ASIA - PACIFIC

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The Global Guide to
Pharma Marketing Codes
Vol.4.2 Book 3

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.

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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.

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 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.

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- 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.

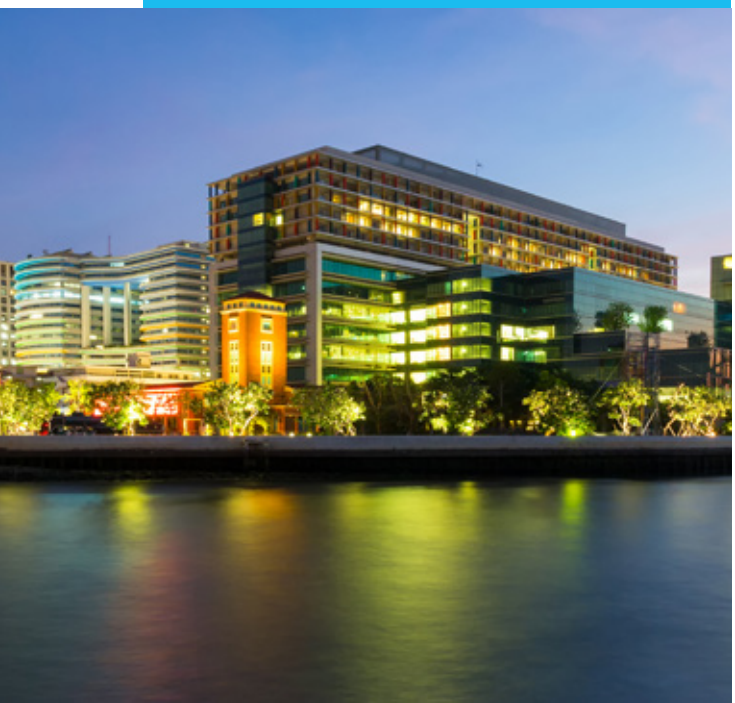
Similar to healthcare professionals, pharmacists must comply with The Pharmacy Council Regulations on Pharmaceutical Ethics Preservation, B.E. 2546 (2003), Part 6: Pharmaceutical Practice:

- 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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