisement.

What promotional or media materials must be pre-approved by authorities?

In general, no laws or codes require advertising to be approved before use. However, the regulations state that no advertisement for a medicine may contain a statement that conflicts with or goes beyond the evidence submitted to and accepted by the Medicines Control Council in the process of that medicine's registration. Additionally, a decree of prior approval must be inserted into a medicine's approved package.

The ASA may direct an advertiser that has breached the ASA Code to submit a proposed amendment to the advertisement for pre-publication advice. Also, the ASA may require an advertiser that has been the subject of more than one adverse ruling within 12 months to submit all future advertising to the ASA prior to publication for the next six months.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

The most recent development is Regulation 42 of the General Regulations published under the Medicines Act (GN 859/25 August 2017). The MCA Code and its associated guidelines are updated annually.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

Per the MCA Code, promotional activity is defined as 'any activity associated with Health Product promotion'. As such, the provision of information involving a branded pharmaceutical product could be considered promotional activity. Promotional events are defined as events organised in association with a health product's promotion. CPD or CME events that comply with the MCA Code's requirements are not considered promotional events.

Companies may provide training and education to the

general public and may also sponsor training that other organisations provide. Educational materials should offer accurate, balanced information on a subject area and include a clear indication of which company has produced or sponsored the material. However, under the Medicines Act and the General Regulations, advertising a Schedule 2, 3, 4, 5 or 6 medicine to the general public is a criminal offence.

How is a media event defined?

No explicit legal provisions define media events for medicinal promotion as a distinct entity.

Do the regulations differentiate between consumer and clinical publications?

Advertising a Schedule 2, 3, 4, 5 or 6 medicine to the general public is a criminal offence. Schedule 2 and above medicines may only be advertised to pharmacists, medical practitioners, dentists, veterinarians and other authorised prescribers, or in a publication which is only accessible to such persons, as there is a legal separation between publications directed to consumers and those directed to healthcare professionals.

Do regulations differentiate between print and broadcast media?

No.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

No person may 'sell' any medicine prior to it being registered. Section 14(1) of the Medicines Act does not distinguish between healthcare professionals and the general public in its application. The term 'sell', in turn, is defined to include 'advertise'. The provision of a pharmaceutical product's off-label information prior to its registration is considered promotional and the prohibition applies irrespective of whether or not the product has been registered with a medicines regulatory authority in another jurisdiction outside South Africa.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

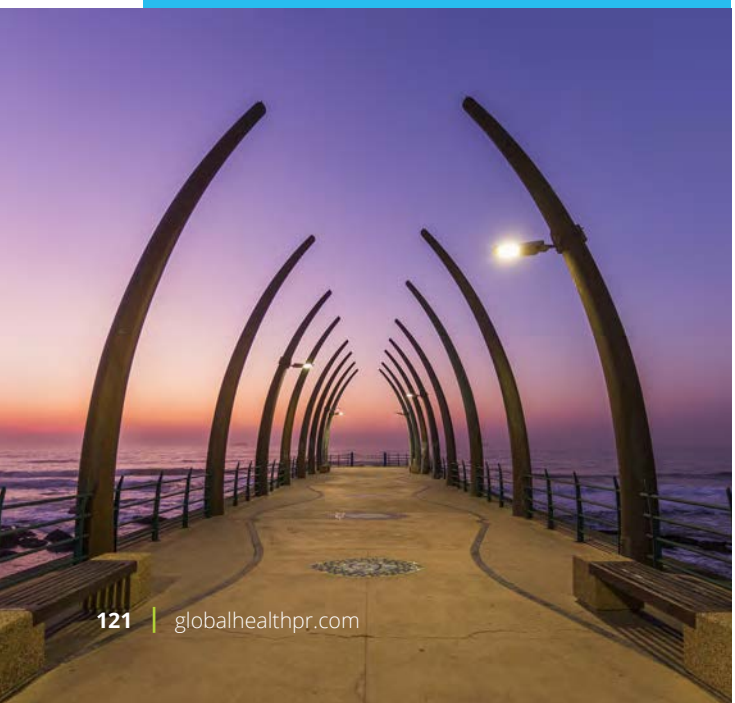
No explicit regulations govern press releases, media materials or media attending clinical events.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

No references are made about the distribution of press releases and media materials.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

No rules govern how the press should cover congresses and scientific meetings.



If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
Journalistic output from scientific meetings is not covered in any acts, codes or guidelines. However, the resulting work should be independent and balanced. A company that sponsors a journalist must not place conditions on the journalist's reporting on the company's product.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Regulatory information does not specify how case studies or third-party advocacy should be handled.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
The regulations don't differentiate between online, print and broadcast media. However, the requirements for all also apply to promotional material on the internet and other forms of advertising.

What levels of web security are required?
Applying a password-protection scheme to promotional material is prudent in relation to prescription-only medicines. This also applies to promotional material that is placed on the internet outside of South Africa by or with a South African company's authority or its affiliate's authority and that makes specific reference to a medicine's availability or use in South Africa. Companies must also clarify any time a user leaves any of their websites and is directed to a site not belonging to them and, therefore, is not necessarily covered by the MCA Code.

Do the regulations cover funding of, or provision of information to non-company owned websites?
Per the MCA Code, internet users must be clearly informed when they leave any of a company's sites, or sites sponsored by a company, or they are directed to a site not belonging to the company. Any references or links to other reputable information sources must be to those that provide valuable educational material that would enhance the quality of products' use. When a company makes such a reference or link, it must clearly display the following statement before the user accesses the reference material:

> *The information a reader is about to be referred to may not comply with the South Africa regulatory requirements. Information relevant to the South Africa environment is available from the company or via the Package Insert.*
> (Guideline to Clause 22.2 of the MCA Code in the MCA Guidelines)

Companies should also be cautious when including references or links to other informational sites. References or links to any non-compliant sites may put companies at risk of breaching the MCA Code and should be removed without delay.

What are the most popular social networks in your region?

As of 2018, the most popular social networks in South Africa were:

1. Published advertisements appear in print, in Facebook (16 million users)
2. Twitter (8 million users)
3. LinkedIn (6.1 million users)
4. Instagram (3.8 million users)

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

Per the MCA Guidelines, companies that engage in social media activities that include discussion boards and sharing of audio/visual content should consider several factors involving community management, including, but not limited to:

- How to join and the purpose of the forum
- Guidelines for inclusion/exclusion of sensitive or offensive subject matter
- A notice that conversations may be monitored
- The responsibilities for monitoring and reporting adverse events posted via the platform

Are there any self-imposed regulations from social media companies?

Not specifically in regard to South Africa; see the United States chapter for further information on this question.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

Other than the rules stated in the previous question about the use of social media for disease awareness or product promotion activities, no.

In addition, companies may not include lists of healthcare professionals or their hospitals or clinics on company-developed websites. However, it is possible to include a link to healthcare

What is mobile adoption like in your region? Are there separate regulations for it?

As of mid-2018, more than half of South Africa's 56.7 million citizens used a smartphone. Specific rules apply to companies that wish to make promotional and educational materials available to healthcare professionals via various media's mobile platforms or applications (Note 12 to Clause 5 of the MCA Code, as contained in the MCA Guidelines).

What are the disclosure laws like in your region for non-branded websites?

Companies must make clear to internet users when they leave any of a company's sites, or sites sponsored by the company, or they are directed to a site not belonging to the company (Clause 22.5 of the MCA Code). All references or links to other reputable information sources must provide valuable educational material that would enhance the quality of products' use. When a company makes such a reference or link, it must clearly display the following statement before the user accesses the reference material:

> *The information a reader is about to be referred to may not comply with the South Africa regulatory requirements. Information relevant to the South Africa environment is available from the company or via the Package Insert.* (Guideline to clause 22.2 of the MCA Code in the MCA Guideline)

What is the response level needed for adverse event reporting?

The MCA Code states that, 'Healthcare Sales Representatives/consumer promoters must notify their company regarding any information received in relation to the use of health products which they promote, particularly any information relating to adverse event reporting'.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

The MCA Code allows companies to extend hospitality to patient groups. Per the guidelines, 'It is permitted to use [healthcare professionals] and/or patient organisations as consultants and advisers, whether in groups or individually, for services such as speaking at and chairing of meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research, where such participation involves a FFS/Honorarium and/or reimbursement of travel expenses and/or the provision of hospitality.'

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

The MCA Code allows honoraria for healthcare professionals, advocacy groups or third parties in prescribed events—with conditions, as described in answer to the previous question.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Yes. The same provisions from the previous question apply.

What is possible in terms of media or message training for health professionals or advocacy organisations?

No specific rules govern media or message training. However, the MCA Code does state that, 'Companies may provide training and education to Consumers and may also sponsor training provided by other organisations. The relevant training material shall be accurate, contain balanced information on the subject, and include a clear indication of which Company has produced the sponsored material.'

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

No specific regulations govern materials written on behalf of third parties, as opposed to manufacturers. All materials must comply with the MCA Code.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

See answer to previous question.

KEY TAKEAWAYS/ SUMMARY

- Pharmaceutical marketing codes in South Africa are defined by several governmental entities, however, the industry is largely self-regulated. Disputes may be handled in or out of court and can be initiated by the public, competitors or governmental agencies.
- Pharmaceutical marketing codes and guidelines have been universally adopted by the industry to promote high professional and ethical healthcare standards; the safe use of therapeutic goods; and the honest communication of medicines' benefits, uses and effects.
- Direct-to-public marketing of Schedule 2 and higher drugs is not permitted, and the advertising of therapeutic goods to health practitioners is controlled by legislation outlined by the Medicines Act and Consumer Protection Act, which SAHPRA administers. The MCA and ASA are the organisations responsible for interpreting the legislation and defining marketing codes and guidelines.

SPAIN

Any correspondence or material produced by a pharmaceutical company about a medicine or its use is considered promotional, whether or not it makes product-specific claims. All promotional information should be accurate, balanced, fair, objective and sufficiently complete to enable the recipients to form their own opinion about the therapeutic value of the medicine. It must not be misleading and must reflect the most current information.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The main code of ethics is issued by the Asociación Nacional Empresarial de la Industria Farmacéutica (Farmaindustria) and the industry's national business association: the Spanish Code of Practice for the Promotion of Medicines and Relations between the Pharmaceutical Industry and the Health Professional (June, 2014).

Changes in the promotion of pharmaceutical products in Spain has led to a new self-regulation system in the pharmaceutical industry with this new version of the Code of Practice for the Pharmaceutical Industry, approved by the governing bodies of Farmaindustria in December 2013 and ratified by Farmaindustria General Assembly in June 2014.

The Code incorporates, among others, the principles of:

- Directive 2001/83/EC of the European Parliament and of the Council, dated 6 November 2001, on the Community code relating to medicinal products for human use. Farmaindustria CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY 2014 5. These texts are the non-official translation of the Spanish version of the texts approved by Farmaindustria General Assembly. The Spanish versions shall always prevail.
- Law 29/2006, of 26 July, on Guarantees and Rational Use of Medicinal Products and Medical Devices.
- European Federation of Pharmaceutical Industries and Associations (EFPIA) Codes on Interactions with Healthcare Professionals (HCPs), Relationships with Patient Organisations and Disclosure of Transfers of Value.
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practices.

The new code essentially addresses three areas:

1. Promotion of Prescription-Only Medicines. Respecting the right of the scientific community to be completely informed about medical and scientific progress, on one hand, and the legitimate interest of companies to inform and promote their products, on the other hand, this section of the code provides for a series of regulations designed to guarantee that the information provided in the context of the promotion of prescription only medicines is appropriate, honest, precise, objective, complete, accurate and truthful.
2. Relationships with HCPs and Healthcare Organisations. The interactions between healthcare professionals and the pharmaceutical industry have a fundamental influence on patient care and research development; for this reason, it is necessary to establish criteria and guidelines to guarantee that these activities are conducted in a professional and responsible manner.
3. Relationships with Patient Organisations. patient organisations and the pharmaceutical industry share common interests, such as improving the quality of life of patients and attention to their interests. The rules included in this section guarantee that the manner in which companies interact with patients and with the organisations that represent them is appropriate and in compliance with, among others, the principles of independence, mutual respect and transparency.

The continuous commitment of pharmaceutical companies to the development, efficacy and rigor of the self-regulation system is the result of the responsible attitude of Farmaindustria members and those companies that have decided to adhere to the Code voluntarily. This commitment is proved by the companies' implementation of robust internal procedures designed to guarantee compliance with the Code, with the aim of ensuring appropriate training of their employees. The transparency of the self-regulating system is offered as an essential tool for promoting and strengthening confidence in the pharmaceutical industry, facilitating public access to their actions. Proof of this commitment is the publication of the Resolutions of the

Jury of the Association for Self-Regulation of Commercial Communications in complaint procedures, information related to clinical trials, collaboration provided to patient organisations and, more recently, the disclosure of transfers of value to healthcare professionals and healthcare organisations.

Apart from that, the government has published the Royal Legislative Decree 1/2015, which does not introduce any changes referred to promotion of pharmaceutical products.

With respect to healthcare technologies and products, Fenin, the Spanish multi-sector federation that groups manufacturing, import and distribution companies and associations of healthcare technologies and products, has not published updates in the last four years.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Public relations is not separately defined. The scope of the Code covers all forms of promotion aimed at health professionals who are qualified to prescribe or dispense medicinal products. It covers all promotional methods, including those traditionally categorised as public relations, such as the sponsorship of scientific congresses and scientific or professional meetings attended by healthcare providers, online communications, the use of audiovisual systems and the provision of gifts and hospitality. It often uses the word advertising interchangeably with the word promotion'

Law 10/2013 modifies Article 78 of Law 29/2006, regarding guarantees and the rational use of medicines and health products. This issue is regulated in paragraphs 5, 6 and 7, establishing:

1. That the possibility of direct or indirect advertising aimed at the public is prohibited in the case of a product financed by the National Health System (this prohibition affects manufacturers, distributors and sellers, and all those entities that may come into direct contact with the patient)
2. That the use of incentives, gifts, discounts, prizes, competitions, bonuses or similar as methods linked to the promotion or sale to the public of these products is prohibited
3. That health products intended to be used or applied exclusively by health professionals may not be advertised to the public.
4. That advertising of medical or surgical techniques or procedures linked to the use of specific health products must respect the criteria established for the advertising of health products

Who is responsible for the enforcement of these rules?

In its major overhaul of procedures in 2002, Farmaindustria started up an Ethics Commission and Code of Practice Surveillance Unit as the body responsible for active monitoring of Code compliance. The aim of the Code is to guarantee that any promotion of medicines for human use is carried out respecting the most stringent ethical principles of professionalism and responsibility. For this purpose, an agreement was signed with the Association

for the Self-Regulation of Commercial Communications (Autocontrol) and any cases not solved by conciliation are referred to this organisation, which has a reputation for harsh enforcement. The Ministry of Health is responsible for the enforcement of The Law of Guarantees and Rational Use of Medical Products and Medical Devices.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

According to the Code of Ethics issued by the Farmaindustria, pharmaceutical companies are not allowed to offer or give healthcare providers any type of gift, incentive or prize. Companies may provide informational or education materials to doctors as long as the materials are inexpensive (no more than $67 USD), are relevant to the practice of medicine or pharmacy and directly benefit patient care.

Events that are sponsored or organised by a company must be exclusively science related. Events of recreational nature are prohibited, although welcome cocktails, working luncheons and gala dinners that occur within official programmes and meetings are not included. A maximum of $67 USD per guest applies to these events.

Hospitality at professional or scientific events must be reasonable and not exceed what healthacare professionals would be willing to pay in the same circumstance. Hospitality includes the costs of travel, registration and accommodation. Payments to rent rooms or attend a meeting/conference are prohibited.

A limited number of free samples may be given to doctors as long as they are authorised to prescribe medicine. Medical samples must bear the statement 'free medical sample – not for sale'.

These regulations are enforced and monitored by the Code of Practice Surveillance and the Code of Practice Committee.

Who receives concerns and complaints? How does this process operate?

Any person or legal entity may submit a legitimate complaint to the Code of Practice Surveillance Unit. The Unit evaluates the complaint and may open an investigation.

The Code of Practice Committee is responsible for mediating between parties involved in a complaint. Both the Surveillance Unit, Practice Committee and the Jury collaborate with 'the aim of promoting effective application of the rules contained in the code, either on its own or at the request of any person with a legitimate interest'. All three bodies are responsible for the complaint process.

'The resolutions of the Jury are reported immediately to the parties for their compliance. Simultaneously, the Jury will communicate these resolutions to the Code of Practice Committee, who will transfer them to the Farmaindustria governing bodies in order to be executed and, where applicable, proceed to collection of pecuniary sanctions imposed by the Jury', (30).

What promotional or media materials must be pre-approved by authorities?

Scientific and promotional meetings and events organised or sponsored by pharmaceutical companies must provide previous notification in accordance with the provisions in the Rules of Procedure of the Control Bodies of the Code (11.8); failure to do so constitutes an infringement of the Code (11.9). This is clarified in the queries that only meetings that meet the following criteria need notification: they are organised or sponsored (directly or indirectly) by the pharmaceutical company; they include an overnight stay; and they involve the participation of at least 20 healthcare professoinals. It is not necessary to notify authorities of congresses organised by a third party (scientific societies, professional organisations, etc.) and sponsored by several pharmaceutical companies, or satellite symposia and other parallel activities, provided that they are listed in the official congress programme. In any case, pharmaceutical companies are recommended to voluntarily report any event organised by third parties in which they plan to participate. Pharmaceutical companies usually submit advertisements to the Ministry of Health, but this is not obligatory. Patient information leaflets have to be reviewed by the Spanish Agency for the Evaluation of Medical Products.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

The last fifteen years have seen a great deal of change in the marketplace. In early 2002, the Farmaindustria General Assembly approved a much more stringent guide than that which previously existed, which was a version of the old EFPIA Code and had been in existence for almost 15 years. This latest version was enhanced by the addition of implementation guides, the formation of the above-mentioned body to enforce compliance and the establishment of a query system. Queries are henceforth addressed to and answered by the Code of Practice Surveillance Unit, are resolved by the Code of Practice Committee and are binding. Despite these far-reaching changes, approval of the new EFPIA Code late in 2004 required the Farmaindustria Code to incorporate additional European elements to bring its Code in line with the European regulations. These were finally approved and issued in June 2005. There are no further planned changes in the next few years. The new Law of Guarantees and Rational Use of Drugs and Health Products was also approved recently and put in place a new price reference system and promotion of generics and drug prescription by active ingredient. The previous Drug Law was put into effect in 1990, under a socialist government. These kinds of laws generally change to reflect the perspectives of the political group in power.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

In general, the Code implies that any correspondence or materials produced by a pharmaceutical company about medicines or their use is promotional, whether or not it makes product specific claims. All promotional information should be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicine. It must not be misleading and must reflect the most current information. Gifts, merchandising and meetings for physicians are included in promotional activity.

How is a media event defined?

Regulatory information does not specify a definition for a media event.

Do the regulations differentiate between consumer and clinical publications?

Regulatory information does not specify a differentiation between consumer and clinical publications.

Do regulations differentiate between print and broadcast media?

Regulatory information only differentiates between print and broadcast media in regards to the provision of essential information to accompany the materials. All printed material must contain essential information consistent with the data from the summary of product characteristics and prescribing information; different presentations of the product including dosage and form; the selling price and conditions for reimbursement; and, where appropriate, the estimated cost of treatment. For broadcast media, which includes interactive systems, this essential information must be included clearly on the videotape and also be available as a printed document.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

A medicine cannot be promoted prior to the grant of the marketing authorisation allowing its sale or supply. This also covers medicines authorised in another country but hat have not obtained authorisation in Spain. The publication in scientific media of information prior to authorisation would be acceptable if such publication is not deemed to be promotional. Regional guides can be more specific; for example, the Catalonian Guide states that it is possible to engage in the promotion of medicines and indications not authorised in Spain, but authorised in the countries represented at the congress. In these cases, the fact that the product is not licenced in Spain must be clearly stated, and all materials drafted in either the language of the country where the medicine is authorised or in English. Pre-launch information usually refers to generic name, not to the brand name.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

All material relating to medicines and their use that is sponsored by a pharmaceutical company must clearly state that it has been sponsored by that company. This also applies to material that in itself is not directly promotional, such as invitations. Exaggerated or all-embracing statements should not be made, nor should there be any unsubstantiated claim that a product has some special merit or property. Statistics, conclusions or any other data from different studies conducted using different methodologies cannot be mixed or compared unless they come from systematic reviews. The word new cannot be used to describe any medicine that has been generally available or any indication that has been generally promoted for more than two years in Spain. Trademarks or brand names of products from other companies may only be quoted if their ownership is clearly indicated. All information, statements and comparisons must be referenced and well-founded and their foundation made available to physicians on request.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
The Code covers only the distribution of materials to healthcare professionals, not media (Section 7). EFPIA regulations would give the guidance that the Codes of Conduct of both the country of source and distribution should be followed, with the stricter code prevailing in case of conflict.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
It is not permitted to sponsor anyone, whether press or a healthcare professional, to attend a meeting. If a journalist is sponsored, then his or her resulting copy becomes subject to the rules of a contractual relationship.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
Any copy produced by a truly freelance journalist, or one employed to write or broadcast for regular editions or programmes as part of his or her professional work in gathering news at congress, is not bound by the Code.

If a company sponsors a journalist to attend, their relationship becomes a contractual relationship' and any resulting copy will be subject to the letter of the Code. The assumption is that the copy should then go through internal regulation in the same way as any other promotional material.

Do regulations cover the use of case studies or other third-party advocacy in the media?
The regulations specifically state that formal authorisation for any quotation in any media format is required and that all third-party endorsement must accurately reflect the opinion of the author. Whenever a company finances, ensures or directly or indirectly organises publication of promotional material in newspapers or magazines, it should be expressly stated that such material is not included as an independent editorial topic and the name of the sponsoring company should be included in a visible place.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
Section 8 of the Code is dedicated to promotion via the internet and states that any promotional materials for medicines directed to healthcare professionals via this method of communication must have a primarily technical, scientific or professional content. In addition, promotional information must contain a prominent and clearly legible warning indicating that the information contained on the web page is intended only for health professionals qualified to prescribe or dispense medicines and specialised training is therefore required for its adequate interpretation.

What levels of web security are required?
The Code specifies that measures must be taken to ensure that this promotion is only accessible to these professional groups. It does not state how this should be carried out, but the implication is that the site should be password-protected.

Do the regulations cover funding of, or provision of information to non-company owned websites?
This is not specifically covered with relation to the internet, although the general principles of provision of information to the media would apply

What are the most popular social networks in your region?
Facebook, Instagram, Twitter and LinkedIn are the most popular social networks in Spain. Previously, Tuneti, a homegrown network, was the most popular social media platform. However, a rapid decline in the number of users led to a closure of the service in 2016.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
According to the Code, companies must 'possess guidelines and rules of conduct for their employees that establish standards for responsible conduct in the digital environment, both for when sharing information about or in the name of the company as well as when using a medium, means of delivery or channel provided by the company', (8).

Furthermore, any company that is a member of FARMAINDUSTRIA must adhere to the code regardless of medium (8).

Are there any self-imposed regulations from social media companies?
There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Each digital platform has its own rules. There are no general laws.

What is mobile adoption like in your region? Are there separate regulations for it?
As of 2017, 67% percent of Spain's population, over 46 million people, used smartphones. Despite this, there are no specific regulations regarding healthcare apps or other marketing via mobile devices. The general marketing codes still apply.

What are the disclosure laws like in your region for non-branded websites?
Courts make decisions for non-branded websites. Websites about pathologies are only allowed if they do not mention any treatment or product. Either way, any formal complaints might be solved by the court.

What is the response level needed for adverse event reporting?
All adverse event reporting is completed in accordance with official regulations.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Section 11.3 clearly states that hospitality, including travel and attendance at professional and scientific events, should not be extended to anyone other than healthcare professionals, although, advocacy/ patient groups are usually invited by the industry. Pharmaceutical companies cannot give any information directly to patients or patient groups.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Honoraria are possible for healthcare providers only to cover the payment of reasonable fees and reimbursement of out-of-pocket expenses, including travel, for speakers and moderators at meetings, congresses, symposia and similar scientific or professional events. Hospitality, which includes travel, registration and subsistence expenses, must not exceed what the recipients would normally be prepared to pay for themselves in the same circumstances. Hospitality cannot be extended beyond a reasonable period before or after the event. This is clarified in the published queries as being one day before or after the event. In addition, hospitality must always be secondary to the main purpose of the meeting and 'in no case shall social or cultural aspects predominate over scientific issues'. Answers to the published queries further clarify that reasonable would prohibit anything greater than a four-star hotel.

Regarding disclosure obligation, companies subject to the Code as established in articles 19.1 and 19.3 must document and disclose payments and transfers of value that they make, either directly or indirectly, to or for the benefit of the recipients.

Payments or transfers of value associated with activities not detailed in Appendix 1 of the Code include the provision of materials regulated in Article 10, Guarantees of Independence, samples regulated in Article 13, hospitality associated with dinners or luncheons regulated in Article 11 Scientific and Professional Meetings

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting? No, money cannot be offered to healthcare professionals to attend events.

What is possible in terms of media or message training for health professionals or advocacy organisations?
This is not specifically outlined, although Clause 5.2 states that 'promotional material and activities should not be designed to disguise their actual purpose or nature'. Given the spirit of the entire Code, it would be reasonable to assume that all briefing materials relating to such an activity must be clearly referenced, substantiated and marked as having been sponsored by a pharmaceutical company.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?
Although this is not specifically addressed, it would seem fair to assume that any materials that are written directly or indirectly by a pharmaceutical company must have sponsorship and involvement clearly indicated and explained.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
This is not covered in the regulations. However, it would be reasonable to assume from EFPIA regulations that matters pertaining to human health and disease without mention of specific products would be permissible, while copy with brand messages would be promotional and need to be clearly marked as promotion.

KEY TAKEAWAYS/ SUMMARY

Pharmaceutical marketing continues to develop in Spain due to:

- Strict ethical codes
- Global rules for pharmacies
- New stakeholders (autonomous regions, patient associations and scientific societies)
- Increased control by the government

SWEDEN

In Sweden, the promotion of medicine is governed by the Pharmaceutical Law, by the Medical Products Agency's regulations for marketing pharmaceuticals and by Läkemedelsindustriföreningen's (LIF's, the trade association for the research-based pharmaceutical industry in Sweden) Ethical Guidelines (LER). Although not legally binding, the LER rules are widely recognised by the pharmaceutical industry and applied by courts as an expression of fair and ethical marketing. The national regulatory framework for promoting medicinal products is largely based on EU legislation. For example, it's prohibited to advertise medicinal products that are not authorised for sale in Sweden or to target children when advertising medicinal products. Advertising prescription medicinal products to the general public is also prohibited, with the exception of vaccination campaigns against human infectious diseases.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

Information distribution on pharmaceuticals is governed by the Pharmaceutical Law, by the Medical Products Agency's regulations for marketing pharmaceuticals and by LIF's LER.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Information that is clearly intended to enhance sales and increase the demand for a product and that mainly focuses on the benefits and not the potential risks of a product might be considered an advertising or promotional activity.

Who is responsible for the enforcement of these rules?

The pharmaceutical companies themselves are responsible for following LER rules and regulations. Companies are not subject to legal requirements for having specific standard operating procedures (SOPs) governing promotional activities, however, according to LER, Article 129, every member company must have at least one individual responsible for ensuring that its communication complies with rules and regulations. This person approves all material before it is distributed. If a company appears to be violating the rules, it can be reported to the Information Audit Board (IGN).

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

According to the provisions and guidelines issued by LIF, Läkemedelsverkets föreskrifter (LVFS) 2009:6 §7, companies may not have healthcare providers, scientists or any individual who could use his or her position to promote pharmaceuticals participate in marketing pharmaceuticals to the general public.

And according to LER, Chapter 2, Article 2a, all cooperation between pharmaceutical companies and healthcare providers must follow the principles of usefulness, transparency, proportionality, moderation and documentation. Article 4b further states that, if there is a legitimate need, healthcare providers may participate in research, education, conferences, product development and advisory boards as part of their normal duties. Such participation must be outlined in writing between the healthcare provider, his or her employer and the pharmaceutical company. All remuneration must be reasonable and paid to the employer. The healthcare provider is also required to disclose the cooperation when making public statements on a subject that is part of the engagement.

Who receives concerns and complaints? How does this process operate?

IGN functions under LIF with one chairman and two board members. Member companies send to IGN copies of all their marketing materials that target the public and healthcare professionals. IGN will then audit the companies' pharmaceutical information on an ongoing basis and, by its own initiative or after external reports, rule on whether marketing measures and market activities regarding pharmaceuticals are compliant with good business practices. If they are not, IGN may issue a fine of up to 500,000 Swedish Krona (SEK) to be paid to LIF. IGN's rulings may be appealed to the Committee for Assessment of Pharmaceutical Information (NBL). The committee may issue a nonbinding statement if it deems such action appropriate. If a governmental body is the party filing the concern or complaint, NBL issues the final ruling.

What promotional or media materials must be pre-approved by authorities?

Pharmaceutical companies that are members of LIF can apply for pre-approval of a website or vaccination campaign. Websites must provide pharmaceutical treatment information to patients who are actively searching for it. Thus, a company cannot actively promote a website. Additionally, the company providing

the information must clearly identify itself and include its mailing address and e-mail address. A medically responsible person at the company must approve all information on a website and the information needs to be covered in the Summary of Product Characteristics or at www.fass.se. Every web page or relevant section of a page should include the date of its latest update. Information on prescription drugs may only be published after IGN has reviewed and approved it. A prescription drug's product name is permitted to be visible in a domain name and also permitted to be mentioned (but not occupy an essential amount of space) on a website.

Promoting a prescription treatment to the public is allowed in the case of vaccination campaigns only, which IGN needs to review and approve. These campaigns aim to inform the public about necessary protection against infectious diseases. A product name, product logotype, generic name or such may not be promoted.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

LER is updated, on average, once or twice a year. The latest version is available on its website. When the European Federation of Pharmaceutical Industries and Associations and the International Federation of Pharmaceutical Manufacturers and Associations update their codes of conduct and regulations, LER is also updated.

At the time of this guide's publication, the most recent update from August 2016 is valid beginning 15 June 2016, when the 'pharmacy agreement' was replaced with new ethical rules for associations with pharmacy staff (LER, Chapter 2, Section 2).

On 1 January 2017, the Information Audit Function (IGM) was replaced with IGN. IGM had been divided into two sections: IGM Public and IGM Professional. IGN is a board that covers both areas.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

Provision of information regarding pharmaceuticals is characterised by being meaningful and balanced. It is not scant, incomplete or easily misunderstood. Further, pharmaceutical information needs to be simply recognised as such. The sender of the information shall be easily recognisable, and the information needs to meet the criteria for 'minimum information'.

Promotional activity is characterised by methods that attempt to sell a product.

How is a media event defined?

This term is not specifically defined.

Do the regulations differentiate between consumer and clinical publications?
No, the regulations are the same.

Do regulations differentiate between print and broadcast media?
No, the regulations are the same.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?
The rules do not specifically address this in regards to media.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
After a verdict by the Medical Products Agency in 2011, journalists are considered part of the public and do not have a special status. Hence, pharmaceutical companies should not provide them with press releases about prescription pharmaceuticals, because this would be considered marketing to the public. However, LIF continues to advise its members to proceed in accordance with current business practices, saying that press releases are allowed, given that they are directed towards journalists and contain news of public interest. Press releases, however, must be medically correct, relevant, balanced and not have any marketing character. Certain information might vary in relevancy between medical journalists and regular media. Accordingly, two different press releases with different depth of information are often issued for these two target groups. If a company is reported to IGN for issuing an imbalanced press release, IGN would have to adhere to the rule that journalists are part of the public. For this reason, pharmaceutical companies are now more careful when presenting information in press releases.

Invitations to clinical events (for healthcare providers) must state the purpose and content of the event, the expected time frames, the time and place, which costs are covered by the pharmaceutical company and any side arrangements. If specific pharmaceutical information is going to be part of the event, it must be clearly stated in the invitation.

For media events, if there is a risk that journalists will ask questions about prescription drugs during the presentation, LIF would consider the event marketing towards the public, because the company should be able to anticipate such questions when planning the event. Hence, LIF advises companies not to host educational media events for journalists about disease.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
The method of distribution is not regulated. Materials from outside Sweden also must fulfil Swedish rules and regulations.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
Journalists are allowed to receive congress reports containing news on research, ongoing studies and preliminary research findings, if the information is relevant and balanced. Even if journalists, according to the Pradaxa verdict of 2011, are considered part of the public without special status, they are still considered able to make independent decisions about how to handle the information they receive.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
The resulting copy is independent in all cases.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Third-party advocacy, by healthcare providers or patients on behalf of pharmaceutical companies or their PR agencies, of medicinal products in media is not allowed. However a journalist may write an article on his or her own initiative about a patient, because this is protected by the freedom of speech. Pharmaceutical companies are still not allowed to use such articles, or refer to them, because this would breach LER, Article 8 and Article 108.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
There is no difference in the regulations for online media and print media.

What levels of web security are required?
This is not specified.

Do the regulations cover funding of, or provision of information to non-company owned websites?
Cooperation with third parties (e.g., patient advocacy groups) is allowed but must be transparent. Their regular activities may not be funded, and any project that is subject to cooperation must be defined in writing and may not be so extensive that the third-party organisation cannot survive without the company's support.

What are the most popular social networks in your region?
Facebook, Twitter, YouTube, LinkedIn, Snapchat and Instagram.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Yes, LIF has a document regarding their regulations and its adaption to social media.

Are there any self-imposed regulations from social media companies?
No. While social media companies have their own codes of conduct, limitations to what pharmaceutical companies may publish on social media are not governed by such codes of conduct, but by local laws and ethical guidelines for the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Yes, LIF has a document regarding their regulations and its adaption to digital platforms.

What is mobile adoption like in your region? Are there separate regulations for it?
Mobile devices have no separate regulations. Use of social media through such devices is widespread.

What are the disclosure laws like in your region for non-branded websites?
The pharmaceutical company behind a non-branded website must always disclose the name of the company or its Swedish agent and its contact information.

Pharmaceutical information on websites must also clearly include information about the intended target group. This also applies to links to other websites containing pharmaceutical information (e.g., from non-branded websites); the information near the link needs to clarify the target group for that website. If the link leads to a page with healthcare provider information, it is wise to have a disclaimer through which the visitor confirms his or her category before accessing the information.

What is the response level needed for adverse event reporting?
Pharmaceutical companies must report all adverse events to the Medical Products Agency without further notice.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Congresses or meetings arranged by a pharmaceutical company must address its area of expertise, and the majority of the program must be scientific or profession-related. A company is allowed to sponsor members from an advocacy or patient group's participation in congresses in another country, but only to an extent of 50% of the total cost. A company is not allowed to sponsor an advocacy or patient group's ordinary or internal activities. While meetings should be held in Sweden, if possible, travel to another country is permitted if necessary for holding the conference. Cities holding major concurrent international events must be avoided and companies should not financially sponsor meetings that take place during such events. Whether a city is acceptable or not is decided by the LIF compliance officer, whose decision cannot be appealed.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Yes, a company may offer honoraria if a healthcare provider or advocacy/patient organisation representative is participating in a media activity targeting journalists. Honoraria must be reasonable regarding the time required to perform the activity and must be paid to the healthcare provider's employer. Expenses for travel, meals and accommodations, within reasonable limits, may be covered.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

No, a company may not pay a healthcare professional to attend a scientific meeting.

Pharmaceutical companies may, however, sponsor an advocacy/patient group's participation at a conference, including the expenses for travel, meals and accommodations within Sweden. For international conferences, companies may only sponsor up to 50% of the total expenses. Companies are not allowed to contribute more to an activity than the actual cost of the activity, which is specified in a written agreement.

What is possible in terms of media or message training for health professionals or advocacy organisations?

There are no limitations for message training.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

If pharmaceutical companies, or PR agencies operating on companies' behalf, produce written material on behalf of third parties, the companies' support must be announced for transparency.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

Pharmaceutical companies' relations and meetings with advocacy groups and other organisations are regulated by LER, Chapter 3, Section 1: 'Ethical rules for cooperation between pharmaceutical companies and organisations/advocacy groups'.

KEY TAKEAWAYS/ SUMMARY

- The distinction between PR and advertising in cases of promotion of medicinal products has become less relevant from a regulatory point of view. Promoting prescription medicinal products may not be aimed at the general public, with the exception of vaccines.
- Regardless of being a member of LIF or not, the best way to avoid any breach of law or regulations is to ensure that your company adheres to its ethical guidelines.
- Even though journalists are considered part of the public, according to the law, who may not receive information on prescription drugs, LIF advises its members to continue issuing balanced and relevant information to journalists on prescription drugs and to make their own decisions on publishing. However, LIF advises against pharmaceutical companies hosting media education events, which opens them up for questions from journalists on prescription drugs and creates the obvious risk of marketing.

UNITED KINGDOM

In the United Kingdom, the promotion of medicine is controlled by legislation and codes of practice. The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry is the code that outlines the guidelines and ensures compliance with legal requirements. It covers the promotion of prescription medicines and is relevant to public relations activities.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The promotion of medicines is subject to UK and European Law and to self-regulation by the pharmaceutical industry. The main UK legal requirements have been consolidated in the Human Medicines Regulations 2012, implemented in July 2012. UK law reflects the requirements of European Directive 2001/83/EC ('on the Community code relating to Medicinal products for human use') and amendments. The Medicines and Healthcare products Regulatory Agency (MHRA) has summarised the legal requirements in The Blue Guide, Advertising and Promotion of Medicines in the UK, the third edition, first revision published in September 2014.

Self-regulation is based on industry codes of practice. For prescription medicines, the ABPI Code of Practice (The Code) applies. The Code is based on UK law and incorporates the principles of the International and European Codes. All members of the ABPI and many non-members have agreed to follow The Code. It is regularly revised, most recently in 2019.

The Proprietary Association of Great Britain (PAGB) is responsible for advertising codes and guidelines for over-the-counter medicines.

The Association of British Healthcare Industries (ABHI) is responsible for the ABHI Code of Business Practice for medical device manufacturers.

- IFPMA Code of Practice (International Federation of Pharmaceutical Manufacturers Associations)
- EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals; EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (European Federation of Pharmaceutical Industries and Associations)

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

The Code does not specifically define the term public relations, although public relations activities are covered. Prescription-only medicines must not be advertised to the public. However, non-promotional information about prescription medicines may be provided to the public, 'either in response to a direct enquiry from an individual, including enquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities and the like' (Supplementary Information to Clause 26.2).

Public relations activities are unlikely to be considered promotional if they are restricted to the provision of factual information. If the purpose is to raise awareness of claims about a product, the activity is likely to be a form of promotion.

Who is responsible for the enforcement of these rules?

The Prescription Medicines Code of Practice Authority (PMCPA) is responsible for administering The Code and the complaints procedure. It also provides advice, guidance and training. Although established by the ABPI, it operates independently of the Association.

Enforcement of The Code is carried out mainly through the complaints procedure. In addition, the PMCPA arranges for the scrutiny of samples of advertisements, other promotional items and meetings in relation to the requirements of the Code. Sanctions are applied against companies ruled in breach of the Code.

The MHRA scrutinises journals, magazines and the internet for the promotion of medicines and it vets advertising for new active substances. The MHRA also investigates complaints made to it about advertising. Where necessary, it can take legal enforcement action

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

Clause 17 of the Code discusses how pharmaceutical companies may only send samples of a product to a qualified healthcare professional (17.1), no more than four samples may be provided to the same doctor during the course of one year (17.2), samples may only be supplied after a written request has been signed and dated (17.3) and the sample must be labeled 'free medical sample – not for resale' (17.5, 17.9).

According to the Code, 'No gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3' (18.1).

Healthcare providers attending a company organised scientific meeting or conference may not use materials (pens, notebooks, pencils) that bear the names of donor companies, the name of any medicine or any information about medicines.

If the Code is breached, complaints are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on completed cases are published by the PMCPA in its Code of Practice Review and on its website.

The Code is administered by the PMCPA, which is responsible for the provision of advice, guidance and training on the Code as well as for the complaints procedure.'

Who receives concerns and complaints? How does this process operate?

Clause 18.1 (Supplementary Information) states that, 'The General Medical Council (GMC) is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics'. According to the GMC, during an investigation evidence is collected and reviewed. After the investigation, the GMC may, 'issue advice or a warning to the doctor' or agree with the doctor that he or she will 'restrict their practice, retrain or work under supervision'.

The Medical Practitioners' Tribunal Service (MPTS) may also be called upon for a hearing.

'When action is needed to protect the public or to maintain public confidence in doctors, an MPTS tribunal can suspend a doctor's right to work, or restrict their practice – for example by requiring them to work under supervision, or undergo further training. If necessary, a tribunal can also suspend or restrict a doctor's right to work while the investigation is conducted.'

In serious cases, the GMC can remove a doctor from the medical register, which means that they are no longer able to work as a doctor in the UK. After this decision has been made, the GMC must inform other regulators around the world.

The General Pharmaceutical Council (GPC) is the regulatory body for pharmacists and pharmacy technicians. The GPC operates in a similar manner to the GMC. After a concern is brought to attention, an investigation is opened about potential misconduct.

What promotional or media materials must be pre-approved by authorities?

The MHRA vets advertising and promotional materials, before they may be used for new active substances. Related non-promotional materials such as press releases, associated media materials and patient support materials are also examined. It may also pre-vet advertising for other products if, for example, there are safety concerns or if previous advertising has breached the regulations. According to MHRA guidelines, the vetting period usually lasts for about two to three

months, but it may go on for longer depending on the nature of the promotional materials and any problems found.

Companies found in breach of the Code may be required to submit materials to the PMCPA for pre-vetting.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

A new edition of the Code was published in January 2019, with changes in a number of areas:

- An updated definition of promotion and additional clarification concerning risk minimisation plans (Clause 1.2)
- Additional information about Conditional Marketing Authorizations, the Early Access to Medicines Scheme and Compassionate Use; clarification on advance notification of new products/product changes (Clause 3)
- Changes to reflect updated requirements by the General Pharmaceutical Council and the Code of the Nursing and Midwifery Council on the provision of gifts and hospitality (Clauses 18.1 and 22.1)
- Updated information on:
  - Requirements for legibility of Prescribing Information (Clause 4.1)
  - Prescribing Information for digital and audio-visual materials (Clauses 4.4, 4.5 and 5.2)
  - Required text for adverse event reporting (Clause 4.9)
  - Journal advertising and the the provision of journal reprints (Clauses 6.1, 6.2, 6.3 and 10.1)
  - Certification requirements (Clauses 14, 14.1, 14.2, 14.4)
  - Provision of genetic, biomarker or other specific testing (Clause 18.1)
  - Value of patient support items (Clause 18.2)
  - Transfers of value (Clause 24.1)
  - Reporting of financial information (Clause 26.2)
  - Disclosure of support to patient organisations (Clause 27.7)

These changes are reflected where appropriate in the revised ABPI Code of practice and do not impact on the wording of the text under review.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

The Code defines promotion as, 'any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines' (Clause 1.2). Prescription-only medicines must not be promoted to the public (Clause 26.1).

Provision of certain types of information is not considered promotion. Examples are listed in Clauses 1.2 and 26 of the Code. They include:

- Replies to enquiries from health professionals if the information provided is directly relevant, is accurate, does not mislead and is non-promotional.

- Information on health or diseases, provided it does not refer directly or indirectly to specific medicines.
- Non-promotional information provided to the public about prescription-only medicines, including in response to enquiries from journalists or through public relations activities and the like.
- Information provided about prescription-only medicines must be factual, balanced and must not mislead with respect to their safety. It must not raise unfounded hopes of successful treatment and must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine (Clause 26.2).

The Blue Guide advises that, 'particular care should be taken in providing information in response to direct approaches from the media where a company has little or no control over the final production, for example, with television programmes, and which could result in the promotion of prescription only medicines to the general public'.

How is a media event defined?

The Code and the regulations do not use the term media event. Pharmaceutical companies or their agents may organise meetings with journalists from the medical or general press, television, radio or other media. Such meetings may take the form of press conferences, face- to-face or virtual briefings or media advisory boards.

Additional guidance on working with the media and journalists is provided by the UK's Healthcare Communications Association (HCA).

Do the regulations differentiate between consumer and clinical publications?

Yes. Advertisements for prescription-only medicines may appear in medical journals or other clinical publications intended for health professionals, but not in consumer publications intended for the public. In appropriate circumstances, however, it is permissible to provide factual information about a prescription-only medicine to a journalist working for a consumer publication. Such information must comply with the requirements of the Code.

A publication that has been sponsored by a pharmaceutical company must clearly indicate this sponsorship so that readers immediately understand the company's involvement (Clause 9.10).

Do regulations differentiate between print and broadcast media?

The regulations and the Code apply equally to print and broadcast media.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

A product or indication must not be promoted before the marketing authorisation has been granted. In certain circumstances, however, a pharmaceutical company or its agent may provide non-promotional information relating to an unlicenced product or indication.

It is permissible to issue a news release to the medical or general media about an as-yet unlicenced product or indication if the subject is genuinely newsworthy and appropriate for the intended audience. For example, it may be appropriate to issue a news release to the medical press about the results of a major clinical trial. The information provided must be factual, balanced and non- promotional. The use of brand names should be kept to a minimum. Non-promotional information about products in development may also be made available to shareholders and others with a business interest.

With regard to congresses, scientific meetings and major publications, The Code permits, 'the legitimate exchange of medical and scientific information during the development of a medicine...provided that any such information or activity does not constitute promotion' (Supplementary Information to Clause 3).

Therefore, pharmaceutical companies may sponsor medical and scientific meetings at which research findings on products or indications in development are presented. The purpose of such meetings must be educational and not promotional. Sponsorship must be disclosed in all the papers relating to a meeting and in any published proceedings (Clause 22.4).

Companies may sometimes promote products or indications that do not have a UK marketing authorisation at international scientific meetings held in the UK. The Code allows this only if all the following conditions are met (see Supplementary Information to Clause 3):
The meeting has a high scientific standing, with a significant proportion of attendees from countries in which the product is licenced.

- The medicine or indication is relevant to the purpose of the meeting.
- Promotional materials must clearly state that the product/indication does not have a UK marketing authorisation.
- The names of countries where the mdicine or indication is authorised must be given, including at least one major developed country.
- It must be stated that registration conditions differ from country to country.

In addition, if the product is authorised in the UK but the indication is not, the UK prescribing information must be available.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

The regulations and the Code allow for the provision of non-promotional information about prescription-only medicines to the media through press releases and other media materials. Requirements of the Code (Clauses 7, 8 and 26) include the following:

- Information about a product must be factual, balanced, must not mislead and must be capable of substantiation.
- Information about safety should reflect the evidence and a product must not be described as safe.
- Any mention of competitor products must not be misleading or disparaging.
- Superlatives must not be used to describe a product unless they relate to an indisputable fact.
- A product must not be described as new if it has been available in the UK for more than a year.
- Information must not raise unfounded hopes of successful treatment and must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine.

'It is good practice to include the summary of product characteristics with a press release or press pack relating to a medicine' (Supplementary Information to Clause 26.2).

Once a press release is issued, a company should have no control over the placement of any subsequent article. If a company or its agent controls or pays for the placement of an article about a product it will be regarded as an advertisement for the product.

The MHRA considers that press releases should be issued only if their content is genuinely newsworthy. The context in which the medicine will be used and the population for which it has been licenced should also be provided. The content of a press release and the language used should be appropriate for the target readership. The use of brand names should be kept to a minimum.

Pharmaceutical companies are responsible for information issued about their products by their public relations agencies (Clause 26.5). In accordance with the supplementary information to Clause 14.3 of the Code, appropriate company staff must examine press releases and media materials to ensure that they do not contravene the requirements of the Code or the regulations.

Invitations to journalists to attend media or clinical events must also comply with the Code and they must be checked by appropriate company staff before being issued.

If the PMCPA receives a complaint about an article or other report in the media about a medicine, it will judge the case on the information provided by the pharmaceutical company or its agent to the media and not solely on the content of the article itself. All relevant media materials may be reviewed, including press releases, invitations to meetings, etc.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

The method of distribution of media materials is not specifically covered in the Code. However, materials intended for the UK must comply with the Code, even if the company responsible is based outside the UK.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

The Code applies to UK press briefings held by or on behalf of pharmaceutical companies and to sponsorship of journalists to attend congresses and scientific meetings. It applies to both licenced and non-licenced products, though information provided about the latter must be considered carefully.

In the case of press briefings and meetings held outside the UK, the local regulations will apply. The requirements of the Code should be followed if a company invites UK journalists to attend.

If companies sponsor journalists to attend such meetings, the requirements of Clause 22 of the Code on meetings and hospitality should be observed. In particular:
Any hospitality offered must be limited to reasonable travel costs, accommodation, registration fees and subsistence and must be secondary to the purpose of the meeting.

- If air travel is involved, only economy class may be offered unless a journalist is providing professional services for the company (e.g., as a speaker).
- Journalists should not be paid simply for their time to attend media events.
- Those participating in media advisory boards or providing professional services for the company may receive appropriate honoraria.

Companies must check any materials that they issue to journalists to ensure that they comply with the Code. It is good practice to include the Summary of Product Characteristics for any medicine discussed.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?

Journalists—whether freelance or not—whose travel and accommodation are paid for by a company do not have to submit their copy for approval unless the company pays for what they write or influences its content. If the company provides briefing material, it must review this for compliance with the Code; should there be a complaint under the Code about any resulting article, the case will be judged on the basis of that material.

If a journalist submits copy for an independently written article to a company to review it or to check its accuracy, the company may be regarded as being responsible for the content.

If a company pays a journalist to write an article, it will be held responsible for the content and it must review it for compliance with the Code. Sponsorship should be declared in the article. However, it is good practice, as advocated by the HCA, not to pay journalists for writing news or feature stories, as they should receive payment for copy from the publications in which their material appears.

Do regulations cover the use of case studies or other third-party advocacy in the media?

It is permissible to use patients' case studies, but they should, 'focus on the disease and the impact it has on the patients rather than the specific medicine' (The Blue Guide). They should represent typical, not exceptional, cases. The use of case studies or third-party advocacy must comply with the Code. In particular, case studies must not be promotional and must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine. Companies must review any briefing materials they produce in connection with case studies or third- party advocacy to ensure compliance with the Code.

Companies must not use health professionals, patient organisations or patients themselves as advocates to promote particular products in the media.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

The same rules about compliance apply. The Code applies to information about the availability or use of a prescription medicine in the UK if this information is provided on the internet by, or on behalf of, a UK company, or by an affiliate. This is the case even if the information is put on the internet outside of the UK. Companies should review such information to ensure compliance. If there is a complaint under the Code, the PMCPA will require full details about the information provided.

What levels of web security are required?

Promotional material about prescription-only medicines may be placed on a website that is owned or sponsored by a pharmaceutical company. Such material must not be directed at the public. If the website is publicly accessible, it should have separate areas for consumers and healthcare professionals (Supplementary Information). The Blue Guide states that the public should not be encouraged to access material not intended for them.

Do the regulations cover funding of, or provision of information to, non-company owned websites?

Any funding or support given to a non-company owned website must be clearly stated on the website. If a company provides information for such a website, it must ensure that it complies with the Code.

If a company-owned or sponsored website includes links to other websites, it should inform users when they are being directed to a non-company site.

What are the most popular social networks in your region?

Social media such as Facebook, Twitter and others are widely used in the UK. Each has its own terms and conditions of use and privacy policy, but they do not have self-imposed regulations specifically relevant to the pharmaceutical industry.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

The promotion and advertising of medicinal products in the UK is governed by general laws on advertising. This self-regulatory practice is founded on the Codes of Practice, the ABPI's Code of Practice for the Promotion of Prescription-Only Medicines (the ABPI Code) and the PAGB's Medicines Advertising Codes that relate to over-the-counter medicines.

The main challenge for companies at this point is to combine the existing regulatory framework with additional specific guidance provided by the above mentioned codes and then apply that to social media.

Are there any self-imposed regulations from social media companies?

There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

The general principles set forth in the regulations and the Code apply. The PMCPA issued informal guidance on digital communications in March 2016. This notes that companies can use any method of communication, including social media, provided that relevant requirements of the Code are followed. A company may sponsor a page on a platform that it does not own (e.g., a company Facebook page), but it must make its involvement clear to users.

A company hosting a discussion forum on its website or facilitating a forum on a third-party website is likely to be responsible under The Code for its content. A company that is considering doing this must ensure that it can moderate the site, that the content complies with The Code and that it is appropriate for the intended users, whether they are health professionals or the public.

The requirements of The Code also apply if an employee of a company—or of an agency working for the company—contributes to a non-company discussion forum.

What is mobile adoption like in your region? Are there separate regulations for it?

The use of mobile phones and mobile computing through smart phones, tablets, etc. is widespread in the UK. The general principles set forth in the regulations and The Code apply to communications by or on behalf of pharmaceutical companies, irrespective of the communication medium or the device used to receive the information. Clause 9.9 of The Code requires that the telephone (including mobile phones), text messages, email and other electronic communications must not be used for promotional purposes unless the recipient has given prior permission.

What are the disclosure laws like in your region for non-branded websites?

A company can sponsor a non-branded website that provides non-promotional information about health or diseases, but the company's involvement must be clearly declared (Clause 9.10, The Code).

What is the response level needed for adverse event reporting?

The ABPI Pharmacovigilance Expert Network (PEN) has issued guidance on the management of adverse events from social media and company-sponsored websites (http://www.abpi.org.uk/our-work/library/guidelines/). This notes that companies should regularly screen websites for which they are responsible and collect any reports of adverse events with their products. It is advisable on any company-sponsored site to provide a

mechanism for the user to report adverse events to the company—for example by providing online reporting forms or company contact details.

Companies are not expected to screen external websites but if they become aware of adverse events reported on non-company websites they should review the details and determine whether they should be reported.
A company may 'listen in' to a social media site or actively communicate with users on the site. If it does so, the ABPI PEN recommends that it has a project plan specifying the objectives and responsibilities, including the management of any adverse events reported. It also recommends that monitoring for adverse events should be carried out only for the period of the project specified in the project plan. The company should, where feasible, declare its presence by registering on the site using the company name.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

Companies may provide support to patient organisations (Clause 27, The Code). There must be a detailed written agreement stating the arrangements (Supplementary Information to Clause 27.3) and companies must publish a list of organisations supported, with information about the support provided (Clause 27.7).

The requirements of Clause 22 of The Code are relevant to meetings and hospitality for patient/ advocacy groups. Meetings must be held in appropriate venues—lavish or deluxe venues or those renowned for entertainment facilities should not be used. Any hospitality offered must be limited to reasonable travel costs, accommodation, registration fees and subsistence and must be secondary to the purpose of the meeting. Exceptionally, if a representative of a patient group has a disability, companies may also pay such costs for an accompanying caregiver (Supplementary Information, Clause 27.2). Otherwise, hospitality must not be offered to accompanying persons unless they are participants in their own right. If appropriate, travel to other countries may be paid for, though companies should not organise meetings abroad unless most of the participants are from outside the UK, or expertise or resources relevant to the meeting are located outside the UK.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

Companies may pay reasonable costs for participants' travel, accommodation (if needed) and subsistence but should not pay participants simply for their time in attending meetings.

Reasonable honoraria may be paid to those providing services—for example, speakers.

The Code (Clauses 23.1 and 27.8) states that use of healthcare professionals and representatives of patient organisations as speakers, consultants or advisors must comply with a number of requirements. In particular, there must be a written agreement in place beforehand specifying:

- The services to be provided;
- The basis of the remuneration, which should reflect the fair market value of the services; and
- The obligation of the healthcare professional or

patient organisation to declare their relationship with the company whenever writing or speaking in public about a matter covered by the agreement or any other issue relating to the company.

Contracting a healthcare professional or patient organisation to provide services must not be an inducement to prescribe, provide or recommend any medicine.
Companies must publish details of payments made for such services each year (Clauses 23.2 and 27.8).
Companies sponsoring delegates' air travel to meetings should pay only for economy class, though this restriction does not apply to speakers or those providing other services.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Companies may pay for reasonable travel costs, accommodation, registration fees and subsistence. They may not pay participants for their time in attending meetings, though they may pay honoraria to speakers, advisory board members, etc. Details of such payments should be specified in written contracts or agreements and must be disclosed on an annual basis.

What is possible in terms of media or message training for health professionals or advocacy organisations?

Neither the Code nor The Blue Guide provides specific guidance on media training. If a company works with health professional or advocacy organisations that communicate with the media about a disease or its treatment, it is appropriate to provide them with media training. Anybody who provides information to the media on behalf of a company must be made familiar with the requirements of the Code.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

Clause 9.10 of the Code states that material relating to medicines and their uses that is supported by a company must clearly declare the company's sponsorship. This applies to materials written on behalf of patient advocacy organisations or other third parties. Companies must review the information in these materials to ensure that it complies with the Code. Materials written for patient advocacy organisations must not constitute the advertising of prescription-only medicines to the public. Briefing materials written for third parties that communicate with the media about a company's products must comply with the requirements of the Code. In particular, they must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

When working with any patient organisation companies must ensure that the arrangements comply with the Code (Clause 27) and that their involvement is made known from the outset. They must have a detailed written agreement (Clause 27.3) describing the arrangements. Companies must publish a list of all patient organisations to which they provide financial or significant non-financial support each year. They must also report on the support provided to each organisation in sufficient detail to enable readers to understand the significance of the support. Details must be provided of financial support and the value of non-financial support (Clause 27.7).

Any information that a company provides to a patient organisation must not constitute advertising of prescription-only medicines to the public. Information relating to the company's products must comply with the Code. It must be factual, balanced and must not be provided with the aim of encouraging the public to ask prescribers for a specific prescription-only medicine. Other important considerations in connection with patient advocacy groups are:

- No company may require that it be the sole funder of a patient organisation or any of its programmes (Clause 27.4);
- A company must not make public the use of a patient organisation's logo or proprietary material, such as leaflets, without the organisation's written agreement (Clause 27.5); and
- A company must not seek to influence the text of patient organisation material in a manner favourable to its own commercial interests (Clause 27.6).

KEY TAKEAWAYS/ SUMMARY

- Communications by pharmaceutical companies or agencies, including media briefings, must comply with the requirements of The Code: information must be accurate, balanced, must not mislead and must not promote prescription-only medicines to the public.
- Relations with patient advocacy groups must be open, with details—including financial arrangements—being made publicly available.
- Companies may sponsor healthcare professionals, journalists and members of patient advocacy groups to attend media events or scientific meetings; hospitality must be limited to travel costs, accommodation, registration fees and subsistence and must be secondary to the purpose of the meeting.

ASIA - PACIFIC

AUSTRALIA

The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods, and the promotion of medicines is self-regulated by the pharmaceutical industry's Medicines Australia Code of Conduct. Direct-to-consumer promotion is allowed for the majority of medicines available for over-the-counter (OTC) sale, while promotional activities and/or advertising to the general public for prescription-only and some pharmacist-only medicines is prohibited.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The promotion of medicines is subject to legislation requirements of the Therapeutic Goods Regulations and the Therapeutic Goods Act (TGA) and by self-regulation of the pharmaceutical industry.

Self-regulation is based on Medicines Australia's Code of Conduct (the Code), which sets the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia. The Code complements the legislation requirements of the Therapeutic Goods Regulations and the TGA.

Code provisions include standards for appropriate advertising, the behaviour of medical representatives and relationships with healthcare professionals. Medicines Australia's Code of Conduct, established in 1960, is revised on a regular basis to reflect the current community and professional standards and current government legislation. The latest Code of Conduct edition is available at www.medicinesaustralia.com.au.

The Code is recognised by the TGA, the regulator of medicines for marketing and promotion by the prescription medicines industry. The TGA supports the system of self-regulation as being consistent with supporting the Therapeutic Goods Regulations.

TGA is Australia's regulatory authority for therapeutic goods. It performs a range of assessment and monitoring activities to ensure that the therapeutic goods available in Australia are of an acceptable standard, with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

Non-prescription medicines, such as over-the-counter (OTC), pharmacy-only or complementary medicines are not covered by the Medicines Australia Code of Conduct. These medicines are regulated by co-regulatory and self-regulatory arrangements operated by the TGA, the Therapeutic Goods Advertising Code Council, the Australian Self-Medication Industry (ASMI) and the Complementary Healthcare Council (CHC).

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

According to the Medical Board of Australia, an advertiser is any person or business that advertises a regulated health service. Advertising includes all forms of printed and electronic media that promote a health service, in addition to situations in which practitioners make themselves available or provide information for media reports, magazine articles or advertisements.

Who is responsible for the enforcement of these rules?

In August 2012, Medicines Australia established a broad-based transparency working group to draft and develop measures and policies to improve transparency of payments and other transfers of value between healthcare providers and the pharmaceutical industry. Informed by the Principles for Transparency, the working group has developed a model which aims to improve transparency about payments and transfers of value between companies and healthcare provider. Australia's government's Transparency Principles dictate that the relationship between healthcare professionals and patients should be based on trust and mutual respect. This trust and the quality of the relationship between a healthcare provider and patient can be threatened when the decision-making by healthcare professionals may seem to have been compromised by outside interests.

Transparency Principles aim to:

a. Promote trust and mutual respect between the community and healthcare providers
b. Reduce the risk that payments and other transfers of value from a company to healthcare providers

undermine the independence of their decision-making
c. Allow consumers to make informed decisions on their health, and take into consideration their healthcare provider's relationship with companies
d. Report monetary transactions and transfers of value in a form that is readily accessible and easy-to-understand for the public
e. Provide access to information in a single, public platform that can be reviewed by healthcare professionals and companies prior to publication
f. Encourage active participation and learning in the transparency reporting process through educational workshops aimed at assisting all relevant parties to adapt to new requirements

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

Transparency reporting has grown exponentially in popularity globally, with the introduction of the Association of British Phamaceutical Inustry's (ABPI) Code of Practice for the UK, the European Federation of Pharmaceutical Industries and Associations' (EFPIA)Code of Practice and the continued reporting in the United States using the Sunshine Act. In Australia, the main development in transparency reporting is the requirement in the Medicines Australia Code of Conduct for member companies to report payments or transfers of value to healthcare professionals, for sponsorships, consultancies, and travel and accommodation costs. Company reporting of relevant information began in April 2016 and is required to be made public on each company's website. The Australian Competition and Consumer Commission (ACCC) has also asked the Medicines Australia to consider the development and implementation of a central database to store this information. These new requirements require a thorough understanding of a company's source systems, the accessibility of information for collection, legal documentation and contracts. Companies will therefore need to invest in additional resources and communicate regularly with healthcare professionals in order to ensure the accuracy of transparency reporting.

According to the 2015 PricewaterhouseCoopers's (PwC) Pharmaceutical Industry Survey, there has been a mixed response to the growth of transparency reporting using the new Medicines Australia Code of Conduct. Some industry professionals have expressed concern that the recent changes may inhibit collaboration between healthcare providers and the pharmaceutical industry, as healthcare providers may be hesitant to get involved if there is any chance they could be viewed as accepted funding from industry. This in turn could limit the vital transfer of education that takes place between healthcare providers and pharmaceutical companies. In spite of this, the general consensus is that the increase in transparency reporting will lead to an improvement in the pharmaceutical industry's reputation.

Pharmaceutical companies are not allowed to give or offer healthcare professionals any gifts in exchange for a recommendation, prescription and promise of dispersal or administration of a product. It is not acceptable to give healthcare professionals any gifts that do not directly relate to the practice of medicine or pharmacy.

Pharmaceutical companies must also adhere to the following guidelines:

- The maximum cost of a meal provided by a pharmaceutical company must not exceed $120, including beverages.
- Air travel for healthcare professionals attending a company educational meeting must be by economy class only. Travel may only be provided in direct association with the educational event(s), without allowing for more time at the destination than is reasonably justified to enable the healthcare professional to effectively participate in the educational meeting.
- Interactions between companies and healthcare professionals must not include entertainment.
- A company may provide company-branded pens and notepads to delegates attending a company educational event (9.4.9).
- Companies may legitimately seek the services of suitably qualified and experienced healthcare professionals to provide a service, advice and/or guidance on a range of matters. A legitimate need for the services must be clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants.

Medicines Australia's Code of Conduct has clear and thorough guidelines about pharma company's interactions with healthcare professionals. These regulations are enforced by Medicines Australia's Code of Conduct Committee, who is able to:

- Suspend or expel a member from the company; or
- Censure or impose a fine on a member.

Who receives concerns and complaints? How does this process operate?

In August 2012, Medicines Australia established a broad-based transparency working group to draft and develop measures and policies that will improve transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry. Informed by the Australian government's Transparency Principles, the working group developed a model which improves transparency regarding payments and transfers of value between companies and healthcare professionals. These Transparency Principles dictate that the relationship between healthcare professionals and patients should be based on trust and mutual respect. This trust and the quality of the relationship between a healthcare professional and patient can be threatened when the decision-making by healthcare professionals may be seen to have been compromised by interests other than those of the patient.

Transparency Principles aim to:

1. Promote trust and mutual respect between the community and HCPs
2. Reduce the risk that payments and other transfers of value from a company to HCPs undermine the independence of their decision-making
3. Allow consumers to make informed decisions on their health, and take into consideration their healthcare provider's relationship with companies
4. Report monetary transactions and transfers of value in a form that is readily accessible and easy to understand for the public

5. Provide access to information in a single, public platform that can be reviewed by healthcare professionals and companies prior to publication
6. Encourage active participation and learning in the transparency reporting process through educational workshops aimed at assisting all relevant parties to adapt to new requirements

Non-industry generated complaints may be submitted through the Medicines Australia website, https://medicinesaustralia.com.au/code-of-conduct/. Before filing a complaint, Medicines Australia encourages the individual/organisation to contact the company, as a 'satisfactory explanation or solution may be immediately available' (Appendix 2).

Industry-generated complaints should only be filed if, 'despite every effort on the part of both the complainant and the subject company, resolution of the matter has not been achievable' and the complaint will promote intercompany dialogue (Appendix 2).

Once a complaint is filed, the company must respond to the issues raised by the complaint within ten business days. A meeting between the company and complainant must also be scheduled within those ten days. Medicines Australia will serve as a mediator if the company desires. If a meeting is not organised within the ten days, senior executives from both companies must schedule a meeting within two business days.

Both parties have five business days to reach a consensus. The record of this meeting must be sent to Medicines Australia. If the subject company and complainant cannot reach a decision on their own, Medicines Australia will make a decision about the complaint, which will be provided to the subject and complainant within ten working days. Appeals to this decision must be submitted to the Appeals Committee as soon as possible. The Appeals Committee will provide a decision and reasons for the Appeals Committee's decision to both parties within ten business days.

What promotional or media materials must be pre-approved by authorities?

Any prescription medicine materials intended for healthcare professionals are not subject to pre-approval by the relevant authorities before they are used. However, advertisements for non-prescription medicines appearing on television or radio or in newspapers, consumer magazines, billboards or films require approval before publication.

If a company is found to be in breach of the Medicines Australia Code of Conduct for any materials once they are used, the Code Committee may issue corrective action to the company, including revised content and a letter to specifically correct the statement found in breach of the Code. This corrective letter must be provided to the Code Committee for pre-approval prior to publication.

What are the most recent significant developments in regulations? Are there planned changes to codes of conduct and regulations in the next few years?

Medicines Australia reviews the Code of Conduct every three years after seeking input from interested parties. The latest edition (Edition 18) was authorised by the ACCC on 24 April 2015 and came into effect on 16 May 2015. The most significant developments during the last review include:

1. Companies must have policies and procedures in place that will ensure that educational events for healthcare professionals comply with the Code.
2. Company websites must not directly link disease-specific education to the company's prescription products for a condition.
3. New requirements for reporting transfers of value to individual healthcare professionals have been passed.
4. Companies will provide healthcare professionals for whom they have collected information about payments and transfers of value the opportunity to review and submit corrections to the information.

Medicines Australia has collaborated with Princeton Publishing to create an iPad App of the Code of Conduct and the Guidelines. This App provides Code provisions and guidelines, in addition to annotation, bookmarking and sharing.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

Medicines Australia defines promotional activity and promotional materials as, 'any representation concerning the attributes of a product conveyed by any means whatsoever for the purpose of encouraging the usage of a product'.

Information is defined as, 'educational facts regarding the attributes of a product' whereas an educational material is defined as, 'any representation or literature which is intended to provide information about a medical condition or therapy which does not contain specific promotional claims'.

Promotional activity for prescription medicines directed at the general public would be in breach of the Code. However, educational materials are allowed. The content of all promotional and educational materials directed at healthcare professionals must be balanced, accurate and correct. It also must be validated by the product information (PI), literature data on file and appropriate industry source.

How is a media event defined?

The TGA and Medicines Australia do not specifically refer to a media event. However, there are references in the Code of Conduct to communication with healthcare professionals and the general public and their media. This includes the provision of educational or information-based materials or activities (directed at healthcare professionals and the general public media) and/or promotional activities (directed at healthcare professionals and their media only).

Companies are encouraged to seek the advice of the Medicines Australia chief executive or delegate prior to arranging press statements or media conferences directed at the general public (Section 12.4).

Do the regulations differentiate between consumer and clinical publications?

The Code of Conduct differentiates between communication with healthcare professional media and the general public/lay media.

Media releases directed at healthcare media must include product precaution information, adverse reactions, warnings, contraindications and interactions. Media articles directed at the general public must not refer to specific prescription products and should be solely informative and educational.

Do regulations differentiate between print and broadcast media?

The Code of Conduct refers to strict requirements regarding the various types of promotional materials directed at healthcare professionals and their media, including print media and audiovisual media materials. However, the regulations apply equally to print and broadcast media.

What is permitted in relation off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?

Promotional activities are not permitted for products or indications pending approval in Australia by the TGA. A company must formally receive TGA approval for the product or indication and its product information before proceeding with any promotional activities.

Product-specific media releases (educational, not promotional) should not be directed at the general public until the product has been registered in Australia and reasonable steps have been taken to inform the medical and pharmacy professions of its availability.

For international congresses or meetings held in Australia, starter packs of products (approved overseas but not in Australia) may be displayed but not distributed, and educational and promotional materials may be made available only if the majority of attendees originate from the country in which the product has been approved.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

The Medicines Australia Code of Conduct specifically covers media releases intended for healthcare professionals and their media. The general principles include:

- The purpose of the media release is to provide current, accurate and balanced information about products available in Australia.
- A media release may be issued to announce a new product, indication, dosing or formulation, to announce a new Pharmaceutical Benefits Scheme (PBS) listing (government subsidy programme) in response to a change to the safety profile of a product or to alert healthcare professionals to the results of significant new research (provided such research is consistent with the PI).
- The media release must include product precautions, adverse reactions, warnings, contraindications and interactions.

Media materials such as media releases intended for the general public must not promote a product, but rather provide current, accurate and balanced information about products available in Australia. Media releases intended for the general public media must include product precaution information, adverse reactions, warnings, contraindications and interactions. Companies listed on the Australian Stock Exchange (ASX) may issue a non-promotional, product-specific media release using the continuous disclosure requirements of the ASX. Such media releases must adhere to the principles of the Code of Best Practice for Reporting by Life Science Companies.

Companies may sponsor journalists to attend medical conferences, provided they are only writing for healthcare professionals (e.g., GP or pharmacy trade media). The sponsorship should not be conditional upon any obligation by the journalist to report on a company's product(s).

Is the method of distribution of such materials covered (with particular reference to the origin of the country where the publication is intended)?

All media materials intended for healthcare professionals and their media should not be readily accessible to the general public, including print, broadcast and web-based media materials.

Any media materials used or intended for Australia must comply with the relevant sections of the Medicines Australia Code of Conduct.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media? Do these regulations apply to both licenced and non-licenced products equally?

Companies or third parties may arrange press statements or media conferences, but they are encouraged to first seek advice from a Medicines Australia delegate (ideally, the chief executive).

Medicines Australia acknowledges media briefings as a legitimate and useful addition to the distribution of a media release (Code of Conduct Guidelines), provided they are educational with the intention of providing information to healthcare professionals and their media.

The company should not initiate statements or comments regarding products that are not approved for marketing in Australia during press statements or media conferences.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?

The sponsorship of a journalist by the company must not be conditional upon any obligation by the journalist to report on a company's product(s).

Do regulations cover the use of case studies or other third-party advocacy in the media?

There are no specific regulations covering the use of case studies. Third-party advocacy groups, such as health consumer organisations (HCOs), may receive an unrestricted grant for educational purposes from a pharmaceutical company provided the company does not seek to influence the text or content of HCO material in a manner favourable to its own commercial interests.

- Disease education activities in the media are permitted solely to provide information, promote awareness and educate the public about health, disease and their management. The following conditions apply to disease education activities in any media (Section 12.7).
- References to a specific prescription product must not be made. References to the availability of different treatment options are allowed, but they should not be used to encourage the general public to seek a prescription for a prescription-only product.
- The emphasis of the activity should be on the condition and its recognition and should cover the key characteristics of the disease.
- If discussed, management options should be presented in a comprehensive, balanced and fair manner that does not unduly emphasise particular options or the need to seek treatment.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

Medicines Australia's Code of Conduct refers to online media under the umbrella term internet, which includes websites, podcasts, e-newsletters and social media activities. The rules governing online media promotion and education are consistent with the print and broadcast guidelines in the Code of Conduct and are regulated and monitored in the same way.

In relation to the use of the internet or online media, Medicines Australia supports a company's right to provide accurate and scientifically reliable information on a product, intended for the healthcare professional only. Promotional online media activities or materials must be designed to prevent access by members of the general public.

What levels of web security are required?

Any online media materials that are promotional in nature must be designed to only allow access to healthcare professionals. A company-controlled website for healthcare professionals, for instance, should be secured with a password or other login requirement (e.g., provider number). The password should not be easily identifiable, such as the product name.

Do the regulations cover funding of, or provision of information to, non-company owned websites?

Companies may sponsor health consumer organisations via an unrestricted educational grant. The grant may be used to fund an educational activity or programme, including but not limited to a non-company-owned website. The company must not direct or influence the health consumer organisation, unless the company is seeking to correct any factual inaccuracies on the non-company-owned website or document.

The Code of Conduct states that when companies make a reference or linkage to non-company-owned website:

'The information a reader is about to be referred to may not comply with the Australian regulatory requirements. Further information relevant to the Australian environment is available from the company or via the Product Information' (Section 2.4.1).

What are the most popular social networks in your region?

The most popular social network in Asia Pacific and Australasia is Facebook. The most popular social networks in Australia are Facebook, YouTube, Wikipedia, Blogspot and Twitter.

The Medicines Australia Code of Conduct defines social media as various activities that integrate technology, social interaction and the creation of content. The Code cites popular social media platforms, such as Facebook, YouTube, MySpace, Twitter, blogs and wikis. The promotion of products via social networks must comply with the relevant sections of the Code relating to advertising to healthcare professionals as well as education and information to the general public.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

On Nov. 14, 2013, the Australian Self Medication Industry (ASMI) launched new industry social media guidelines to help guide non-prescription healthcare marketers to continue to engage with new audiences through social platforms in a code compliant, responsible and ethical manner.

The ASMI Social Media Guidelines highlight the evolution of the Australian consumer healthcare market and the heightened importance of ensuring responsible conduct is upheld in the social media era.

These guidelines include:

1. Any comment or post made by a user on an owned channel is the responsibility of the organisation. Any comment in breach of any requirement should be removed within a reasonable time. ASMI suggests that a reasonable time frame is 24 hours for large companies, and one week for small to medium enterprises (SMEs).
2. Commencing marketing in social media channels to establish moderation principles and the crisis management approach, should an issue escalate. Organisations should make their social media moderation approach publicly available. Any adverse event must be reported in accordance with the TGA's and the organisation's reporting requirements.

The promotion of products covered by the Code of Conduct to the general public via the internet, including social media would breach Section 13.3 of the Code and the Commonwealth Therapeutic Goods Legislation, which stipulates that prescription products must not be promoted to the public.

All use of social media by companies should comply with the following principles:

- Companies are responsible for all content on company-initiated and/or controlled social media sites and activities. Content which does not conform to community standards of ethics and good taste or which relates to unapproved products or indications should be promptly removed from the site.
- All companies should have policies and procedures which describe the roles and responsibility of its employees and contractors when interacting in the social media space to ensure compliance with the Code of Conduct. Any activity on a social media site by a company employee, or the employee of an agency acting on the company's behalf, must comply with the Code of Conduct.
- Suspected adverse drug reactions noted during monitoring of social media sites must be reported to TGA in accordance with the current TGA document, Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch.

Are there any self-imposed regulations from social media companies?

There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

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These guidelines highlight the evolution of the Australian consumer healthcare market and the heightened importance of ensuring responsible conduct is upheld in the social media era.

These guidelines include:

a. Any comment or post made by a user on an owned channel is the responsibility of the organisation. Any comment in breach of any requirement should be removed within a reasonable time of you becoming aware of it. ASMI suggests that a reasonable time frame is 24 hours for large companies, and one week for Small to Medium Enterprises (SMEs).
b. A risk assessment is recommended prior to commencing marketing in social media channels to establish moderation principles and the crisis management approach, should an issue escalate. Organisations should make their social media moderation approach publically available. Any adverse event must be reported in accordance with the TGA's and the organisation's reporting requirements.

All use of social media by companies should comply with the following principles:

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- All Companies should have policies and procedures which describe the roles and responsibilities of its employees and contractors when interacting in the social media space to ensure compliance with the Code of Conduct. Any activity on a social media site by a company employee, or the employee of an agency acting on the company's behalf, must comply with the Code of Conduct.
- Suspected adverse drug reactions noted during monitoring of social media sites must be reported to TGA in accordance with the current TGA document, Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch.

What is mobile adoption like in your region? Are there separate regulations for it?

In Australia, there are more than 1.16 mobile phones for every person. Promotional material directed at healthcare

professionals and educational/informative materials directed at the general public by mobile phones must adhere to the same guidelines for traditional print and broadcast media as specified in the Medicines Australia Code of Conduct. In addition, electronic messaging of promotional material directed at healthcare professionals (including mobile media platforms like iPhone and iPad applications) must comply with Sections 1 and 2 of the Code, and also comply with the Commonwealth Spam Act 2003 (the Act). Under the Act, no person is permitted to send spam, or unsolicited commercial electronic messages, via email, instant messaging, Short Message Service (SMS) or other phone messaging.

What are the disclosure laws like in your region for non-branded websites?

The Medicines Australia Code of Conduct states that all items of an educational nature (e.g., non-branded website), whether intended for the education of healthcare professionals or to be used by the healthcare professional in consultation with a patient, must be dedicated to improving the quality use of medicines and/or assisting a patient in his or her understanding of a condition or disease.

Company disease state websites should not focus on the company's product(s). In discussing prescription product options for the disease state, a company may list all of the available products, but it must not compare any products. A company-sponsored disease state website must not have links to websites with information on a company's product(s). The website should always contain a statement to the effect, 'For further information, talk to your doctor.'

What is the response level needed for adverse event reporting?

The TGA relies on healthcare professionals, the public and industry to identify and respond to safety matters associated with medicines or medical devices in Australia.

Manufacturers and sponsors of medicines and medical devices and their authorised representatives are required to report an adverse event (AE) to the TGA (section 41MP in the Therapeutic Goods Act 1989).

Third parties representing pharmaceutical companies, such as PR agencies, must report an adverse event matter to the pharmaceutical company within 24 hours of the matter being identified. Therefore, third parties must become familiar with the procedure for identifying and tracking adverse event matters when conducting patient-oriented programmes on behalf of the organisation's clientele.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

In August 2012, Medicines Australia established a broad-based transparency working group to draft and develop measures and policies that will improve transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry. Informed by the Principles for Transparency, the working group has developed a model which aims to improve transparency about payments and transfers of value between companies and healthcare professionals. The Principles for Transparency dictate that the relationship between healthcare professionals and patients should be based on trust and mutual respect. This trust and the quality of the relationship between a healthcare professional and a patient can be threatened when the decision-making by healthcare professionals may be seen to have been compromised by interests other than those of the patient.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel not allowed?

Transparency reporting has grown exponentially in popularity globally, with the introduction of the ABPI Code of Practice for the Pharmaceutical Industry in the UK, the EFPIA Code of Practice in Europe, and the continued reporting in the U.S. under the Sunshine Act. In Australia, the main development in the field of transparency reporting is the requirement under the Medicines Australia Code of Conduct for member companies to report payments or transfers of value to healthcare professionals, for sponsorships, consultancies, and travel and accommodation costs. Company reporting of relevant information commenced in April 2016 and is required to be made publically available on each company's website. The ACCC has also called Medicines Australia to consider the development and implementation of a central database to store this information. These new requirements require a thorough understanding of a company's source systems, the accessibility of information for collection, legal documentation and contracts. Companies will therefore need to invest in additional resources and to communicate regularly with healthcare professionals in order to ensure the accuracy of transparency reporting. According to the 2015 PwC pharmaceutical industry survey, there has been a mixed response to the growth of transparency reporting under the new Medicines Australia Code of Conduct. Some industry professionals have expressed concern that the recent changes may inhibit collaboration between healthcare providers and the pharmaceutical industry, as healthcare professionals may be hesitant to get involved if there is any chance they could be viewed as accepting funding from industry. Consequently, this could limit the vital transfer of education that takes place between healthcare professionals and pharmaceutical companies. In spite of this, the general consensus is that the increase in transparency reporting will lead to an improvement in the pharmaceutical industry's reputation.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Healthcare professionals or advocacy/patient groups are prohibited from being paid by the pharmaceutical company for their attendance at an Australian or international educational event. However, the Medicines Australia Code of Conduct states:

'Sponsorship may be provided to a healthcare professional to attend an educational event provided the meeting is directly related to the healthcare professional's area of expertise' (Section 9.7.1).

Sponsorship must be formally documented and may include flights within Australia (economy class only), flights outside of Australia (economy or business class only), a reasonable level of accommodation and any meals and beverages secondary to the educational content. A company may not sponsor entertainment nor the travel costs and expenses for family or travelling companions. Financial or material benefits should not be conditional upon any obligation by the healthcare professionals to recommend, prescribe, dispense or administer a company's prescription product(s).

Companies may only sponsor patients and HCO representatives to attend third-party scientific and medical conferences if the event is based on a specific therapeutic area of particular interest or relevance to that patient or HCO representative.

What is possible in terms of media or message training for health professionals or advocacy organisations?

Where companies undertake sponsorship of a healthcare professional or advocacy organisation, the sponsorship must be able to successfully withstand public and professional scrutiny, conform to community standards of ethics and good taste, and/or enhance the quality use of medicines.

Companies should also ensure that any sponsored experts are fully briefed on the provisions of the Code in the event they may have direct contact with the general public or lay media.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

Sections 13.2 and 13.3 of the Code state that a company must not seek to influence materials written on behalf of or by HCO in a manner favourable to the company's commercial interests. Company use of a HCO logo or proprietary material must have formal consent of the HCO.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

Advocacy groups are covered under the Relationship with Health Consumer Organisations (HCOs) section of the Code (Section 13), whereby companies may enter into relationships with HCOs with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community.

Companies and HCOs must remain mindful of the Medicines Australia Guidelines, entitled Working Together— A Guide to Relationships between Health Consumer Organisations and Pharmaceutical Companies, which involve the following components:

- Respect for independence
- Achieving and maintaining public trust
- Fairness
- Openness and transparency
- Accountability

In addition, no company may request to be the sole funder of an HCO or any of its major programmes, make public use of an HCO logo or proprietary material without prior consent, or seek to influence HCO written materials to serve its own commercial interests. The company must provide a list on its website of HCOs to which it provides financial support and/or significant direct/indirect non- financial support

KEY TAKEAWAYS/ SUMMARY

In Australia, therapeutic goods guidelines and requirements are adopted to ensure high public health standards, the safe use of therapeutic goods and the honest communication of its benefits, use and effects.

Direct-to-consumer advertising is allowed for the majority of medicines available for OTC sale, while advertising to the general public of prescription-only and certain pharmacist-only medicine is prohibited. Government-controlled public health campaigns that have been approved by health ministers are exempt from this prohibition.

The advertising of therapeutic goods to consumers and health practitioners is controlled by a combination of statutory measures administered by the TGA and self-regulation through the Codes of Practice administered by the relevant therapeutic goods industry associations.

CHINA

While the promotion of medicines is governed by a number of different laws, the review of drug advertisements is the responsibility of the drug regulatory departments within their administrative regions under the supervision of the China Food and Drug Administration (CFDA). Regulations for consumer and clinical publications as well as those for print, broadcast and online media are clearly defined and are separate. The social media landscape differs significantly from other countries with local social media platforms being popular in the absence of Facebook. These platforms are also subject to certain regulations.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

1. Advertisement Law of the People's Republic of China;
2. Drug Administration Law of the People's Republic of China
3. Regulations for Implementation of Drug Administration Law
4. Criteria for Examining and Publishing Drug Advertisement

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Public relations (PR) is the practice of managing the spread of information between an individual or an organisation and the public.

Who is responsible for the enforcement of these rules?

The drug regulatory departments of the provinces, autonomous regions or municipalities directly reporting to the Chinese Central Government are the drug advertisement examination authorities responsible for examining drug advertisements within their administrative regions. The administrative departments for industry and commerce at or above the county level are the supervisory authorities for drug advertisements.

The CFDA shall guide and supervise the examination conducted by drug advertisement examination authorities and punish, in accordance with law, the examination authorities that have violated the provisions.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

According to the Drug Administration Law of the People's Republic of China:

Article 59
Drug manufacturers, drug distributors or their agents are prohibited from offering money, things of value or other benefits to leading members, drug purchasers, physicians or other related persons of the medical institutions where their drugs are used.

Article 61
No unscientific, categorical assertion or warranty of described function may be contained in drug advertisements; no names or images of government departments, medical or pharmaceutical research institutions, academic institutions, or experts, scholars, physicians and patients may be used as evidence for drug advertising.

Article 91
Leading members, drug purchasers, physicians or other related persons of medical institutions who accept money, things of value or other benefits offered by drug manufacturers, drug distributors or their agents will be sanctioned by the administrative department for health or the institutions to which they belong, and the illegal gains shall be confiscated. With regard to licenced physicians who seriously violate laws, the administrative department for health shall revoke their licences for medical practice. If it is determined a crime has been committed, criminal liabilities will be determined in accordance with law.

Who receives concerns and complaints? How does this process operate?

If any illegal advertisement that exaggerates the ability of the drug without authorisation, or misleads customers, the drug regulatory department at or above the provincial level shall take mandatory administrative measures to suspend the sales of the drug within their administrative area and order the company that published the drug advertisement to issue a correction notice in appropriate local media.

What promotional or media materials must be approved by authorities?

When a drug manufacturer or distributor applies for a

drug advertisement approval number, they must submit an Application Form for Drug Advertisement with a sample manuscript (sample film or sample record) and a drug advertisement application.

What are the most recent significant developments? Are there planned changes to codes of conduct and regulations in the next few years?

In order to encourage drug innovation, standardise evaluation and approval, improve drug quality, promote industrial upgrading and reform current chemical drug registration classification, CFDA developed a reform plan for chemical drug registration classification. CFDA issued an announcement on 4 March 2016 that released the reform plan for chemical drug registration classification, effective immediately.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

A drug promotional activity refers to any advertisement published through various media or forms containing drug name, indications (functions) or other relevant content.

How is a media event defined?

Instead of paying for advertising time, a media event seeks to use PR to gain media and public attention. Media events may center on a news announcement, a corporate anniversary, a press conference in response to a major media event or planned events like speeches or demonstrations.

Do the regulations differentiate between consumer and clinical publications?

Yes. As per the Drug Administration Law of the People's Republic of China, Article 60, prescription drugs may be introduced in the medical or pharmaceutical professional publications jointly designated by the administrative department for health and the drug regulatory department under the State Council. However, their advertisements may not be released by mass media or distributed to the general public by other means.

Do regulations differ between print and broadcast media?

The same conditions apply. As per the Advertising Law of the People's Republic of China, Article 15, no advertisement may be made concerning narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs or other specific drugs, pharmaceutical precursor chemicals, as well as drug addiction treatment medicines, medical devices and treatment methods.

For other prescription medicines, advertisements can be made only on the medical or pharmaceutical journals as designated by the public health administrative authority and the drug administration under the State Council.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?
The general rules and guidelines apply.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
Per the Drug Administration Law of the People's Republic of China, Article 61, the content of drug advertisements shall be truthful and lawful, and must fill in the exact sheet approved by the drug regulatory department under the State Council must be used for the content.

No unscientific, categorical assertion or warranty may be contained in drug advertisements; no names or images of government departments, medical or pharmaceutical research institutions, academic institutions, or experts, scholars, physicians and patients may be used as evidence for drug advertising.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
Drug advertisements shall be subject to approval by the drug regulatory department of the government of the province, autonomous region or municipality directly under the Chinese Central Government where the enterprise is located. An approval number of drug advertisement shall be issued by the drug regulatory department. No one may launch advertisements without the approval number.

Prescription drugs may be introduced in the medical or pharmaceutical professional publications jointly designated by the administrative department for health and the drug regulatory department under the State Council. However, their advertisements may not be released by mass media or distributed to the general public by other means.

An application for an import drug advertisement approval number shall be submitted to the drug advertisement examination authority in the place where the agent of the import drug is located.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
No specific rules exist.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
No specific rules exist.

Do regulations cover the use of case studies or other third-party advocacy in the media?
The Advertising Law of the People's Republic of China,

Article 16, states that any advertisement for medical treatment, pharmaceuticals or medical devices shall NOT contain the following items:

1. Any assertion or guarantee for efficacy and safety
2. Any statement on cure rate or effective rate
3. Comparison with the efficacy and safety of other pharmaceuticals or medical devices or with other medical institutions
4. Use of the advertisement to make endorsements or testimonials
5. Other items as prohibited by laws and administrative regulations. Contents of advertisements for pharmaceuticals must be consistent with those indicated on the instructions approved by the drug administration under the State Council, and contraindications and adverse reactions shall be clearly marked. Any advertisement for prescription medicines shall indicate the words, 'the advertisement is intended for medical and pharmaceutical professionals only' clearly, and any advertisement for non-prescription drugs shall indicate the words, 'please follow the instructions or purchase and use the medicine according to a pharmacist's suggestions' clearly.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

The Regulation on Internet Information Service of the People's Republic of China is formulated to regulate internet information services.

Article 5: Anyone who intends to provide internet information service related to news, publication, education, medical and healthcare, pharmaceuticals and medical equipment etc., before applying for licences for filing for record, must obtain approval from appropriate industry authorities as required by relevant laws and administrative regulations.

(Compared with print media and broadcast, online media are more instant, flexible, interactive, and have extremely high amount of information.)

The Communist Party of China's position on a responsible media, tight censorship of the internet and non-harmful contents is as follows:

1. All content must comply with legislative rules
2. It provides a technical regulation system focused on blocking and filtering information
3. It is a self-regulating system based on hotline prosecution, and advocates the internet ethic and morality to internet users

What levels of web security are required?

On 23 July 2015, the China Internet Security Forum was held at the 2015 China Internet Conference. The Ministry of Industry and Information Technology (MIIT) gave four suggestions on network security:

1. Strengthen the network infrastructure security protection and build a sound foundation for the development of the internet.
2. Attach significant importance to data security and protection of users' personal information and build a safe and reliable network environment.
3. Cultivate network security technology innovation and improve the capacity of network security technology.
4. Actively promote information-sharing and address network threats.

Do the regulations cover funding of, or provision of information to, non-company owned websites?

The general rules and guidelines apply.

What are the most popular social networks in your region?

Due to strict government regulation, oversight and censorship of media in China, the social media environment looks very different than the rest of the world.

WeChat is the most popular social network with 900 million daily users. Operated by titanic Chinese tech conglomerate Tencent, its closest international comparison would be a WhatsApp/Facebook hybrid platform. It is followed in popularity by Weibo (i.e., Sina Weibo), a microblogging platform similar to Twitter, with 340 million active users.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

No specific rules exist for social media.

Are there any self-imposed regulations from social media companies?

Yes. Weibo's regulations can be found in the User Contract. The Sina Weibo Community Management Center is in charge of overseeing and implementing the rules. The committee consists of Weibo users, as well as expert members. Current laws and regulations as well as this contract, establish the Sina Weibo Community Agreement as the authority to determine the factual accuracy of any questionable posts .

For digital platforms,like forums, does your regulatory body have specific rules for customer/company interactions?

No specific rules exist.

What is mobile adoption like in your region? Are there separate regulations for it?

There were 1.3 billion mobile mobile phone subscribers in China in July 2016, or 94.1percent of China's population, and 211 million (16-20 percent) of which were 3G users; 646.3 million (49.5 percent) were 4G users; and 1.049 billion (80 percent) were mobile

internet-access users, according to statistics published by China's MIIT.

As of 2017, 51.7% of Chinese citizens had access to a smartphone.

What are the disclosure laws like in your region for non-branded websites?

Regulation on Internet Information Service of the People's Republic of China:

Article 8

A non-profitable internet information service provider shall file its activities with telecommunications administrative authorities of the provinces, autonomous regions and cities under the direct control of the Central Government or the Ministry of Information Technology (MIT). The following documents shall be submitted:

1. Basic information of the service provider and the person-in-charge
2. The website address and services provided.

Article 12

Internet information service providers shall post their Operating Permit numbers or record-filing numbers in a prominent place on the home page of their website.

Article 13

Internet information service providers shall provide good service to online subscribers and ensure that the information provided is lawful.

What is the response level needed for adverse event reporting?

According to the Provisions for Adverse Drug Reaction Reporting and Monitoring of the Ministry of Health, the CFDA shall be in charge of implementation of adverse drug reaction reporting and monitoring across the nation. Local drug regulatory departments shall be in charge of implementation of adverse drug reaction reporting and monitoring within their respective jurisdiction.

When drug manufacturers, drug distributors and medical institutions become aware of any suspected adverse drug reaction, they shall report through the adverse drug reaction monitoring information network. If online reporting is not available, a hardcopy report shall be submitted to the local adverse drug reaction monitoring body instead, and the local adverse drug reaction monitoring body shall make online reporting accordingly. The reported information shall be true, complete and accurate. Drug manufacturers, drug distributors and medical institutions shall support the investigation on adverse drug or cluster adverse drug events conducted by drug regulatory authorities, health administrative departments and adverse drug reaction monitoring bodies, and shall provide necessary materials to facilitate the investigation as well as set up and maintain an adverse drug reaction reporting and monitoring file.

China encourages all citizens, legal persons and other organisations to report adverse drug reaction.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

There are no specific regulations about hospitality to advocacy/patient groups.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel not allowed?

There is no specific regulation on the honoraria. Generally speaking, healthcare professionals, advocacy organisations or other third parties can get honoraria for their participation in media activities and events.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Yes, health professionals or advocacy/patient groups can get payment for attending a scientific meeting.

What is possible in terms of media or message training for health professionals or advocacy organisations?
There are no limitations regarding participation in media training programmes.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?
Please see previous answer regarding third party matierals.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
Please see previous answer regarding meeting with advocacy groups.

KEY TAKEAWAYS/ SUMMARY

- Prescription drugs may be introduced in the medical or pharmaceutical professional publications jointly designated by the administrative department for health and the drug regulatory department under the State Council. However, their advertisements may not be released by mass media or disseminated to the general public by other means.
- Drug advertisements shall be subject to approval by the drug regulatory department of the government of the province, autonomous region or municipality directly under China Central Government where the enterprise is located.
- According to the Provisions for Adverse Drug Reaction Reporting and Monitoring of the Ministry of Health, the CFDA shall be in charge of implementation of adverse drug reaction reporting and monitoring.

HONG KONG

In Hong Kong, the promotion of medicine is mainly regulated by the Undesirable Medical Advertisements Ordinance (Cap. 231) (UMAO) and controlled by the Code of Practice written by the Hong Kong Association of the Pharmaceutical Industry (HKAPI). All promotional materials for medicine that fall under the definition of 'advertisement' under the UMAO must comply with its prohibitions and exemptions. Broadcasted (via television and radio) medical preparation advertisements are further regulated by the Broadcasting Ordinance (Cap.562) (BO), Telecommunications Ordinance (Cap. 106) (TO), Broadcasting (Miscellaneous Provisions) Ordinance (Cap. 391) and Communications Authority's (CA's) code of practices.

To protect consumers' interests, all advertisements must also comply with the Trade Descriptions Ordinance (Cap.362) (TDO). The information in an advertisement must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment, mislead with respect to a product's efficacy and safety or exaggerate a product's claims.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

UMAO

The UMAO aims to protect the public by prohibiting or restricting advertisements for medicines, surgical appliances or treatment that may compel consumers to seek improper care for certain health conditions. The restrictions apply to 14 major diseases and conditions (such as cancers, venereal diseases and diseases of the heart or cardiovascular system), as well as other restricted conditions and claims, some of which also apply to orally consumed, non-drug products. However, medicine for minor ailments (such as common colds, coughs, influenzas, rhinitis, indigestions, headaches and dry skin) can be advertised to the public.

TDO

The TDO controls advertisements' content to ensure truthfulness and to keep consumers from being misled. It prohibits specified unfair trade practices that traders use against consumers, including false trade descriptions of services, misleading omissions, aggressive commercial practices, bait advertising, bait-and-switch practices and wrongly accepting payment. The 'fair trading' portions of the TDO are sections 4, 5, 7, 7A, 13E, 13F, 13G, 13H and 13I, which specify the relevant criminal offences.

TO, BO and Their Codes of Practice

These two ordinances regulate licencees for advertising on broadcast media (i.e., television and radio). Additionally, two codes of practice set advertising standards for advertisements' and programme sponsorships' presentation and content. Advertising should be legal, clean, honest and truthful. All sponsor involvement must be declared as such so the viewer/listener knows who is funding a programme. Typically, a licencee should ensure that all medical advertisements conform without limitations to the UMAO. The codes further restrict medical preparation advertising related to the drugs mentioned under Part 1 of the Poisons List Regulations (Cap. 138B) and Schedule 1 of the Antibiotics Regulation (Cap. 137A).

Public Health and Municipal Services Ordinance (Cap. 132)

Section 61 prohibits false labelling and advertisement of food and drugs.

HKAPI Code of Practice (18th Edition, 2017)

The HKAPI publishes a Code of Practice (CoP). This CoP and its supplementary guidelines were formed in accordance with internationally defined standards of good practice for the pharmaceutical industry. It is intended to serve as a basis for the HKAPI's member companies to make ethical decisions in their conduct of professional work and for judging formal complaints with respect to professional ethical standards.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

'Public relations' and 'promotional activities' are not separately defined, but 'advertisement' is. The UMAO defines advertisement as any notice, poster, circular, label, wrapper or document, as well as any announcement made orally or by any means that produces or transmits light or sound. Advertisements can generally be categorized into two categories: published advertisements and verbal promotions:

1. Published advertisements appear in print, in broadcast, online or on a product label (e.g., advertisements published in newspapers and magazines, on leaflets, on signboards, on the radio, on television, on websites and on the labels of a product's container or package).
2. Verbal promotions include health talks and verbal promotion by salespeople.

Although the HKAPI is not a regulator, its CoP defines 'promotion' as informational and marketing activities, including audio and visual material, that a pharmaceutical company or its authority undertakes to ensure proper and rational use, supply or administration of its pharmaceutical products. Marketing activities are further explained as the activities of representatives and all other

forms of sales promotion, such as journal and direct mail advertising; participation in exhibitions; the use of audio cassettes, films, records, tapes and video recordings; the use of internet and digital media; viewing data systems and data storage devices, such as memory discs accessed and reproduced on television; visual display units and the like; and the provision of samples, gifts and hospitality.

Who is responsible for the enforcement of these rules?

UMAO

The Department of Health Drug Office is responsible for enforcing the UMAO.

TDO

The Customs and Excise Department (CED) is the principal agency responsible for enforcing the TDO. The CA has concurrent jurisdiction to enforce the TDO's fair-trading sections in relation to the commercial practices of the CA's licencees. To ensure that every case is handled by the appropriate enforcement agency, the CED and CA coordinate their efforts through a memorandum of understanding.

TO, BO and Their CoP

The CA is the enforcement agency that handles breaches of the CoP for television and radio licencees.

HKAPI's CoP

The HKAPI is responsible for addressing complaints that its members and the public make about its members breaching its CoP.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

The current regulations do not govern interactions between healthcare providers and pharmaceutical companies. However, companies are usually bound by their internal policies and the HKAPI's code of conduct. In general, healthcare providers can be separated into two categories: healthcare professionals and healthcare organisations.

The HKAPI's CoP specifies that member companies' relationships with healthcare providers are intended to benefit patients and to enhance the practice of medicine, therefore the interactions should focus on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education. Financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice-related items) provided or offered to a healthcare provider should not be in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue the above. Healthcare providers may not receive anything in a manner or on conditions that would have an inappropriate influence on their prescribing practices.

Who receives concerns and complaints? How does this process operate?

The Department of Health Drug Office receives complaints through its hotline and by email. When determining whether an advertisement contravenes the UMAO, the advertisement's full content is considered. This includes its wording, the name of the product, its pictures, any graphs, any symbols or other means and the concept and/or message being advertised. The usual process starts with an investigation of a filed complaint. If the respondent is found to have violated the UMAO, it will send a warning letter to both the publisher and pharmaceutical company in question. Then, if the respondent further breaches the regulation and is found guilty of an offence, it will be liable (upon first conviction) to a fine at Level 5 (50,000 HKD) and imprisonment for six months. Upon a second or subsequent conviction for an offence under the same section, the respondent will be fined at a higher level (Level 6, 100,000 HKD) and imprisoned for one year.

The commissioners of the CED and CA are responsible for handling complaints regarding those who do not comply with the TDO (based on enforcement guidelines, a case will be referred to one of these departments). Similarly, the CA handles complaints

about advertisements that are suspected to breach the TO and BO. The procedure for filing a complaint against a broadcast is listed on the CA's website. If there is prima facie evidence of a breach, the complaint may be referred to the Broadcast Complaints Committee for consideration and recommendation to the CA. The CA may impose appropriate sanctions according to the seriousness of the case, including advice, warning, correction and/or apology, financial penalty or suspension of licences. In some instances in which the breaches are minor, the director general of communications, acting under the CA's delegated authority, may be brought in to handle the case in a suitable manner.

The HKAPI responds to complaints when its members, as well as the general public, have possibly violated its CoP.

Member companies:

- are encouraged to seek resolution amicably, for example, through direct communications between a respective member company's country/general manager and mediation by the HKAPI and
- may file a complaint to the Code of Practice Committee (CPC) at any point during a dispute, regardless of whether the parties have attempted to resolve the dispute amicably or not.

Members of the public:

- are defined as any member of the public – healthcare professionals and companies – acting in good faith within the spirit and intention of the code and
- should make complaints in writing to the correspondence address of the HKAPI.

The CPC will make a decision within 30 days of receiving all necessary information and supporting documentation, including the complaint and the respondent's answer. The CPC will send its decision, along with an explanation, to the parties through registered mail.

What promotional or media materials must be pre-approved by authorities?

The Department of Health does not have a pre-approval system and does not provide comments on individual examples or cases.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

The Legislative Council enacted the UMAO's amendments in 2005. The amendments to Schedules 1 and 2 have been in place since 2006, and the remaining provisions took effect 1 June 2012.

The Legislative Council passed the TDO's amendment on 17 July 2012, and it took effect on 19 July 2013. The Amendment Ordinance extends the TDO's coverage to prohibit specific unfair trade practices that traders use against consumers, including false trade descriptions of services, misleading omissions, aggressive commercial practices, bait advertising, bait-and-switch tactics and wrongly accepting payment.

What is defined as promotional activity as opposed to the provision of information?

According to the CA's Generic Code of Practice for Television and Radio, 'advertisement' and 'advertising material' are referred to as materials broadcasted in a television or radio programme service that is designed to:

1. advance the sale of a product or service or
2. promote the interests of any organisation, commercial concern or individual.

This includes messages delivered through words, sound effects (including music), visual presentation, direct announcements, slogans, descriptions or otherwise, as well as promotional reference in a programme to any products or services.

However, there are no specific definitions for how promotional activities differ from the provision of information.

How is a media event defined?

This term is not specifically defined.

Do the regulations differentiate between consumer and clinical publications?

Under the UMAO, if an advertisement breaches Sections 3, 3b and 4, then a defence is permissible to prove that proceeding is in a publication of technical character that is intended for healthcare professionals.

In all other circumstances, the law does not further differentiate between consumer and clinical publications. Companies can assume that all advertisements are consumer-oriented because the UMAO, TDO, TO and BO aim to protect the interests of public health and consumers.

Do regulations differentiate between print and broadcast media?

Within the UMAO's definition of 'advertisement' for medicines, surgical appliances or treatments, it includes any notice, poster, circular, label, wrapper or document, as well as any oral announcement or announcement made by producing or transmitting light or sound. Therefore, the UMAO is an overarching regulation for all advertisements covering all types of media.

Furthermore, advertising on broadcast media (television and radio) is further regulated by the CA's CoPs along with the TO (Cap. 106) and BO (Cap. 562). The codes set restrictions for the content in advertisements. In terms of advertisements for medical preparations and treatment, Part 1 of the Schedule to the Poisons List Regulations (Cap. 138B) and Schedule 1 to the Antibiotics Regulations (Cap. 137A) are not acceptable. The HKAPI does not differentiate between print and broadcast materials. According to paragraph 4.1 of the

HKAPI's CoP, all materials (including journal advertising and internet posting) that manufacturers issue (or are issued with their authority) for promotional purposes should include all items A–F under that paragraph.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

There are no regulations that prohibit off-licence or pre-launch media activities in Hong Kong.

However, for claims of unregistered orally consumed products, under Schedule 4 of the UMAO, the advertisement must include the following language:

This product is not registered under the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance. Any claim made for it has not been subject to evaluation for such registration. This product is not intended to diagnose, treat or prevent any disease.

According to the HKAPI's CoP, paragraph 3.9, pharmaceutical products may not be promoted for use in a city until it has received the requisite approval for marketing them. The provision is not intended to abridge or restrict the rights of the scientific community and the public concerning scientific and medical progress. Activities include appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

There are no specific regulations governing press releases or media materials, nor are there for media attending clinical events.

Paragraph 12.2 of the HKAPI's CoP states that any materials made available to the general public either directly or indirectly must be factual and presented in a balanced way. The materials must not raise unfounded hopes of successful treatment or be misleading about a product's efficacy and safety.

Paragraph 1.3 states that promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties. This also corroborates with the CA's CoP for advertising on television and radio for medical preparations and treatments.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

No reference covers the distribution of press releases and media materials.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

No specific regulations govern activities related to press releases, media materials and media attending clinical events.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
If a journalist is sponsored to attend a scientific meeting, the resulting copy must be independent. If a report goes through the sponsoring company's regulatory procedure, it may breach Article 27 of the Basic Law, which is the freedom of speech and of press and publication. Journalists who belong to the Hong Kong Journalists Association (HKJA) should also comply with its Code of Ethics, which states:

> (2) A journalist shall at all times defend the principle of the freedom of the press and other media in relation to the collection of information and the expression of comment and criticism. He/she shall strive to eliminate distortion, news suppression and censorship.
> (3) A journalist shall strive to ensure that the information he/she disseminates is fair and accurate , avoid the expression of comment and conjecture as established fact and falsification by distortion, selection or misrepresentation.
> (8) A journalist shall not accept bribes or shall he/she allow other inducements to influence the performance of his/her professional duties.
> (9) A journalist shall not lend himself/herself to the distortion or suppression of the truth because of advertising or other considerations.

Furthermore, if a journalist is not a member of the HKJA and not employed by a media outlet, then his or her practice is governed by the company's ethical code and possibly the terms of the sponsorship or policies among the journalist, media agency and sponsoring pharmaceutical company.

Do regulations cover the use of case studies or other third-party advocacy in the media?
No.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
Online media are currently not regulated under the CA. Unless the online media are owned by one of the licencees under the CA, they might be able to regulate if a complaint arises. In general, the CA regulates telecommunications and broadcast media only.

What levels of web security are required?
No legal web security level is required.

Do the regulations cover funding of, or provision of information to non-company owned websites?
No regulations govern the provision of information on websites.

What are the most popular social networks in your region?
Based on statistics from the third quarter of 2017, 78% of the population is active on social media. The most popular social platform is Facebook, with a 75% penetration rate.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Although no regulations govern promotional activities on social media, any 'advertisement' on any type of media may not breach the UMAO's rules.

More detailed guidelines can be found in the HKAPI's CoP. According to it, in paragraph 4.1, all materials (including journal advertising and internet posting) that manufacturers issue (or are issued with their authority) for promotional purposes should include all items A–F under that paragraph.

Paragraph 4.7 states that the same requirements applied to print materials (paragraph 4.1) apply to electronic promotional materials. Specifically, in the case of pharmaceutical products' websites:

> (a) the identity of the pharmaceutical company and of the intended audience should be readily apparent;
> (b) the content should be appropriate for the intended audience; and
> (c) the presentation (content, links, etc.) should be appropriate and apparent to the intended audience.

Information about pharmaceutical products that is made available to the general public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading about a product's efficacy and safety.

Are there any self-imposed regulations from social media companies?
The Association of Accredited Advertising Agencies of Hong Kong has written regulations to ensure a minimum standard across its members. The association is a self-disciplining body, and it will penalise members who have failed to comply with the regulations.

The general principle is that advertising must be legal, decent, honest and truthful (similar to the UMAO, TDO and HKAPI CoP). In addition, the regulations state that advertisements must be clearly identified as such to avoid confusion with editorials.

Section (H) stipulates standards for scientific and medical terms:

> (i) All quotations from laboratory data statistics and containing scientific terms shall be taken from competent sources. Excerpts of data which distort or fail to disclose the true test results shall not be

used in support of claims. Pseudo-scientific terms shall not be used in advertisements to make claims appear to have a scientific basis they do not possess.
(ii) Testimonials by medical doctors, dentists, paramedical personnel including nurses, pharmacologists, physiotherapists, radiographers, and medical and dental technologists should not be used. Nor should any suggestion be made that a product or method of treatment is recommended generally by doctors, or approved by a particular hospital, unless the advertisement is intended only for publication in a bona fide medical journal.
(iii) Special care should be taken where medical preparations, alleged cures and treatments are involved. Members are recommended to read the following for further clarification:

- Pharmacy and Poisons Ordinance (Cap. 138)
- Undesirable Medical Advertisement Ordinance (Cap. 231)
- Medical Registration Ordinance (Cap. 161)
- Antibiotics Ordinance (Cap. 137)
- Dangerous Drugs Ordinance (Cap. 134)

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

No.

What is mobile adoption like in your region? Are there separate regulations for it?

Government statistics show that smartphones have become increasingly popular over the past few years. In 2016, nearly 5.5 million people ages 10 and older had a smartphone, and the penetration rate was 85.8%. Furthermore, the rates in 2016 for people ages 15–54 having a smartphone were between 95.9% and 99.3%. About two in five people 65 years old or older had a smartphone in 2016.

What are the disclosure laws like in your region for non-branded websites?

There are no laws that regulate the disclosure to non-branded websites.

What is the response level needed for adverse event reporting?

All serious adverse drug reactions occurring in Hong Kong must be reported to the Department of Health Drug Office as soon as possible, and no later than 15 days after such information is known. Follow-up reports must also be submitted. Additional reporting may be specified on the Certificate of Drug/Product Registration 19.

'Serious adverse drug reaction' is defined as any untoward medical occurrence that at any dose:

- The distinction between PR and advertising in cases results in death;
- is life-threatening;
- requires inpatient hospitalization or results that prolong existing hospitalization;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

No regulations restrict hospitality to advocacy and patient groups.

Under the HKAPI's CoP, Section 13, paragraphs 13.1 to 13.4 set out guidelines of interaction with a patient organisation and its member companies. In general, a patient organisation's independence must be respected, and under no circumstances may the company request to be the sole funder of a programme or the patient organisation. Companies may provide financial support or benefit-in-kind contributions to patient organisations with clear documentation that sets out the nature of the support, including the purpose of any activity and its funding.

This is because the motive behind financially supporting a patient organisation is primarily professional, educational, scientific in nature or otherwise supportive of the patient organisation's mission. When companies can also hold meetings for patient organisations, the companies must ensure that the venue and location are appropriate and conducive to informational communication. In addition, any meals or refreshments that a company provides must be modest (as judged by local standards).

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

The HKAPI provides a guideline for its member companies to follow when interacting with healthcare professionals and patient organisations. According to the HKAPI's CoP, Section 5.5 (Fees for Services), healthcare professionals may engage as consultants and advisers for services such as speaking at and/or chairing meetings and events; being involved in medical/scientific studies, clinical trials or training services; participating in advisory board meetings; and participating in market research when the participation involves remuneration. Given that the compensation for these services includes their fair market value according to where a healthcare professional practices, reasonable reimbursement for out-of-pocket expenses (including travel and accommodations) by the locality's standards is allowed.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

The Prevention of Bribery Ordinance (Cap. 201) (PBO) forbids the unlawful offering, soliciting or accepting of an 'advantage' (which includes gifts under its legal definition) to or by:

(a) a government employee/official or public servant or
(b) any person acting as an agent of another person (which would cover doctors in private hospitals).

Therefore, healthcare professionals in both the public and private sectors are covered by the PBO. Usually, prior consent by a recipient's employer or affiliated organisation would make this lawful.

The HKAPI's CoP allows its member companies to sponsor healthcare professionals to attend events (symposiums; congresses; or other promotional, medical/healthcare or educational programmes) if the sponsorship complies with the requirements set out in paragraph 5.3 of the HKAPI's CoP. The sponsorship is limited to payment for travel, meals, accommodations and registration fees. This activity is permitted because such events are not for entertainment purposes (e.g., theatre, concerts, etc.) and the hospitality provided is reasonably related to the event by the city's standard. All sponsorship has to comply with the travel, venue and accommodations guidelines set out in paragraph 5.2.

What is possible in terms of media or message training for health professionals or advocacy organisations?

Guidelines for such training are not covered.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

If materials fall under the UMAO's definition of an advertisement, they should comply with the UMAO. In addition, if the materials will be broadcast on television or radio, further restrictions must be followed according to codes issued by the CA.

The HKAPI CoP paragraph 12.2 states that any material made available to the general public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to a product's efficacy and safety. Paragraph 1.3 states that promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

There are no regulations covering this. Companies should ensure that this form of communication does not breach the schedules set out under the UMAO and in general comply to the HKAPI's CoP for the provision of information.

KEY TAKEAWAYS/ SUMMARY

- The main regulation that controls how pharmaceutical products are advertised is the UMAO, which is enforced by the Department of Health Drug Office.
- Companies should be mindful of breaching the TDO, which is enforced by the CED, as well as the CoP for television and radio, which is issued by the CA for the licencees under the respective ordinances.
- All offences found to breach the above regulations are criminal matters that could lead to sanctions and imprisonment, depending on the severity of the offence.
- In general, no regulation specifically governs the media, apart from broadcasting (television and radio), which is overseen by the CA.
- Article 27 of the Basic Law stipulates that 'Hong Kong residents shall have freedom of speech, of the press and of publication…'
- The main code that provides detailed guidelines for practicing pharmaceutical marketing is published by the HKAPI. This code acts as a self-regulating guideline for its member companies to follow when engaging in promotional activities.

INDIA

The promotion of medicines in India is controlled by the Drugs and Cosmetics Act, The Drugs and Magic Remedies Act and Rules and the newly formed Code of Marketing Practice. Direct-to-consumer promotion of prescription-only medicines is not permitted. Major emphasis is on responsible behavior, and compliance with regulations and codes.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

In India, the import, manufacture, distribution and sale of drugs and cosmetics are regulated by the Drugs and Cosmetics Act of 1940 (DCA) and the Drugs and Cosmetics Rules of 1945 (DCR)1.

Advertising and promotion for a certain category of drugs is controlled by the Drugs and Magic Remedies (Objectionable Advertisements) Act of 1954 and Rules of 1955. These aim to prevent people from medication due to misleading or exaggerated advertisements. There are 54 ailments covered under this action, including fever.

Over-the-counter (OTC) and direct-to-consumer (DTC) have no legal recognition in India, consequently regulations apply to all drugs that are not included in the list of prescription-only drugs.

Drugs in the system of traditional medicine, such as Ayurveda, Siddha, Unani and Homeopathy, are also controlled by the DCA of 1940 and the DCR (1).

Very recently, the Department of Pharmaceuticals formulated a voluntary Code of Marketing Practice for the Indian Pharmaceutical Industry. The code states that all promotional material issued by a product authorisation holder must be consistent with the requirements of this Code.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Public relations is not separately defined, and there are no special rules for public relations activities.

Under the Drugs and Magic Remedies Act, advertisement includes any notice, mailing, label, wrapper or other document and any announcement made orally or by any other means.

The recent Code of Marketing Practice states that, 'where a pharmaceutical company pays for or otherwise secures the publication of promotional material in journals, such promotional material must not resemble editorial matter'.

Who is responsible for the enforcement of these rules?

The State Food and Drug Administration (FDA) is responsible for enforcing the DCA and the Drugs and Magic Remedies Act. If a complaint is received, the rules are strictly implemented. The Code of Marketing Practice was only recently released so it remains to be seen how strictly it will be implemented.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

According to the Uniform Code of Pharmaceuticals Marketing Practices (UCPMP), pharmaceutical companies are not allowed to extend, 'any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vouchers, etc.' to healthcare providers (clause 7.1). They are also not allowed to extend any hospitality accommodations or cash/ monetary grants, 'in an individual capacity under any pretext,' (clause 7.1, 7.2).

These regulations are enforced by the Ethics Committee for Pharmaceutical Marketing Practices (ECPMP).

Who receives concerns and complaints? How does this process operate?

The ECPMP receives concerns and complaints. It is comprised of three members. In the event of a complaint, a review committee of five members will convene and make a decision, which will be provided to the complainant and respondent company in writing. 'If there is no request of review within the stipulated period (clause 13.4), the decisions of the ECPMP shall be final and binding and adherence to the decision shall be a condition of continued membership of the Association. The decisions shall be uploaded on the website of the Association' (clause 11.12).

What promotional or media materials must be approved by authorities?

No preapproval is needed, but the material is expected to be consistent with the requirements of the Code and laws.

What are the most recent significant developments? Are there planned changes to codes of conduct and regulations in the next few years?

The most significant development is the introduction of the voluntary Code of Marketing Practices for Indian pharmaceutical industry in June 2011. After a six-month review, if it is found that the Code has not been implemented effectively by the pharmaceutical associations/companies, the government will consider making it a statutory code. The Code cites that the promotion of prescription medicines to medical professionals must be consistent with its requirements.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

While there is no clear differentiation under the Drugs and Magic Remedies Act, an advertisement includes any notice, circular, label or wrapper and any announcement made orally or by any means.

The Code of Marketing Practice, cites information about medicinal products that must be:

- Up-to-date, verifiable and accurately reflect current knowledge or responsible opinion
- Accurate, balanced, fair and objective and must not mislead directly or by implication
- Be capable of substantiation

Also, promotional material such as mailings and journal advertisements must not be designed to hide their real nature. If a pharmaceutical company pays for, secures or arranges the publication of promotional material in journals, the promotional material must not resemble editorial matter. Promotional materials in journals that refer by brand name to a product of the sponsoring pharmaceutical company must comply with Clause 3.3 of this Code as appropriate, irrespective of the editorial control of the material published.

How is a media event defined?

There are no legal provisions regarding media events for medicine promotion.

Do the regulations differentiate between consumer and clinical publications?

Yes, you cannot advertise any ethical prescription medicines directly to consumers by print, TV or other electronic media. Any education materials aimed at consumers are to be distributed via a doctor.

For medicines not covered by the schedules of the DCA such as OTC medicines, a company can directly advertise through print or electronic media.

Do regulations differentiate between print media and broadcast media?

No, they do not.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?

Prelaunch media advertisements in lay press or media conferences involving consumers are not allowed as a means of promotion. The Continued Medical Education (CME) programmes may be held for doctors in India, but not at exotic locations that facilitate entertainment versus scientific proceedings. The record of expenses incurred in this regard must be maintained by the company. However, results of clinical trials can be published in medical or professional journals and company websites that are viewed only by medical professionals.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
There are no specific regulations, and all such material is expected to meet requirements of the Code of Marketing Practice.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
No reference is made to the distribution of press releases and media materials.

With respect to technical and other informative material within promotional material, the date of printing or the last review must be stated. Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising or unsuitable for public view.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
There are no rules about how the press should cover congresses and these kinds of meetings.

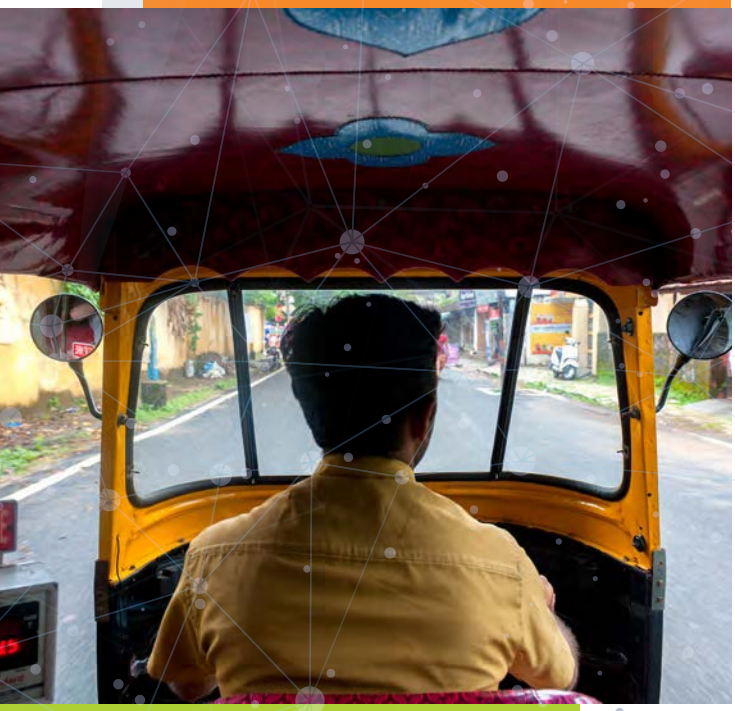
If a company sponsors a journalist at a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
Journalists are never sponsored by the company, and the copy written by the journalist is independent. The company has control of the press release, which will go through the company's regulatory procedure.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Yes, case studies can be given to doctors, but not with key opinion leader (KOL) brand endorsements. For example, the name and photograph of a KOL cannot be included. The Medical Council of India (MCI) does not permit doctors or medical organisations to endorse or recommend products to members of the medical community or the lay public. The same applies to third-party advocacy.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
No, online media are currently not differentiated. As a rule of thumb, the regulations that are applicable to print and broadcast are applied to online media.

What levels of web security are required?
Levels of web security are not defined.



Do the regulations cover funding of, or provision of information to, non-company owned websites?
Information on websites must comply with legislation.

What are the most popular social networks in your region?
The top social networks in India are Facebook, Whatsapp and Instagram. Only the standard marketing regulations apply, with no special regulations for social media.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
There are no specific provisions on the use of social media for promotion.

Are there any self-imposed regulations from social media companies?
There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
The standard global regulations apply here.

What is mobile adoption like in your region? Are there separate regulations for it?
As of 2017, there were over 1.16 billion mobile phones in India, roughly 89 phones per 100 people. Despite the high rates of mobile penetration, there are no regulations specific to mobile phones, though general regulations apply.

What are the disclosure laws like in your region for non-branded websites?
Disclosure laws are currently not defined.

What is the response level needed for adverse event reporting?
This is not defined. The Central Drugs Standard Control Organisation (CDSCO) and Directorate General of Health Services introduced in 2010 the Pharmacovigilance Programme of India (PvPI) to protect the health of the patients by ensuring drug safety.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
No regulations exist for advocacy/patient groups or travel.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for

their travel and other expenses? Is a particular category for travel disallowed?

There are no regulations regarding honoraria as payment for healthcare professional or advocacy organisation collaboration in media activities or events. However, the Indian Medical Council Regulations of 2009 state that a medical practitioner shall not receive any cash or monetary grants from a pharmaceutical or allied healthcare company for individual purpose.

Medical practitioners may, however, work for pharmaceutical and allied healthcare companies in advisory capacities as consultants, researchers, or treating doctors or in any other professional capacity. In doing so, a medical practitioner shall always ensure that:

- His or her professional integrity and freedom are maintained
- Patient interests are not compromised in any way
- Affiliations are within the law
- All affiliations are fully transparent and disclosed

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

With respect to hospitality, sponsorship and meetings, the Code of Marketing Practice states the following companies may provide financial assistance for events that are directly related to continuing education of healthcare professionals. Such support must not attempt to influence a healthcare professional judgment. Where appropriate, support to healthcare professionals may cover travel expenses, meals, refreshments, accommodation and registration fees for events organised and held in India only.

Companies must not organise meetings to coincide with sporting, entertainment or other leisure events or activities. Venues that are extravagant or renowned for entertainment or leisure facilities or must not be used.

Any hospitality offered to healthcare professionals must: be reasonable in level

- Be strictly limited to the main purpose of the event at which it is offered
- Not exceed the level that recipients would normally be prepared to pay for themselves
- And must not be extended to spouses or other accompanying persons unless they are healthcare professionals who qualify as participants in their own right

Funding of healthcare professionals to compensate them for the time spent in attending the event is not permitted.

All promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events such as visits to research or manufacturing facilities that are organised or sponsored by or on behalf of a company must be held at an appropriate venue in the country that is conducive to the main purpose of the event. Companies must maintain a detailed record of expenditures incurred for these events. Moreover, Indian Medical Council Regulations of 2009 state that a medical practitioner shall not accept hospitality like hotel accommodations, for themselves or family members.

What is possible in terms of media or message training for health professionals or advocacy organisations?

There are no rules, but all concerned professionals are expected to comply with the Code of Marketing Practice and the MCI guidelines.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

Materials written by a third party, such as clinical trial reviews, drug reviews or monographs, should truly reflect the product merits and clearly state the contraindications, precautions, warnings, side effects and so on. They should not overstretch the benefits or conceal any weakness. No KOL endorsements are allowed. Brand names must not be used to refer to products in promotions.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

There are no regulations, but all concerned professionals are expected to comply with the Code of Marketing Practice and the MCI guidelines.

KEY TAKEAWAYS/ SUMMARY

- The regulatory environment in this emerging market is currently changing. Health is being taken more seriously by the government.
- New codes are now paving the way for marketing practices, both from the ministry for the industry and from the MCI for the doctors.
- Compared to a strictly controlled manufacturing environment, the marketing environment for the pharmaceutical industry in India is less regulated but is moving towards greater regulation.

JAPAN

In Japan, compliance with pharmaceutical marketing regulations is strictly enforced by both the government and the Japan Pharmaceutical Manufacturers Association (JPMA). There are clear regulatory guidelines that companies can follow to promote their products safely. The Code of Practice in Japan details all of the necessary information for communication to the healthcare professionals by the industry as 'all requisite information on quality, efficacy, and safety relating to the use of its drugs'.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The pharmaceutical industry must strictly comply with the Pharmaceutical Affairs Law, the Anti-Monopoly Act and all other relevant laws and regulations, as well as the industry's self-regulations.

The Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry enacted the Fair Competition Code in 1984 and continues to increase fair and transparent dealings for member companies.

The JPMA enacted the JPMA Promotion Code for Prescription Drugs (JPMA Promotion Code) in 1993, the Charter of Corporate Behavior in 1997 and the JPMA Compliance Programme Guidelines in 2001.

JPMA revised the Promotion Code following the amendment of International Federation of Pharmaceutical Manufacturers Associations (IFPMA), the Pharmaceutical Affairs Law and the Personal Information Protection Law.

After receiving the IFPMA's issue of a Code of Practice, the JPMA accordingly revised its Promotion Code in September 2012, adding the JPMA Promotion Code, and enacting it in April 2013.

The JPMA Code of Practice is a comprehensive, self-imposed regulation relating to interactions with the healthcare community and contains the JPMA Promotion Code. There was no significant amendment of the code itself.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Public relations and advertising are both equally categorised as promotion.

Who is responsible for the enforcement of these rules?

The Promotion Code Committee, composed of members of the JPMA and opinion leaders selected from the outside, is charged with administering the Code, including measures relating to infractions.

What are the regulations regarding heathcare providers engagement by pharmaceutical companies? How are these regulations enforced?

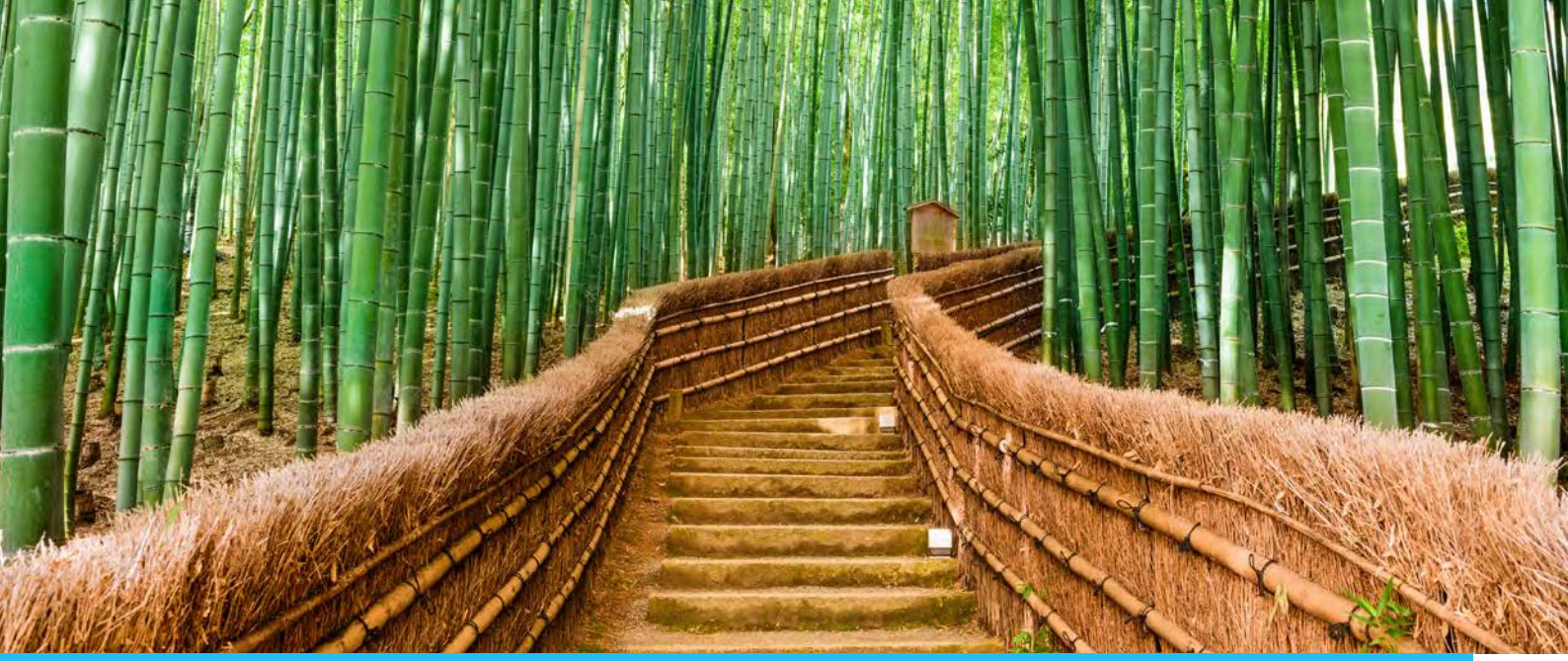
According to the Code, interactions with healthcare professionals must be focused on informing them about the product, providing academic and educational information and supporting medical research and education.

The member companies must adhere to individual company codes covering promotional activities targeting healthcare professionals and medical institutions. They must also comply with the Fair Competition Code of the Ethical Drug Manufacturing Industry and the IFPMA Code as it relates to the handling of money, goods, food and drink or the like.

When member companies engage Japanese healthcare professionals overseas by holding seminars or scientific meetings they must comply with the JPMA Promotion Code. When member companies invite healthcare professionals from overseas to seminars and scientific meetings in Japan, they must also comply with the promotion code of the pharmaceutical industry in the relevant nation, or, if no such local code exists, to the IFPMA Code.

Member companies shall not offer to healthcare professionals, medical institutions, etc. any gift that could potentially affect the appropriate use of drugs or any gift that is not in good taste.

Member companies shall not offer, either directly or indirectly, any cash or its equivalents to health



professionals, medical institutions, etc., for the purpose of potentially influencing the appropriate use of drugs.

Member companies shall always supply clinical samples only in the minimum quantity necessary, together with related drug information.

Seminars held by member companies about their drugs for healthcare professionals must not be extravagant. Food, drinks and gifts at the seminars must not be extravagant, nor must they tarnish the dignity of the company. Cash or cash equivalents are limited only to travel expenses and payment to the lecturer.

Regulation of the code is carried out by the JPMA Code Committee. If the Promotion Code is believed to have been breached, the committee has the authority to carry out the necessary actions, as established in the Rules of Actions against the Breach of the Promotion Code, against the relevant member company.

Who receives concerns and complaints? How does this process operate?

Concerns and complaints are received by the JPMA Code Committee established by the JPMA Code. In response to complaints and concerns, the Committee shall carry out necessary procedures according to the separately established Procedures for Inquiries and Complaints Related to the Promotion Code. When the Promotion Code is judged to have been breached, the Committee shall take actions against the relevant member company to address the violation, according to a separately established Rules of Actions against the Breach of the Promotion Code.

What promotional or media materials must be approved by authorities?

No materials are subject to approval.

What are the most recent significant developments and are there planned changes to codes of conduct and regulations in the next few years?

The latest version is dated September 2012. There was no significant amendment of the code itself.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

Promotional materials are defined in the JPMA Promotion Code as 'brochures, advertisements in medical journals, Internet webpages for the medical profession, audiovisual materials such as slides and VTR and other materials'.

Member companies of JPMA shall produce and use those materials in compliance with the Pharmaceutical Affairs Law and relevant self-regulations.

The statements contained therein shall be correct and objective based on scientific data.

Statements regarding indications, dosage and administration, and any other statements, shall not deviate from the approved items. When scientific data are presented at international scientific meetings, such statements can also refer to unapproved drugs (except for drugs not approved in any country) when based on the attached guidelines.

1. No false, exaggerated or misleading expression shall be used regarding efficacy and safety. Advantageous claims relating to safety such as 'there are few adverse reactions' shall not be cited without qualification and must be supplemented with a summary of data on which such claims are based.
2. Fair statements shall be made by presenting both efficacy data and safety data, including adverse reactions.
3. Comparisons with other drugs shall be based on scientific data and, in principle, shall be made using their generic names.
4. Competitors or competitors' drugs shall not be slandered or defamed.

5. Extraordinary data shall not be presented by using an expression that may give an impression that the data represents a universal fact.
6. Misleading or indecent photos, illustrations and the like that are not suitable to the socially respected role of drugs shall not be used.
7. When an advertisement is aimed mainly to promote only the name of a drug, the statements in such advertisements shall include the name (brand name), therapeutic category (product abbreviation), regulatory classification, generic name status of NHI drug price listing and the contact and address for more detailed information.
8. Member companies shall appoint a management representative for promotional materials, advertising and the like and establish an in-house auditing system so that only audited promotional materials and advertisements are used.

How is a media event defined?

There is no specific definition of a media event.

Do the regulations differentiate between consumer and clinical publications?

The Japanese Government Ministry of Health, Labour and Welfare (MHLW) prohibits companies from advertising and promoting prescription drugs directly to consumers. Anything bearing the product's brand name should not be seen by the general public.

However, disease awareness advertisements are exempt from regulations by the current administrative guidance in Japan. The purpose of a disease awareness ad, a type of direct-to-consumer advertising, is to inform consumers about a disease, make them aware of disease symptoms and encourage them to consult a doctor. Companies, although not allowed to show their brand names, are able to expand their market by disease awareness ads.

Meanwhile, when producing promotional and advertising materials on clinical publications, the correctness, fairness and objectivity should be considered on a scientific basis. Information should be provided about not only the effects, but also drug safety.

Do regulations differentiate between print and broadcast media?

No differentiation is made.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

When scientific data are presented at international scientific meetings, information about off-licenced or pre-launched drugs is permitted to be offered under certain conditions based on the guidance in the JPMA Promotion Code Permission will not be given for drugs not approved in any country.

What regulations specifically cover press releases and media materials? What are the general

principles? Are invitations to media or clinical events treated the same?
All communications are classified in the same way.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
The JPMA Promotion Code states:

- **Dissemination of information on drugs overseas**
  Member companies shall provide, either directly or indirectly through local agents, information on drugs that is globally consistent and in accordance with relevant pharmaceutical affairs laws, regulations and promotion codes to the overseas healthcare professionals.
- **Subsidiary companies overseas**
  When an overseas subsidiary company of a member company (a company in which the member company holds more than 50 percent of the equity or shares) conducts promotional activities, the member mompany shall ensure that the subsidiary will adhere to the promotion code established by the national organisation of pharmaceutical companies of the country or, if no such local code exists, to the IFPMA Code.
- **Overseas licencees and agents**
  Member companies entering into licensing and agency agreements shall require their licencees and agents to respect the promotion code established by the seven national organisations of pharmaceutical companies of the country or the IFPMA Code.
- **Activities overseas for the Japanese healthcare professionals**
  Member companies shall comply with the JPMA Promotion Code when they undertake activities aimed at the Japanese healthcare professionals overseas by holding seminars, study meetings or scientific meetings.
- **Activities in Japan for healthcare professionals from overseas**
  When member companies invite healthcare professionals from overseas to seminars or study meetings in Japan, they shall comply with the promotion code established by the national organisation of pharmaceutical companies of the country or, if no such local code exists, to the IFPMA Code.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
No specific indication about press activity is given.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
No direct guidance is given about journalists and editorials. Editorial coverage is determined by journalists who are expected to report facts in the most objective and unbiased way.

Do regulations cover the use of case studies or other third-party advocacy in the media?

Guidance is noted in the JPMA Promotion Code as:

a. Comparisons with other drugs shall be based on scientific data and, in principle, shall be made using their generic names.
b. When making a comparison with another drug, the drug that it is being compared against shall, in principle, be referred to using its generic name.
c. However, when making a comparison with one's own product or when agreement has been obtained from the company supplying the comparison drug, the proprietary name may be used.
d. Further, when the data of a competitor is used in literature, the agreement of the company concerned must be obtained.
e. In using the results of clinical trials performed for comparison with drugs supplied by a competitor, careful attention must be paid to the contractual conditions between the companies, as noted in the JPMA's 'discussions regarding the supply and acceptance of drugs for comparison.
f. Competitors or competitors' drugs shall not be slandered or defamed.
g. According to the Guideline for Specifying Product Information Summaries for Prescription Drugs, member companies must take great care in preparing the product information summaries so that they are not perceived as slander or defamation. In these summaries and other promotional printed matter, it is not permissible to include everything just because it is a fact.
h. Including comparative data that emphasise the advantages of one's own product is biased against a competitor's product and is deemed to be slander or defamation.
i. There is a possibility that the supply of improper information, including the falsified price-related information or misleading price comparison in promotional materials or promotional activities, may be deemed as slander or defamation.
j. Careful attention is being paid to the introduction of clinical results and non-clinical results, such as animal studies. But areas in which attention tends to be insufficient include background of development and analysis of interactions.
k. In background of development, the purpose of development may in some cases be stated as developing a drug that represents an improvement over an existing drug. In such a case, excessive emphasis on the disadvantages of the existing drug could be taken as slander or defamation, and the inclusion must be worded carefully.
l. When introducing data on using a combination of drugs, reference the curve (AUC) for blood concentration versus time documentation requirements.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

There are basically no different regulations among print, broadcast and internet/digital media, but some guidance for internet media is noted in the JPMA Code as below:

The internet is a means by which anyone can freely access all information, but when a pharmaceutical manufacturer uses its website to provide healthcare professionals with product-related information, the Code of Fair Practice in the Advertising of Drug and Related Products requires it to restrict access to persons who are not healthcare professionals.

So long as it does not infringe the laws of Japan (it does not appeal to patients or the general public), the website is recognized as appropriate provision of information when it fulfils the conditions set forth below.

- The name of the pharmaceutical company is provided, information is targeting healthcare professionals and access is allowed only if the website user confirms that the information is targeting healthcare professionals.
- The information is appropriate for healthcare professionals.
- The content and the website are appropriate for healthcare professionals and the owner (author) of any linked external website is recognised.

What levels of web security are required?

When a pharmaceutical manufacturer uses its website to provide healthcare professionals with product-related information, the Code of Fair Practice in the Advertising of Drug and Related Products requires it to restrict access to persons who are not healthcare professionals. No other guidance is given relating to this subject.

Do the regulations cover funding of, or provision of information to, non-company owned websites?

Yes, the information on non-company-owned websites must abide by the related regulations that the company's websites must follow.

What are the most popular social networks in your region?

Twitter is by far the most popular social network in Japan, followed by Facebook and a growing number of Instagram users. Line is also popular.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

With regards to the use of digital communications or social media, it is required that all member companies bear full responsibility for the content while checking for JPMA Code compliance with related subsidiaries, planning companies, agencies, etc. The member companies are required to give special attention to the below:

a. Compliance with the Pharmaceutical Affairs Law and advertising regulations of the Standard for Adequate Advertisement of Pharmaceutical Products.
b. When planning or supporting social media, etc., the member company concerned shall take responsibility for confirming the appropriateness of the content of postings, including the content of contributions made by third parties, and shall take appropriate measures as its own responsibility in the event that there has been a posting of inappropriate information on unapproved use, slander and/or defamation of other companies' products, etc., or of information on adverse events.
c. Only information that has passed scrutiny by the appropriate department within the member company shall be released by member companies.
d. When a member company is acting as a sponsor, it shall clearly indicate the name of the company.

Are there any self-imposed regulations from social media companies?

If business activities come under the Law Concerning the Protection of Personal Information, privacy policies and statements have to be noted on social network sites. As with the rest of the world, major global social networks like Twitter and Facebook are still developing their internal regulations.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

There are no specific rules, but the Law Concerning the Protection of Personal Information, the Pharmaceutical Affairs Law, the Anti-Monopoly Act, the PPMA Promotion Code and related regulations are applied to digital platforms.

What is mobile adoption like in your region? Are there separate regulations for it?

As of 2017, 50.1% of Japan's population had access to a smartphone, with 2016 data indicating that over 90% of the population had access to some form of mobile device.

There are no specific regulations for mobile, but the Law Concerning the Protection of Personal Information, the Pharmaceutical Affairs Law, the Anti-Monopoly Act, the PPMA Promotion Code and related regulations are applicable to mobile.

What are the disclosure laws like in your region for non-branded websites?

Regulations do not specify this information.

What is the response level needed for adverse event reporting?

Regulations do not specify this information.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

No specific mention is made of patient groups. However, the commentary that accompanies Section 7 of the JPMA Code, on seminars and study meetings, states that social gatherings and other events held in conjunction with seminars or study meetings must be on a modest scale, so that they do not obscure the original objective of the seminar or study meeting, or appear to a third party as unusual.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel not allowed?

See answer to the question above. Section 7 of the JPMA Code also goes on to say that using an opportunity set up for the provision of information as an excuse to offer entertainment 'fundamentally undermines the status of the pharmaceutical enterprise'. It defers to the IFPMA Code on the specifics, which states that payments of reasonable honoraria and reimbursement of expenses for speakers are customary and proper.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

It is possible to pay doctors for their time if such payment is kept to a modest level. In the case of health professionals who work for a public hospital, such as a national hospital organisation, such payment could be subject to a charge of bribery under both the Criminal Code and the National Public Official Moral Code.

What is possible in terms of media or message training for health professionals or advocacy organisations?

No specific guidance is given.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

No specific mention is made. IFPMA regulations on transparency are clear that if materials are sponsored by a company, either directly or indirectly, then that fact should be clearly stated.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

Meetings are permissible provided that the nature of the meeting is reasonable and modest. Provision of any material should not include brand names of drugs and must comply with the guidance on promotion to the lay audience.

KEY TAKEAWAYS/ SUMMARY

- The Japanese domestic prescription drug market in 2012 was more than 9 trillion yen. In spite of the reduction of prescription drugs' standard prices and the spread of generic drugs, the figure surpassed the existing record.
- The generic drug market share in Japan in 2012 was around 25 percent, which surpassed the MHLW target figure of 30 percent. MHLW will promote and accelerate generic drugs to curtail medical expenses. With this MHLW's strong policy and the decline of innovative drug development capacity, name-brand drug makers have been strengthening generic drugs.
- The discovery by Shinya Yamanaka, a Nobel Prize winner, has been influencing the understanding of the mechanisms that cause disease, furthering the potential for new drugs and regenerative medicine.

KOREA

The Korean drug marketing landscape is tightly regulated by the Pharmaceutical Affairs Act (PAA) with clearly defined regulations for consumer and clinical advertising. While there are no specific regulations pertaining to social media, promotion related to medicinal drugs must be conducted according to regulations.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

Drug marketing is regulated by the PAA and is supervised by the Ministry of Food and Drug Safety (MFDS). In addition, the Fair Labelling and Advertising Act, which governs advertising activities and is supervised by the Korea Fair Trade Commission, may also apply.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Public relations is not separately defined.

Who is responsible for the enforcement of these rules?

The Ordinance of the Ministry of Health and Welfare.

For a manufacturer who has obtained product approval or for a drug importer who intends to advertise drugs, they must pass a review conducted by the Commissioner of the Korea Food and Drug Administration. The Commissioner may entrust an association incorporated pursuant to Article 67 with affairs concerning deliberation on advertisement of drugs.

All reviews of advertisements are conducted by The Ordinance of the Ministry of Health and Welfare.

What are the regulations regarding healthcare providers engagement by pharmaceutical companies? How are these regulations enforced?

The PAA prohibits pharmaceutical companies and wholesalers from providing undue economic values to healthcare professionals for the purpose of promoting drugs - that is, the prohibition of kickbacks. The Korea Pharmaceutical Manufacturers Association (KPMA) Code and the Korea Research-based Pharmaceutical Industry Association Code (KRPIA) Code act as quasi-statutory regulations. The main purpose of these codes is to prevent pharmaceutical companies from providing healthcare professionals with economic endorsements.

Marketing activities to professionals include: sample distribution, sales calls and product presentations. Restrictions include:

- Provision of medical journals or medical books is prohibited, but article reprints are allowed.
- Provision of gifts or educational items.
- Sponsorship of studies is allowed, but only on the condition that there is a legitimate business need - that is, not for promotional purposes.
- The provision of samples is generally allowed once in the lifetime of the drug.
- Detailing, a marketing technique used by pharmaceutical companies, is allowed four times a month, if meals or drinks are provided.

Hospitality is prohibited unless the PAA, the KPMA and KRPIA industry codes specifically allow otherwise. Details include:

- For a multi-centre product presentation, meals (up to KRW100,000 per meal), travel expenses (economy class), lodging and souvenirs (up to KRW50,000) can be provided with the prior approval of the KPMA or the KRPIA.
- Hospitality at an academic conference can be provided with the prior approval of the KPMA or the KRPIA.
- A gift whose value does not exceed KRW10,000 can be provided to healthcare professionals at marketing events.

When distributing samples, the word sample must be marked.

According to the Fair Labelling and Advertising Act, comparison advertising must be fair and supported by facts.

Early payment discounts are allowed as long as the requirements of the PAA are satisfied. Volume discounts made within the ordinary course of business are allowed.

All academic grants must be made through the KPMA

or the KRPIA, with their prior review and approval. Attendance at conferences by medical professionals are subject to the same approval.

Who receives concerns and complaints? How does this process operate?

Under the PAA, the Ministry of Health and Welfare has the general authority. In addition , the Korea Fair Trade Commission can investigate pharmaceutical companies and healthcare professionals. In cases where criminal and administrative sanctions can be imposed, the Prosecutor's Office can also conduct an investigation.

What promotional or media materials must be approved by authorities?

Any material with the name, manufacturing methods, efficacy or performance of the drugs, etc. should not be advertised without prior approval.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

The PAA was amended on 29 May 2016. There are no further planned changes expected in the code of conduct and regulations.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

The terms are not clearly defined.

How is a media event defined?

There is no clear definition of a media event.

Do the regulations differentiate between consumer and clinical publications?

Yes.

Regulations for consumer advertising include:

- Direct-to-consumer advertising of prescription medicine is not allowed. However, for over-the-counter products, all direct-to-consumer advertising must be reviewed in advance by the Ministry of Food and Drug Safety (MFDS).
- Pharmaceutical companies are allowed to post information about prescription medicines on their websites.
- A website solely dedicated to a prescription drug is not allowed to be accessed by consumers.
- In the event of non-compliance to these regulations by pharmaceutical companies, administrative and criminal sanctions can be imposed.

Regulations for clinical advertising, advertising to health professionals, include:

- Provision of medical journals or medical books is not allowed, but article reprints are allowed.

Do regulations differentiate between print and broadcast media?

There are no separate regulations for print and broadcast media.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?

Advertising of any kind is allowed only for MFDS-approved products. No specific rules are described in the PAA.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

There are no specific regulations covering press releases and media materials – however, advertising must comply with MFDS's approved efficacies, indications and other conditions. False, deceitful, exaggerated or slanderous advertising is prohibited. Direct-to-consumer advertising

of prescription drugs is prohibited while, for drugs not requiring prescriptions, all advertising material must be reviewed in advance by the MFDS or its designated body.

In addition:

- No efficacy or performance of drugs, etc. shall be advertised by articles, photographs, designs and other methods.
- No materials which suggest induced abortion shall be used.
- Names, manufacturing methods, efficacy or performance, etc. shall not be advertised without getting approval.

There are no regulations governing invitations to either event.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
There are no regulations on the distribution of such material. Materials originating outside of Korea are held to the same regulatory standards as all other promotional materials.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
There are no regulations.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
They copy is independent and belongs to the journalist. The burden is on the journalist to ensure fair and accurate reporting of clinical benefit, safety information, and any other information about the subject.

Do regulations cover the use of case studies or other third-party advocacy in the media?
There are no regulations covering the use of case studies or other third-party advocacy in the media.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
Online media does not have separate regulations from traditional print and broadcast media.

What levels of web security are required?
There are no regulations.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
If a company conducts promotional activities on websites,

the following regulations apply:

- The promoter and the target audience of the promotional activity shall be clearly recognisable through the relevant website.
- The website content shall be appropriate for the target audience.

In the case of promotional activities conducted through websites with social media attributes, the members shall confirm the appropriateness of all postings, including those contributed by third parties. Social media is defined as media through which the exchange of opinions is made in the form of replies or other forms on a real-time basis.

What are the most popular social networks in your region?

YouTube, Facebook, Twitter, Instagram and Kakaotalk are the most popular social networks in South Korea.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

While the PAA applies in general, there are currently no specific regulations that have been established yet to address the use of social media for disease awareness or product promotional activities.

If promotional activities are conducted through websites with social media attributes, the members shall confirm the appropriateness of all postings.

Are there any self-imposed regulations from social media companies?

No, there are no self-imposed regulations from social media companies.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

There are no specific rules for customer/company interactions on digital forums.

What is mobile adoption like in your region? Are there separate regulations for it?

In 2015, South Korea had smartphone penetration of 88 percent. There are no regulations that distinguish between promotional materials for mobile internet use and regular use.

What are the disclosure laws like in your region for non-branded websites?

There are no specific regulations with the respect to disclosure on non-branded websites. The general rules pertaining to promotional activities on websites are applicable.

What is the response level needed for adverse event reporting?

The Adverse Drug Reporting (ADR) system was started in Korea in 1988; however the reporting rate in the first decade was low and the safety actions taken were done passively in response to the US Food and Drug Administration (FDA) or the European Medicine's Agency (EMA) safety alert and communications.

This led to the establishment of the Korean Institution of Drug Safety and Risk Management (KIDS) in April 2012.

The Korean Adverse Event Reporting System (KAERS) was developed by KIDS for reporting and managing adverse event (AE) reports.

- Suspected drug and AE information are reported to KIDS in a form named 'Individual Case Safety Reports' (ICSRs).
- AEs can also be reported via ADR call centre and other routes such as fax and e-mail.
- The minimum criteria for an AE report to be valid are AE information, drug information and patient and reporter information.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

No regulations have been established yet. However, general regulations that are applicable include:

- Interactions with patient organisations must be strictly for the benefit of the patients and not for incurring company profits.
- Advertising of prescription drugs is not allowed.
- A sponsorship to the patient organisation must not be used as a means to disguise provisions of undue benefits to healthcare professionals.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

Member companies may provide travel expenses, lodging expenses, etc. to healthcare professionals should they attend academic conferences for educational and scientific purposes.

Members are not permitted to support those who accompany healthcare professionals. The companies are required to record the details of the support provided as reference.

Support for participation in academic conferences shall not be provided for the purpose of inducing the selection, prescription or transaction of pharmaceuticals.

Sponsorship regarding a physician's attendance at a medical meeting must be submitted to the KMA or the KRPIA for review and approval.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

The regulations only define covering travel and lodging expenses if a healthcare professional is attending an academic meeting. There are no regulations that speak of paying health professionals or advocacy/patient groups to attend a scientific meeting.

What is possible in terms of media or message training for health professionals or advocay organisations?

There are no limits for media or message training for health professionals or advocacy organisations.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

There are no specific regulations; however, member companies must ensure that third parties or institutions which conduct work entrusted by the members will comply with the codes of practice.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

There are no specific regulations; however, member companies must ensure that third parties or institutions which conduct work entrusted by the members will comply with the codes of practice.

KEY TAKEAWAYS/ SUMMARY

- The PAA prohibits pharmaceutical companies and wholesalers from providing undue economic values to healthcare professionals for the purpose of promoting drugs - that is, they prohibit kickbacks).
- Direct-to-consumer advertising of prescription medicine is not allowed. However, for over-the-counter products, direct-to-consumer advertising is allowed but must be reviewed in advance by the MFDS.
- KAERS was developed by KIDS for reporting and managing AE reports.

SINGAPORE

The Singapore Medicines Act governs the promotion of medicines, and the enforcement of these regulations is governed by the Health Sciences Authority (HSA) and the Singapore Association of Pharmaceutical Industries (SAPI). While there is no difference in the regulations for consumer and client publications, general regulations still apply. General principles include truthfulness, accuracy and use of scientific data.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The Singapore Medicines Act, under the purview of the Ministry of Health, was developed in 1977 to provide comprehensive control of all aspects of dealings in medicine and its related products (Western medicines, Chinese proprietary medicines cosmetic products, contact lens substances, etc).

- In the act, a medicine is described as a "substance used for administration to human beings and animals for the diagnosis, prevention or treatment of ailments including preparations intended for the promotion of health, for anesthesia or for contraception".
- All medicinal products imported or sold in Singapore require a product licence from the HSA. Therefore a locally registered company that is responsible for the safety, quality and efficacy of the product must obtain a Product Licence from the HSA.
- For the application, Singapore has a New Drug Application (NDA) and a Generic Drug Application (GDA) process. For products already approved by certain regulatory agencies (such as Australia's TGA, the US FDA, etc.), submitting an abridged dossier is possible. Applicants must submit an online application through PRISM (Pharmaceutical Regulatory and Information System) and also submit an accompanying dossier. The accompanying dossier must be in International Conference on Harmonization (ICH) Common Technical Document (CTD) format.

In line with regulatory systems in many developed countries, all Western medicines are subject to the HSA's post-marketing surveillance programme which includes regular compliance checks, product sampling and Adverse Drug Reaction (ADR) monitoring to ensure that they continue to meet the required safety, quality and efficacy standards. Products found not to comply with the HSA's requirements may be suspended from further sales or recalled from the market.

Regulators in Singapore focus on the following aspects to determine whether a promotional activity is or is not in compliance:

- Truthfulness
- Substantiation
- Accuracy
- Comparisons
- Indiscriminate use
- Use of scientific data
- Avoid use of fear and superstition
- Language
- Refund
- Trial use
- Pregnant or lactating women
- Endorsements and testimonials from healthcare professionals
- Endorsements and testimonials from public figures
- Testimonials by non-professionals
- Logos, initials and trademarks
- Normal lifestyle
- Stress
- Performance in sports and studies
- Cure
- Reference to love and friendship
- Anti-ageing
- Reference to sexual function
- Discourage from medical advice

Descriptions and explanations of each point can be found on pages 10-13 of the HSA's Regulatory Guidance.

All medical advertisements must also comply with the Singapore Code of Advertising Practice (SCAP) drawn up by the Advertising Standards Authority of Singapore, as well as the SAPI Code of Marketing Practice (CMP).

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

The SCAP defines an advertisement as 'any form of commercial communication for any goods or services,

regardless of medium used, including advertising claims on packs, labels and point of sale material.' Advertisements include, but are not limited to, the following:

- Advertisements in newspapers (including classified advertisements), magazines, brochures, leaflets, circulars, mailings, posters, plastic cards (including fare cards, cash cards), tickets and other printed publications
- Advertisements via facsimile transmissions and aerial announcements
- Advertisements displayed on buildings and vehicles
- Television, radio, cinema and video commercials
- Advertisements in information network services, electronic bulletin boards, on-line databases and internet services
- Advertisements in non-broadcast electronic media such as computer games
- Mail orders
- Sales promotions
- Mailing lists
- Digital communications in every format, design and context including the world-wide web (Internet) and social media
- Telephone, etc.

Public relations is an overarching concept for any organized effort to communicate information and to modify attitudes and behaviour on behalf of a client or cause. It is usually earned, unlike advertisement where it is paid.

Who is responsible for the enforcement of these rules?

For medicine: The HSA and the SAPI.

For advertising: Advertising Standards Authority of Singapore (ASAS)

What are the regulations regarding the engagement of healthcare providers by pharmaceutical companies? How are these regulations enforced?

The arrangements for consultancies must, to the extent relevant to the particular arrangement, fulfill the following criteria:

- A written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services.
- A legitimate need for the services must be clearly identified and documented in advance.
- The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service.
- The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.
- The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine.
- The compensation for the services must be reasonable and reflect the fair market value of the services provided.
- Services that can be provided by healthcare professionals include but are not limited to speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration.

The rules are enforced by SAPI.

Who receives concerns and complaints? How does this process operate?

Any complaint regarding a potential breach of the Code against a member company must be sent directly to the SAPI instead of through third parties, e.g. Health Sciences Authority, Ministry of Health.

If a complaint against a member company is referred or directed to the SAPI by any third party, the complaining

member company must pay the applicable processing fee to SAPI to review the complaint.

Complaints to the Marketing Practices Committee should only be a last-resort action after all reasonable avenues have been exhausted. This includes contacts between the CEOs of both companies, to resolve it amicably.

All complaints of breach of SAPI Marketing Code of Practice must be made in writing and submitted by the CEO of the complainant company (so the CEO of that company is aware that a complaint has been submitted) together with a processing fee of $1,500.00 to SAPI. It will first be validated to ensure that:

- It appears to be a genuine matter, submitted in good faith. A documentation to show that there has been a communication between the CEOs of the involved parties, to show that all parties have tried to resolve the issue amicably.
- There is sufficient evidence to enable the complaint to be processed.
- It is not a duplication of any existing case that has already been resolved under the Code.

What promotional or media materials must be approved by authorities?

For general materials, authorities do not have to approve materials. However, it is imperative to ensure that the content of the materials protects the young, does not incite racial/religious feelings, is not in conflict with national interest, and so on.

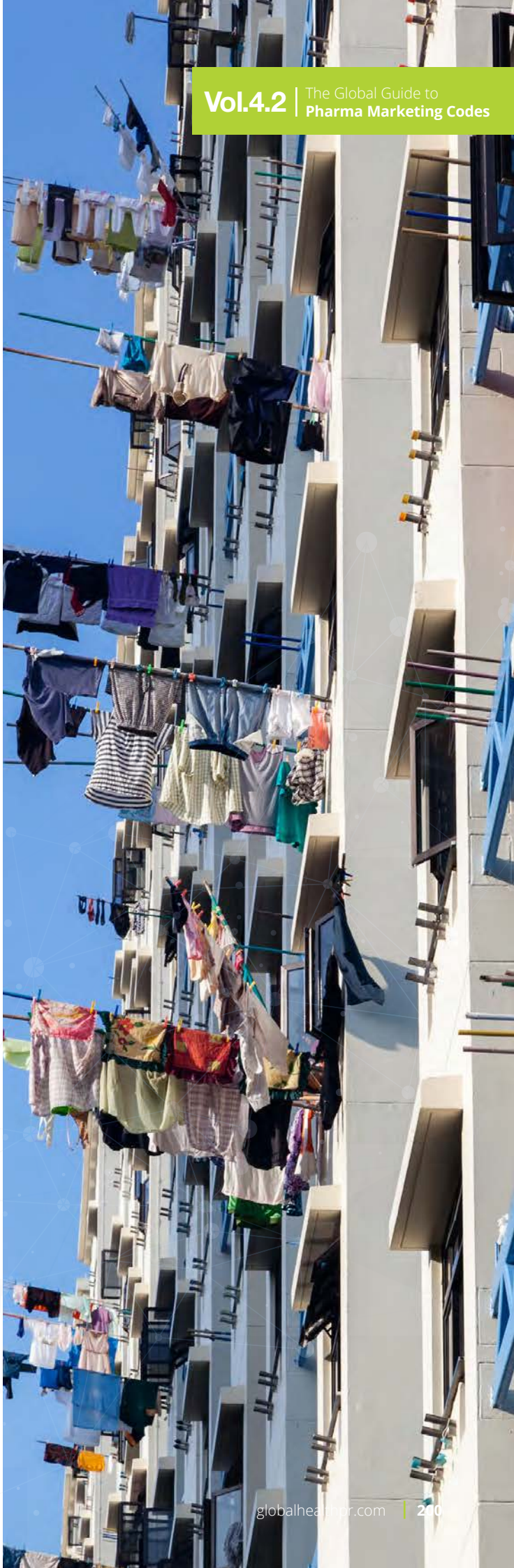
For promotional materials on medicinal products, an application for an advertisement OR sales promotion is needed. The requirements are as follows:

Advertisement

- If an advertisement comes in one copy in more than one language, only one application is required.
- If an advertisement comes in more than one copy, each in a different language, separate applications will be required. As an example, for a leaflet that comes in two copies, one in English and one in Chinese, two applications would need to be made.

Sales Promotion

- Only one application is required for the sales promotion of products in the same range (e.g. different brands of vitamins, up to a maximum of five products) using the same promotional method.
- A copy of the sales promotion mechanics is to be submitted in the application.
- If an advertisement also contains a sales promotion announcement, an application for sales promotion would also be required. The prescribed format is as follows:
  - » Name of Product
  - » Promotion Method (e.g. price discount)
  - » Press Advertisement, if any (to provide a draft artwork as an attachment)
  - » Promotion Materials (e.g. shelf-talker, wobbler), if any (to provide as an attachment)
  - » Promotion Venue (e.g. retail pharmacy, shopping malls)



Both the advertisement permit and sales promotion permit numbers have to be legibly printed on the advertisement. Each permit is valid for 1 year from the date of issuance of permit approval.

The processing time for each application is 14 working days, excluding time taken by applicant to make required changes. Upon successful submission of an application via PRISM, an acknowledgement with an application number will be generated. The application number is not a permit number.

If the application is approved, a permit number will be issued with an endorsed copy of the advertisement or sales promotion.

After the approval of the application AND before the publication of a medical advertisement/a medical sales promotion is conducted, it is mandatory for the company initiating the advertisement and the publisher, media owner or the organiser(s) of the sales promotion to ensure that:

- The advertisement or sales promotion has a valid permit from the HSA.
- The permit number is printed legibly on the advertisement and promotional materials.
- The advertisement has not been amended without prior written permission from the Health Sciences Authority.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

The SAPI CMP was revised in 2016, to include Section 7.1.4 on "Appropriate Venue' for meetings. Essentially, the spirit of the SAPI CMP remains the same and it does not endorse venues associated with gambling.

With regard to other changes in the near future, only the committee is able to comment on this.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

Promotional activity involves the intention to promote the sale or disposal of a good/service while provision of information is to educate or create awareness.

How is a media event defined?

A media event is staged primarily to attract publicity. The spokesperson of the organisation will speak to the invited journalists first. Journalists may pose questions, if they wish to.

Do the regulations differentiate between consumer and clinical publications?

The Media Development Authority (MDA) does not differentiate between publications. However, the general principles for promotion of medicinal products must be followed.

Do regulations differentiate between print and broadcast media?
Yes. In the CMP and guidelines by the MDA, print and broadcast are treated differently. Even though they are differentiated, the general principles for promotion of medicinal products still apply.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?
As long as the activities are not illegal, the regulators will not interfere.

Communications professionals engaging media shall not use any brand's name, unless crucial to the story. The chemical compound of the medicine is usually preferred. This applies to a product launch as well.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
There are no specific regulations that cover press releases and media materials.

The general principles are the same for press releases and media materials. For general materials, companies must ensure that the content of the materials protects the young, does not incite racial/religious feelings, and is not in conflict with national interest. If scientific data are presented, it is best to ensure that all facts are substantiated and have been approved by the HSA.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
Distribution of materials is not regulated, but they should adhere to the general principles noted above.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
There are no known regulations, but all findings should be scientifically sound and substantiated.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
If it is a journalist from a publication, the written article has to be approved by its editors before publication.

If it is a freelance journalist writing for his/her own personal site, the resulting copy is independent. However, if the article is intended for a certain publication, the editors of that publication will have to vet through it first.

Note: No company should provide any form of gift for the journalist in exchange for favorable coverage and/or story angles, as it is against most publications' code of ethics.

Do regulations cover the use of case studies or other third-party advocacy in the media?
No. However, it is highly recommended to use credible or renowned case studies or advocates. Obscure case studies and advocates should be avoided.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
Yes. Online media are regulated through the Broadcasting (Class Licence) Notification. They are required to abide by the conditions of the licence and to exercise judgment in ensuring that their content complies with the Internet Class Licence and the Internet Code of Practice.

The Class Licence scheme operates in a 'catch-all' manner, with internet service providers and internet content providers automatically deemed to be licenced without the need to apply to the MDA for permission to operate a website or publish online. This would include personal homepages, individual 'weblogs' and do-it-yourself online publications.

Such ambiguously crafted rules widen the scope of policy enforcement, giving the authorities discretionary powers to deal with offenders. As a result, self-regulation among Singaporeans is very high.

What levels of web security are required?
This is not specified, but usual web security will suffice. The Infocomm Development Authority of Singapore said the website's level of security is dependent on the developer.

However, as a general guideline, if the users need to share extensive personal information (e.g full name, NRIC number, credit card number etc.), the website should be encrypted so as to protect the user entirely.

Do the regulations cover funding of, or provision of information to, non-company owned websites?

There are no known regulations but websites must abide by the conditions of the Class Licence. For sponsors, they have to adhere to legal and accounting standards – e.g. funding should not be obtained illegally.

What are the most popular social networks in your region?
Facebook is the top social media network in Singapore with nearly four million registered users, or over 70% of the nation's population of 5.6 million people. Other popular social media networks are YouTube, Instagram and Twitter. For mobile messaging apps, WhatsApp is the most popular in Singapore.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
There are no known guidelines yet.

Are there any self-imposed regulations from social media companies?
Social media networks have their own policies, which may differ from company to company.
For instance, Facebook removes content, disables accounts and works with law enforcement when it believes that there is a genuine risk of physical harm or direct threats to public safety. Facebook may also remove certain kinds of sensitive content or limit the audience that sees it. This is to help balance the needs, safety and interests of a diverse community.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
There are no known rules, but a general guideline is not to tarnish the reputation of your competitor.

What is mobile adoption like in your region? Are there separate regulations for it?
According to statistics from Infocomm Development Authority of Singapore, Singapore's 2017 mobile penetration rate is 149 percent, meaning on average Singaporeans have more than one mobile device (e.g. work and personal phones or multiple service providers).

Singapore also ranked highest globally for smartphone penetration in 2015, with nine out of 10 surveyed respondents having access to a smartphone. This smartphone penetration survey was conducted by Deloitte's Global Technology, Media and Telecommunications, using 37,000 respondents across 22 locations.

General principles for promotion of medicinal products apply.

What are the disclosure laws like in your region for non-branded websites?
There are no known disclosure laws in Singapore, but if a third-party website is supported by a company, it should be disclosed regardless.

If the website wants to solicit for donations, it has to register itself as a charity with the Registry of Societies.

What is the response level needed for adverse event reporting?
The HSA's Adverse Event Reporting Programme relies upon voluntary reporting of suspected adverse event (AE). The HSA must be notified when one suspects any causal association between the health product taken and the AE experienced by the patient. Reporting an AE does not necessarily mean that there is a definite link between the event and the product.

Reportable AEFI's include:

- Anaphylactoid reaction (acute hypersensitivity reaction)
- Anaphylaxis
- Persistent (more than three hours) inconsolable screaming
- Hyptonic-hyporesponsive episode
- Toxic shock syndrome
- Severe local reaction
- Sepsis
- Injection site abscess (bacterial/sterile)
- Seizures, including febrile seizures
- Encephalopathy
- Acute flaccid paralysis
- Branchial neuritis
- Intussusception
- Thrombocytopenia
- Lymphadenitis
- Disseminated BCG infection
- Osteitis/osteomyelitis
- Death
- Hospitalisation
- Disability
- Any other severe and unusual events suspected to be associated to the vaccine

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
There are no known regulations yet.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Healthcare professionals from the civil service are not allowed to accept any payments. For the private sector, it is up to the discretion of the two parties. It is worth noting that some pharmaceutical companies like GSK no longer pay doctors to make presentations on their behalf at medical seminars.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Same as response above.

What is possible in terms of media or message training for health professionals or advocacy organisations?
Regardless of who the spokesperson is, he/she should always be media trained. Media training can be done in-house or outsourced.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?
There are no known rules.

What regulations cover meetings with, or provision of non-media information to advocacy groups?
There are no known regulations.

KEY TAKEAWAYS/ SUMMARY

- Like regulatory systems in many developed countries, all Western medicines are subject to HSA's post-marketing surveillance programme, which includes regular compliance checks, product sampling and Adverse Drug Reaction (ADR) monitoring to ensure that they continue to meet the required safety, quality and efficacy standards.
- If media is engaged, they will not use the brand's name, unless crucial to the story. The chemical compound of the medicine is usually preferred. This applies to the product launch as well.
- The HSA must be notified if one suspects there is a causal association between the health product taken and the AE experienced by the patient. Reporting an AE does not necessarily mean that there is a definite link between the event and the product.
- Healthcare professionals from the civil service are not allowed to accept any payments. For the private sector, it is up to the discretion of the two parties.

THAILAND

The Thai pharmaceutical market is governed by the Thai FDA, a department under the Ministry of Public Health. The Pharmaceutical Research and Manufacturer Association (PReMA) is the official industry association. PreMA has issued its Code of Practice for the Ethical Channel written both in English and Thai to guide all members on how to comply with local regulations The most recent Code of Practice, the 11th edition, was issued in 2018.

In addition, the National Drug System Development Committee (NDSDC) of the Ministry of Public Health is responsible for establishing ethical criteria on Thai medicinal drug promotion for all stakeholders. The promotion of prescription drugs must be conducted only to healthcare professionals, as direct promotion to the consumer (DTC) is not allowed.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The Drug Act of 1967 is still in effect with many revisions. The most relevant part is Chapter XI, Advertisement, which has been amended five times. The definition of advertisement from The Consumer Protection Act B.E. 2522 (1979) is any act which, by whatever means, causes the statement to be seen or known by ordinary person for trading purposes.' Advertising Media means 'a thing such as newspaper, printed matter, radio, television, post and telegram, telephone or sign board.

Any advertisement for the sale of a drug must not be boastful of its therapeutic properties or of its ingredients as being miraculously or completely capable of curing, mitigating, treating or preventing a disease or illness, nor shall any other wording or meaning be intended to, whether intentionally or unintentionally:

a. Falsely communicate or exaggerate its therapeutic properties;
b. Cause to be understood that it has a substance as its chief or component ingredient, which in fact it has not or does have but less than the quantity as caused to be understood;
c. Cause to be understood that it is an abortifacient or a strong emmenagogue;
d. Cause to be understood that it is an aphrodisiac or a birth control drug;
e. Not show the therapeutic properties of a dangerous or a specially-controlled drug
f. Contain no certification or recommendation of its therapeutic properties by any other person;
g. Not show its therapeutic properties as being capable of curing, mitigating, treating or preventing disease or symptom thereof as notified by the Minister under Section 77.

Provisions (e) and (f) above do not apply to the statement on the label or accompanying leaflet of a drug, and (a), (b), (e), (f) and (g) do not apply to an advertisement directed to a medical practitioner or a veterinary practitioner.

a. Moreover, the advertisement to sell drugs through radio amplifier, television slides or motion picture or through printed matter must:
   - Receive permission for the text, sound or picture used in the advertisement from the licensor.
   - Follow the conditions set by the licensor.

The latest Ministry notification of Ethical Criteria of Medicinal Drug Promotion (2016) has defined the term 'Advertising' as 'any action for the public to see or be aware of statement as regards medicinal drugs for commercial purposes.'

The other important code in Thailand is PReMA Code of Practice of 2018 that all members company must comply with. PReMA has defined the term 'promotion' as referring to activities undertaken, organised or sponsored by a pharmaceutical company with the objective to encourage the prescribing, supply administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet.'

Promotion includes the activities of sales representatives and all other aspects of sales promotion in whatever form they may occur. Examples of promotion include, but are not limited to, product information presented in any form; public relations activities; advertising via electronic media; journal/print and direct mail; participation in exhibitions; use of audio recordings, films, records, slides, tapes and video recordings; the use of any other data storage and viewing devices reproduced on television; visual display units; the provision of samples. The term 'promotion' does not extend to company responses to enquiries from particular doctors or similar, including letters published in a medical journal.

There are several key principles related to PReMA's code of promtion. Only products registered in Thailand should be promoted by brand name to healthcare

professionals. While promoting products, the information should be accurate, balanced, objective and scientifically valid, and presented in such a way as to conform not only to legal requirements but also to high ethical standards and to be in good taste.

Claims should not be stronger than scientific evidence warrants, and every effort should be made to avoid ambiguity and making off-label product claims.

No pharmaceutical product shall be promoted for use until approval for marketing has been given:

- Information in promotional material should be based on a current evaluation of evidence that is scientifically valid and approved by the Thai FDA.
- Promotion should be clearly labelled as such, and shall never be disguised as clinical assessments, post-marketing surveillance, experience programmes, or post-authorisation studies. Such assessments, programmes and studies must be conducted with a primary scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company, should clearly indicate the sponsor.
- The methods of promotion employed must be appropriate to the learning and professional status of the healthcare profession to whom they are directed.

Currently, most member companies have adapted their corporate codes of conduct to comply with PReMA provisions and local laws and criteria.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

According to the Drug Act, Ministry Notification and PReMA Code mentioned before, there are no specific rules for public relations activities. The regulators were focused on purpose and public relations was included in promotional activities.

Who is responsible for the enforcement of these rules?

The Bureau of Drug Control (BDC) is a division under the Thai FDA and the Ministry of Public Health that handles all drug-related issues including new registration, licencing, dossier evaluation and communication to both healthcare professionals and the general public. The BDC has the authority to regulate information and activities run by pharmaceutical companies.

Any promotional media or activities need regulatory permission prior to any dissemination. An advertiser or attorney must submit all promotional materials to the BDC.

It takes 30 business days for media to healthcare professional. Only prescription or pharmacy-dispensed medicines require such permisison. After the BDC procedure, the permission number lasts for five years from the date of permission. The permission number must be placed on all promotional material and can be revoked if the number is misused, altered or omitted from materials.

What are the regulations regarding healthcare professional engagement by pharmaceutical companies? How are these regulations enforced?

For healthcare professinals, the most relevant regulations are the Medical Council Regulations on Medical Ethics Preservation, B.E. 2549 (2006), Part 8: Behaviors When Having Interactions with Healthcare Product Entrepreneurs.

No healthcare professional shall accept money from a company or enterpreneur except for consulting fees, honoraria for academic lectures, and research grants.

- Article 42: Healthcare profesisonals shall not accept any item, service, or gift worth more than 3,000 Baht (~$90 USD) from a company or entrepreneur, except when an item is an academic contribution/grant beneficial to patient service, which may be destined toward a designated institution.
- Article 43: When being sponsored by a company

for an educational visit, conference attendance, or academic lecture in the country and overseas, a medical practitioner can receive only travel expenses, registration fees, lecture honoraria, meals and accommodation costs for himself or herself, and only for the period of the visit. Other fees or payments are prohibited.

- Article 44: When serving as a presenter in any healthcare product advertisement, a health professoinal shall not use the word 'doctor' or any other wordings or do anything to present messages, images, signs, or acts which make the public understand that he or she is a doctor or a medical practitioner.
- Article 45: When publicising an opinion about any healthcare product properties in spoken, written, or other form, a medical practitioner shall also reveal his or her connection with the company/entrepreneur, for example, as a consultant, as a co-investor, or as a recipient of visiting, conference, or lecture grants.
- Article 46: Royal colleges and colleges under the Medical Council may formulate rules of practice for their members in agreement with the regulations in this part.

In the event of any complaints about a healthcare professional's compliance, the Medical Council can suspend or revoke the licence of the medical practitioner.

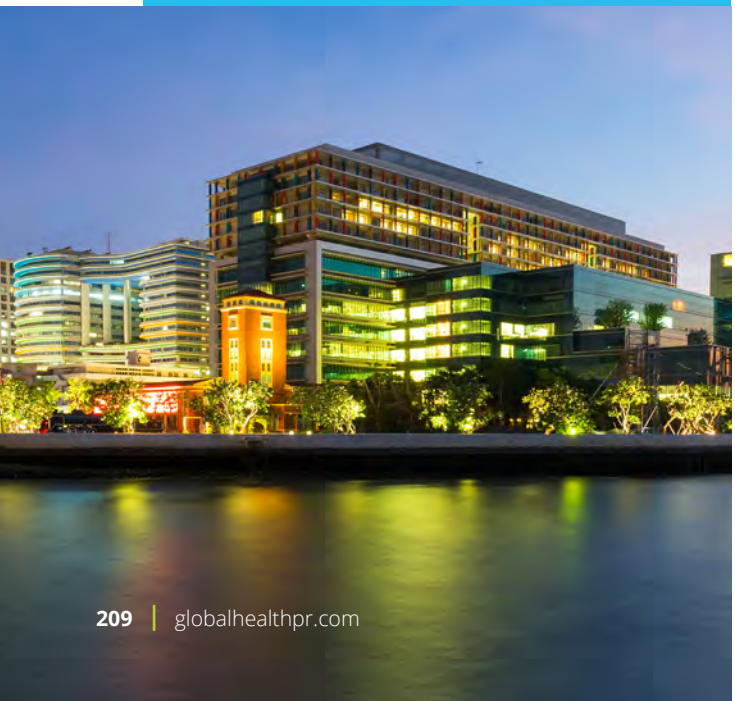
Similar to healthcare professionals, pharmacists must comply with The Pharmacy Council Regulations on Pharmaceutical Ethics Preservation, B.E. 2546 (2003), Part 6: Pharmaceutical Practice:

- Article 30: When speaking/lecturing about any healthcare product on any channel, including presenting messages, images, signs, or acts, a pharmacist shall not, either directly or indirectly, recommend the product lectured about.
- Article 31: When being sponsored or granted to contribute anything or any work ,a pharmacist shall also reveal his or her connection with the entrepreneur/ company; for example, as a consultant, as a co-investor, or as a recipient of visiting, conference, or lecture grants.

The Pharmacy Council has authority to ensure that all members comply with these regulations.

Who receives concerns and complaints? How does this process operate?

The BDC usually monitors drug advertisements. If they suspect deviation from the permission granted (see 'enforcement' question on previous page for detail), the BDC could order the company to stop and make corrections prior to continuing dissemination. The most complaints come from competitors, who often inform both the BDC and PReMA (if a member gets involved). The penalty might vary from requiring written apology all the way up to expelling the guilty company from the association.



What promotional or media materials must be approved by authorities?

Advertisements for medicinal drugs—both the messages to the general public and information for HCPs—require prior approval from the BDC.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in next few years?

In early 2016, the National Committee of Drug System Development announced that the Ethical Criteria on Thailand's Medicinal Drug Promotion ('Ethical Criteria' henceforth) would be employed as the country's reference criteria. All related parties can implement or elaborate them. Parties related to these Ethical Criteria are namely prescribing professionals; executives or authorities at infermaries (state health clinics/hospitals) or relevant agencies; pharmacists at infirmaries, pharmacy service facilities or other agencies; pharmaceutical companies and representatives; and instructors and students at medical and health sciences schools. This criteria corresponds with The Drug Act, The Medical Council Regulations, and The Pharmacy Council Regulations.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

All materials provided by pharmaceutical companies to healthcare considered to be promotional in nature and are thus regarded as advertisements.

The Drug Act and the Ethical Criteria focus on commercial activites, but the PReMA code is more inclusive and considers any action organised or sponsored by a pharmaceutical company to be promotion.

How is a media event defined?

There is no specific definition.

Do the regulations differentiate between consumer and clinical publications?

Yes, they do. Medicines in Thailand have been categorised into three groups: prescription-needed, pharmacy dispensed and household remedy. Advertisements of prescription or pharmacy-dispensed medicines are permitted only to HCPs but prohibited to the general public. Drugs in the household remedy category may be advertised directly to consumers or the general public.

The basic regulations of drug advertisements for clinical publications are similar to those of consumer publications, but the approval for consumer advertisements would require 15 working days after all documents are submitted. For more details, consult answers 1 and 3 in this section and the previous 'The Basics' section.

Do the regulations differentiate between print and broadcast media?

The basic regulations apply to both print and broadcast media. The advertising of healthcare products to the

general public also needs prior approval from the BDC before publication and the advertisers have to declare any active ingredient (or generic name) clearly.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

Any action organised or sponsored by a pharmaceutical company is considered a promotion. The BDC allows the promotion of only registered drugs and the company must promote only at the time time of registration (i.e. approval); off-licence (off-label) or non-registered drug promotions are prohibited.

Communication about an off-licence drugs between pharmaceutical companies and a healtcare professional is only allowed through their medical adviser. Commercial departments such as sales and marketing cannot be involved.

The medical department of a pharmaceutical company can provide the latest information regarding the clinical study of an unlicenced drug to healthcare professionals or organised advisory board, but these actions must aim to be educational support for better patient care and not for promotional purposes.

There are no specific rules around congresses and scientific meetings, but the same conditions apply as stated above. Major publications are considered to be directed toward patients, thus it cannot publish promotional content for perscription drugs. To promote a new drug via a scientific meeting or congress session, the drug must be registered and approved.

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What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

The Drug Act does not specifically mention press releases, but if it is targeted toward consumer publications, it is assumed that branded communications can only be done for non-prescription/over-the-counter drugs.

For invitations to clinical events, the message can be delivered with the condition that it cannot contain the brand name of the product. It is important that the message provides scientific information and that the information is factual, balanced and non-promotional.

Invitations for media to attend talks regarding prescription drugs should not be organised or sponsored by the pharmaceutical company.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

Clinical studies are also published on the Internet and can be consulted by relevant journalists. In general, if a medical company is promoting in its own country, then its local country code is applicable to the conduct of the promotional activity.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

As mentioned, an advertisement or promotion of a medicinal product must relate only to the registered drug and needs prior permission from Thai regulatory authorities.

Fortunately, at scientific meetings it is possible for independent scientific speakers to provide information regarding new active agents or new off-label indications and to discuss recent developments of clinical trials regarding unlicenced products or indications. Usually, the attending press is the healthcare industry or medical press, for example, Medical Times. The objectives of meeting attendance shall not be for commercial purposes, but rather to provide HCPs with educational updates from disease-area experts. It is forbidden to use the brand name of products, so scientists and journalists can only use generic names. If a pharmaceutical company is mentioned in an article coming out of a medical meeting, they may request to see the article before it has been published.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?

Supplements, articles and editorials are subject to the same regulations as advertising (i.e., the brand name of products cannot be mentioned). If it is written by a journalist, the liability is on the journalist and/or the publisher. However, the drug company may ask for the article to review and make sure that there are no trade-name or commercial phrases in the content. Original papers published in scientific journals and signed by their authors can be used and distributed by pharmaceutical industries or others with the permission of the publishing company. There are no specific limitations on the use of freelance journalists. Rules about content and and brand name usage apply as stated above.

Do regulations cover the use of case studies or other third-party advocacy in the media?

Yes. Case studies are defined as advertisements.

DIGITAL & SOCIAL MEDIA

Is online media differentiated from print and broadcast and, if so, how is it regulated and monitored?

Websites must comply with local legislation, Ethical Criteria, and the PReMA Codes. Online media has been assessed as a public promotion. Therefore, companies' websites always contain information on products targeted to a wide range of audiences and can contain product details for informational purposes only.

What levels of web security are required?

Not specified in Thailand, but companies should self-regulate and/or ensure internationally accepted web security criteria are met.

Do the regulations cover funding of, or provision of information to, non-company-owned websites?

The Drug Act expands the scope for all kinds of information that companies will be allowed to make available to the general public, like The Ministry Notification. Additionally, the PReMA code is clearly interpreted for covering this kind of promotion.

What are the most popular social networks in your region?

The most popular social network in Thailand is Facebook. As of 2016, there were 41 million users -- around 60 percent of the Thai population. There are around 700,000 Facebook pages in Thailand. In second place is the LINE application, with 33 million users, and third place is Instagram with 7.8 million users. It is worth noting that Instagram has the greatest growth at 74 percent.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion?

So far, there are no specific regulations for social media. Both the BDC and PReMA subject social media to similar promotional regulations as materials for the general public because they are patient-accessible. Social media promotions need to ensure truthfulness, non-exaggeration, and must get approval by the authorities.

Disease-awareness campaigns adopted by a company's social media channels must contain general information and never refer to a product (it is possible to refer to treatment as a class but a company cannot specify to the individual drug).

Are there any self-imposed regulations from social media companies?

Each social media channel has its own regulations and restrictions; consult United States chapter for additional detail on some of these networks.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

There are no specific rules thus far, so the general rules are applicable.

What is mobile adoption like in your region? Are there separate regulations for it?

At the end of 2016, there were estimated to be nearly 50 million smartphone users in Thailand. The same regulations of online media are applied to mobile devices.

What are the disclosure laws like in your region for non-branded websites?

Non-branded websites must declare who owns and sponsors them. If the site involved is related to a pharmaceutical company, it has to comply with the drug law and PReMA code.

What is the response level needed for adverse event reporting?

The Thai FDA participates in Adverse Event Reporting and there is the Health Product Vigilance Center (HPVC). HPVC monitors potential safety issues associated with the use of the health product (including medical devices) available.

The report forms are available from the HPVC site, not only for HCPs but for companies, as well. There are three systems of Adverse Event reporting in Thailand: Spontaneous, Intensive Monitoring and Clinical Trial. The HPVC has an online report system so that it can be done quickly and easily record and protect the patient's privacy.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

Patient associations are very active in Thailand, but the specific regulations currently apply only to pharmaceutical companies. However, any form of sponsorship by pharmaceutical companies regarding patient associations must be transparent and without promotional objectives.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category of travel disallowed?

The payment from companies towards HCPs is allowed only for academic contributions and most PReMA member companies need prior approval of the activity from a local compliance entity or authorised person. The most related regulation on this is The Medical Council Regulations on Medical Ethics Preservation, B.E. 2549 (2006).

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Sponsorship for attending scientific programme is legally possible but regulations around attendance of advocayc/ patient groups do not curently exist.

However, attendance of such patients or groups should be considered as a promotion to the general public and thus the rules outlined in the 'Media' section of this chapter still apply.

What is possible in terms of media or message training or health professionals or advocacy organisations?

There is no guidance restricting media or message training programmes as of early 2018, eithe from the regulatory agencies or PReMA.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

The basic regulations such as requiring truthfulness and non-exaggeration, and requiring the generic product name only, still apply.

What regulations cover meetings with, or provision of, non-media information to, advocacy groups?

There is no regulation specific to company engagement with the advocacy group, but the Thai FDA considers the patient advocacy groups to be part of the general public. Therefore, The Drug Act and PReMA Code might be applied. See The Basics and Media sections for additional information.

KEY TAKEAWAYS/ SUMMARY

- Advertising aimed directly at the general public shall be limited to non-prescription products or household remedies.
- Any scientific information about prescription drugs, whether provided directly or indirectly by pharmaceutical companies, is considered promotional (to health professionals only) and should be carried out in accordance with the Thai legislation.
- Advocacy groups are increasing their influence in Thailand but there is no is no specific rule which governs them or the ways in which their promotion.

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