PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

In Indonesia, the promotion and advertising of pharmaceuticals falls under National Drug/Medicine and Food Control Agency Regulation No 2 of 2021 on Guidelines for Drug/Medicine Advertising ('BPOM Regulation 2/2021').

The advertising of medical devices falls under Minister of Health (MOH) Regulation No 76 of 2013 on the Advertising of Medical Devices and Household Health Supplies ('MOH Regulation 76/2013').

In addition to the above regulations, the following also cover the advertising of pharmaceuticals and medical devices:

- Law No 6 of 2023 on Health (the 'New Health Law');
- Law No 8 of 1999 on Consumer Protection (the 'Consumer Protection Law');
- Government Regulation No 72 of 1998 on Safeguarding Pharmaceutical Supplies and Medical Devices ('GR 72/1998');
- MOH Decree No 437/MEN.KES/SK/VI/1987 on the Prohibition of Production, Imports, Distribution, Dispensing, and Medicine Samples;
- the Indonesian Advertising Ethics, a set of guidelines issued by the Indonesian Advertising Council ('Etika Pariwara Indonesia or EPI');
- The Code of Ethics for Marketing Pharmaceutical Products in Indonesia, a set of guidelines issued by the International Pharmaceutical Manufacturers Group (2021 edition) (the 'IPMG Code'), which applies to all IPMG members and third parties engaged by IPMG members to promote or market their pharmaceutical products; and
- The Code of Ethics of Gabungan Perusahaan Farmasi Indonesia ('GPFI') ('GPFI Code'). GPFI is an organisation that represents pharmaceutical companies in Indonesia, and this code is binding on its members, which consist of various pharmaceutical companies in Indonesia.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

MOH Regulation 76/2013 defines advertisements as commercial and public service information about the availability of services, goods and ideas that the target audience can use, with or without paying fees to the relevant broadcasting institution.

More specifically regarding pharmaceuticals, under BPOM Regulation 2/2021, a drug/medicine advertisement is defined as any information or statement regarding a drug/medicine that is provided in the form of pictures, writing or other forms created by various means for the marketing and/or trading of drugs/medicines.

The IPMG Code defines promotion as any activity conducted, organised or sponsored by IPMG members aimed at healthcare professionals to promote prescribing, recommending, providing, delivering or using their products through all types of media. Given this definition, the IPMG only refers to promotion targeted at healthcare professionals, not the public, because it mainly focuses on pharmaceuticals/medicine/drugs with a doctor's prescription. On the other hand, the GPFI Code does not include any definitions related to promotions or advertisements.

Therefore, the relevant regulations do not clearly differentiate between the promotion and advertising of pharmaceuticals and medical devices. The IPMG Code only defines 'promotion', not 'advertising'.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

The advertising of pharmaceuticals is supervised by the National Drug and Food Control Agency (Badan Pengawas Obat dan Makanan RI or 'BPOM'). The advertising of medical devices is supervised by the

Ministry of Health through the Directorate General of Pharmaceuticals and Health Devices.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

BPOM Regulation 2/2021 covers the advertising of the following drugs/medicines:

- over-the-counter drugs/medicines;
- limited over-the-counter drugs/medicines;
- prescription drugs/medicines;
- narcotics; and
- psychotropics.

The only drugs/medicines that can be advertised to the public are limited over-the-counter drugs/medicines. Prescription drugs/medicines, narcotics and psychotropics can only be advertised to health professionals.

Health supplements, traditional drugs/medicines and quasi-drugs/medicines fall under BPOM Regulation No 34 of 2022 on the Supervision of the Advertising of Traditional Drugs/Medicines, Quasi-Drugs/Medicines, and Health Supplements.

Meanwhile, MOH Regulation 76/2013 covers the advertising of medical devices and household health supplies.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and if so, which ones?

Pharmaceuticals

Not all pharmaceuticals may be advertised to the public. Only limited over-the-counter drugs/medicines can be advertised to the general public. Prescription drugs/medicines, narcotics and psychotropics may only be advertised to health professionals. Pharmaceutical advertisements are required to be objective, complete and not misleading. The detailed requirements and restrictions that apply to ensure that advertisements are 'objective, complete, and not misleading' under BPOM Regulation 2/2021 are the following:

Objective

- The information provided in the advertisement must be the same as the information approved in the marketing authorisation.
- Advertisements may not include claims that they are 'safe', 'harmless', 'free of/without side effects' or other claims with the same meaning without adequate information to support the claims.
- Claims of awards and the like obtained must not be used in advertisements, even if they are supported by written statements from the relevant authorities or other sources.
- Advertisements must not provide information or give the impression that the use of the drugs/medicines can provide energy, health, vitality, fitness, good shape, growth, intelligence/brilliance/achievement, overcome stress, improve/restore mood, increase sexual ability, matrimonial happiness or other claims with similar meanings.
- Advertisements must not give the impression that they are preventive or suggest the use or consumption of the drugs/medicines before engaging in activities, before falling sick or for the prevention of disease, except according to the approved indications.
- Advertisements must not include information that the drugs/medicines do not contain certain ingredients that are irrelevant or useless for consumers.
- Asterisks (*) must not be used in advertisements to hide, mislead, confuse or deceive the public about the quality, price or anything else about the drug/medicine.
- Advertisements must not include requirements that should have been met (eg, Good

Manufacturing Practices (*Cara Pembuatan Obat yang Baik* or CPOB) and clinically tested).

- Advertisements must not include requirements that have nothing to do with the quality of the drug/medicine (eg, ISO).
- Advertisements must not highlight certain parts or content to promote the superiority of the drug/medicine.
- Drugs/medicines with more than one ingredient must not be advertised by prioritising the use of each active ingredient so that the drugs/medicines appear to have more benefits than have been approved.
- Advertisements must not include claims or visualisations that give the impression that the drugs/medicines are herbal/traditional medicines.
- Drugs/medicines that are beneficial for certain age groups may not be promoted to other age groups.
- Advertisements must not contain hyperbolic expressions or visualisations that are beyond human reason unless they satisfy the required conditions and the message they convey is not misleading.
- Advertisements must not display visualisations or use words that give the impression of an instant/fast effect, except for fast-acting drugs/medicines.

Complete

- Advertisements must include the following information:
  - the composition of the active substance and the strength of the drug/medicine (especially in visual media);
  - the approved indications;
  - the trade name;
  - the name of the marketing authorisation (*izin edar*) holder;
  - the marketing authorisation number (only for visual media);
  - the advertising approval number (only for visual and audio-visual media); and
  - contact information for public information services (especially for visual media).
- Advertisements that include more than one drug/medicine must include the indication for each drug/medicine.
- If the holder of the marketing authorisation changes but new approval has not been issued yet, during the transition period, the name and logo of the new marketing authorisation holder can be included, provided the name of the previous marketing authorisation is also included.
- Attention must be directed to the following warnings:
  - read the instructions for use, if the pain persists, contact a doctor; or
  - read the instructions for use (specifically for drugs/medicines included in the vitamin category).
- The above warnings must satisfy the following requirements:
  - For advertisements in visual media, the warnings must have the same proportions as the advertising page, with a white base colour and black text or black base colour with white text to make them attract attention and be clearly legible.
  - For advertisements in audio media, the warnings must be read out at the end of the advertisement in a clear and firm tone of voice.
  - For advertisements in audio-visual media, the warnings must be provided in clearly legible writing on the last slide or image, with a minimum size of 30 per cent of the electronic screen, and must be displayed for at least three seconds or ten per cent of the total duration of the advertisement.
  - Warnings do not have to be included in advertisements aimed at health professionals.

Not misleading

- The presentation method must not create a specific perception for the public that results in the excessive or incorrect use of the drug/medicine.
- Advertisements must not be performed by and/or contain statements, recommendations or drug/medicine recommendations from health professionals, laboratory officers, government agencies, health professional organisations, religious leaders, teachers or public officials.
- Advertisements must not use settings/locations/backgrounds/atmospheres that indicate health services, laboratories, schools, scientific meetings, mass gatherings, religious rituals or other settings/backgrounds that may be misleading.

- Advertisements must not use such superlatives as 'the most', 'number one', 'top', 'right' or words starting with '*ter-*' (the Indonesian equivalent of the English superlative word endings 'est', or 'the best'), or similar terms with the same meaning.
- Advertisements must not promote drug/medicine side effects. The side effects of drugs/medicines can be provided as information, but not featured as advantages of the advertised product.
- Advertisements must not include a guarantee regarding the efficacy/safety of drugs/medicines, for example, by using the word 'definitely'.
- Advertisements must not include a comparison with other products, unless it is beneficial for consumers, not misleading and does not give the impression that a product is better than other products.
- Advertisements must not include information that encourages continuous use, for example, by using the words 'always', 'routine' and other words that have the same meaning.
- Advertisements must not make claims for or describe a product as if it were a food product, for example, by claiming that it is fresh, delicious, mouthwatering or tasty.
- Advertisements must not exploit superstitions or abuse the trust and ignorance of the public.
- Advertisements must not misuse scientific, statistical or graphic terms to mislead the public or create an exaggerated but meaningless impression.
- The method of presentation must not create a special perception for the public that results in the excessive or incorrect use of the drug/medicine.
- Advertisements for drugs/medicines that can cause drowsiness may not be use actors playing roles involving work that requires concentration regarding their own safety or their surroundings, such as driving a motor vehicle or operating machinery.
- Advertisements must not link the consumption of certain foods to an illness or recommendations for the use of drugs/medicines.
- If foreign languages or terms are used, they must be accompanied by their equivalent in Bahasa Indonesia so as not to be misleading.

Other restrictions

- Advertisements must not display scenes, pictures, signs, writings, sounds or anything else that does not comply with the prevailing norms of decency and culture in society.
- Advertisements must not be directed at children or show children without adult supervision (child endorsement).
- Advertisements must not depict the decision to use the drug/medicine being made by children.
- Advertisements must not include the name of a facility that does not have a pharmacy licence, drug store licence or another facility that does not have pharmacist in charge.
- Advertisements must not promise to give gifts in the form of any goods or services associated with the sale or use of drugs/medicines.
- Advertisements must not stigmatise, insult, demean or disparage any person or group of people.
- Advertisements must not plagiarise advertising materials of other companies.
- Advertisements must not be associated with worship or other religious activities.
- Advertisements must not display any form of discrimination, including that based on ethnicity, nationality, religion, gender, age, disability or sexual orientation.
- *Halal* labels or words must not be used as the main message with the aim of seducing or influencing the buying process. *Halal* labels or the word *halal* can only be included as information or a fact.
- Educational materials, whether in advertorial or other forms, are not treated as advertisements so that there is no bias between education and advertisements.
- Advertisements must not use testimonials, which include either names, initials or signatures that can imply that the advertisement is an experience or official statement of the actor.
- The same advertising material must not be displayed side by side or displayed again more than twice so as not to be redundant.

Furthermore, the New Health Law adds that pharmaceutical supplies (including drugs/medicine) cannot be promoted if they do not meet safety, efficacy/benefit, and quality standards and/or requirements.

Medical devices

The same applies to advertising medical devices; if the devices require the assistance of medical professionals or a doctor's prescription, they can only be advertised in medical and pharmaceutical

scientific print media and scientific forums within the professional healthcare environment. MOH Regulation 76/2013 prohibits the following content from being included in medical device advertisements:

- content that is misleading through emphasis, conspicuous comparisons or the omission of facts;
- comparisons with similar products with the intention of degrading them;
- any direct or indirect encouragement of excessive or unnecessary use of medical devices;
- any exploitation of public ignorance by providing unvalidated or unverifiable scientific data;
- the ınstigation of fear or the utilisation of myths existing in the community;
- the provision of testimonials;
- the use of names, initials, logos, symbols or references suggesting endorsement by health sector institutions or organisations;
- the use of confusing medical jargon or slogans;
- the misuse of research results or quotes from technical or scientific publications;
- direct or indirect suggestions that the device can prevent disease;
- words, sentences or illustrations that claim or give the impression that the device can cure a disorder or disease;
- direct or indirect suggestions that the medical device can prevent, slow down or reverse physiological changes and degenerative conditions related to or associated with aging;
- claims or impressions that the medical device is perfect, guaranteeing that it will provide certainty of recovery;
- content that disregards primary treatment, or offers specific advice, diagnosis or treatment for a serious or chronic illness;
- content that includes or features healthcare professionals or actors portraying healthcare professionals or uses healthcare professional attributes, except for advertisements only published in health magazines, healthcare service advertisements and scientific forums within the professional environment;
- advertisements for medical devices not intended for children may not use or feature children unaccompanied by adults; and
- if they target children, advertisements must not display psychologically disturbing content or exploit children's trust, inexperience or innocence.

More detailed guidelines on practices that are acceptable and restrictions on medical device advertising can be found in the appendix of MOH Regulation 76/2013.

The New Health Law adds that medical devices cannot be promoted if they do not meet safety, efficacy/benefit, and quality standards and/or requirements.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

Yes. Advertising pharmaceuticals in social media to the general public is permitted, as long as the pharmaceuticals are not classified as prescription drugs/medicines, narcotics or psychotropics because they can only be advertised to health professionals.

The same applies to advertising medical devices. They can be advertised in electronic media, which includes social media platforms. However, as explained above, if the use of the medical device requires professional assistance or a doctor's prescription, it can only be advertised in medical and pharmaceutical scientific print media and scientific forums within the professional healthcare environment. The following additional requirements apply when advertising medical devices in electronic media:

- Advertisements featuring dramatisations must include the disclaimer, 'This Scene is Dramatized', and those featuring dangerous scenes must include the warning 'Dangerous Scene, Do Not Imitate'.
- Scenes unsuitable for infants and children must be labelled 'Parental Guidance Required' or with a symbol with the same meaning.
- Text visualisations must meet the legibility and clarity requirements.
- Advertisements for medical devices and household health supplies must not solely feature children under the age of five in any way, unless the medical devices and household health supplies are intended for this age group.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

Yes, prior approvals from authorities are required as explained further below.

Advertising approval for pharmaceuticals

Drugs/medicines that are advertised to the general public require advertisement approval from BPOM. Advertising approval can only be applied to drugs/medicines for which marketing authorisation has been obtained. Applications for advertising approval must be submitted to the BPOM through the BPOM's online system called SIAPIK. To submit an application, the applicant must pay a certain application fee to the BPOM. The applicant must also submit among other items: the drug/medicine's marketing authorisation certificate; the approved label design or label; the advertisement's design; Indonesian translations of all documents in foreign languages or local languages other than English; and any other supporting documents that the BPOM may request.

The BPOM will evaluate the complete application documents and decide whether to grant or reject the application. After completing the evaluation, the BPOM will issue a decision based on the results in the form of an approval or rejection. Advertising approval will be valid for as long as the marketing authorisation for the drug/medicine remains valid and as long as it meets the criteria/requirements for advertising the drug/medicine.

Advertising approval for medical devices

Applications for medical device advertising approval must be submitted to the MOH electronically through **http://regalkes.kemkes.go.id**. Applications must be accompanied by the business licence (medical device distributor's licence), the medical marketing authorisation of the medical devices, the labelling that has been approved, along with the approved brochures (if any), the advertising plan and so on.

If the application is considered complete, the applicant must pay the application fee. Advertisement approval will be received within five days after the payment has been verified.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

The prevailing laws governing pharmaceutical or medical device advertising in Indonesia do not recognise the term 'off-label promotion'. However, the IPMG Code specifically defines off-label promotion as the promotion of certain products before they obtain marketing authorisation or information about certain products for which a licence has not been obtained.

Therefore, neither pharmaceuticals nor medical devices may be advertised without marketing authorisation.

The IPMG Code provides certain exemptions allowing drugs/medicines for which marketing authorisation has not been obtained to be discussed. For instance, they can be discussed by scientists and the public led by a medical department, to obtain information about progress with certain research. However, such discussions should not be a promotion, but must be unbranded, balanced, up-to-date and intended to improve the quality of patient care. Such discussions should not limit public disclosure to shareholders and other parties concerned about the relevant product. Proposals for a discussion and communications about off-label products must be accompanied by:

- an explanatory statement to the effect that the product or indication has not yet been approved by the relevant Indonesian authorities; or
- an explanatory statement to the effect that registration conditions differ internationally; and
- an explanatory statement identifying the countries in which the product is registered and making it clear that it is not available locally.

Similar provisions are also regulated under the GPFI Code, whereas a product may not be promoted before marketing authorisation is obtained from BPOM. However, this provision is not intended to limit the rights of any scientific community and the general public in advancing the field of science and medicine.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

Pharmaceuticals

Under BPOM Regulation 2/2021, advertisements of pharmaceuticals may not include statements comparing them to other products, unless the claims are beneficial to consumers, not misleading and do not give the impression that they are superior to the compared products. In addition, advertisements must not copy advertisements for other brands.

Under the IPMG Code, as well as the GPFI Code, the following requirements apply when comparing products:

- Comparisons between products should be honest, based on facts proved by current scientific evidence. When presenting the results, there should be no attempt to deceive by distortion, unreasonable emphasis or other means. In addition, inappropriate or insulting comparisons with competitors' or their products should be avoided.
- Comparisons of efficacy and safety between different products should be based on valid published data to include all the aspects of efficacy and safety, for example, whether it is head-to-head data, non-comparison data or data based on one parameter only should be clearly stated in the reference.
- Data used to support comparative claims should satisfy the requirements for statistical significance. If the data does not meet these requirements, it should be clearly marked as such and should not be used to generalise or support claims of equality with or superiority over another product. The statistical significance indicator (the 'p' value) should accompany comparative data. In addition, imitating or copying the marketing/promotional/advertising materials of other products might cause them to be misleading or cause confusion.

Medical devices

Comparing medical devices is prohibited if the intention is to degrade a competitor's products (either directly or indirectly). However, comparing medical devices is allowed if it meets the following criteria under MOH Regulation 76/2013:

- direct comparisons can be made, but only of the technical aspects of the product and using exactly the same criteria;
- if the direct comparison involves research data, the methodology, source and timing of the research must be disclosed clearly;
- the use of research data must be approved or verified by the organisation that conducted the research;
- ındirect comparisons must be based on criteria that do not mislead the audience;
- product comparisons must not mention other brands; and
- price comparisons in advertisements are only allowed regarding the efficiency and the benefits of using the products and must be accompanied by a sufficient explanation.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

Law No 17 of 2023 on Health defines medical professionals (*tenaga medis*) as individuals who dedicate themselves to the field of health and have a professional attitude, knowledge and skills acquired through medical or dental education, who require authorisation to engage in health efforts. It defines health professionals (*tenaga kesehatan*) as individuals who dedicate themselves to the field of health and have a professional attitude, knowledge and skills acquired through higher education, some of whom require authorisation to engage in health efforts.

Advertisements aimed at medical or healthcare professionals are allowed. The main restrictions are

explained in the response to Question 13 below.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

MOH Regulation 76/2013 acknowledges advertisements for both pharmaceuticals and medical devices in print, electronic, information technology and outdoor media. However, specific provisions apply to advertising pharmaceuticals and medical devices as explained below.

Advertising pharmaceuticals

The only advertisement platforms acknowledged under BPOM Regulation 2/2021 are visual, audio and audio-visual media. The IPMG Code does not specifically cover online interactions with healthcare professionals, virtual meetings or participation in virtual congresses and symposia, or other 'virtual' meetings. However, it does contain provisions on holding offline scientific discussions.

To hold scientific meetings, IPMG members must ensure that:

- the agenda includes valid scientific content;
- IPMG members do not provide or finance entertainment events or other social activities (concerts and tourism packages) or provide free lunch boxes without holding any scientific discussion and so on; and
- the meetings or discussions are held in an appropriate location and venue that is appropriate for the scientific or educational objectives and the purpose of the event.

The IPMG Code prohibits members from organising or sponsoring events for healthcare professionals that can take place outside of Indonesia, unless appropriate and justifiable from the logistical or security point of view.

Advertising medical devices

For medical devices requiring assistance from healthcare professionals, MOH Regulation 76/2013 allows promotional and advertising activities to be conducted through medical and pharmaceutical scientific print media and scientific forums held in the healthcare professional environment. Therefore, advertisements and promotions are only permitted in scientific discussions in the healthcare environment.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?

Yes. The following restrictions apply to advertising both pharmaceuticals and medical devices.

Advertising pharmaceuticals

Endorsements by healthcare professionals are prohibited. BPOM Regulation 2/2021 prohibits advertisements being acted in and containing statements, recommendations or drug/medicine recommendations made by health professionals, laboratory personnel, government agencies, health professional organisations, religious leaders, teachers or public officials.

In addition, under the IPMG Code and GPFI Code, the names or photographs of healthcare professionals or organisations should not be used in promotional/advertising materials in ways that violate the Indonesian Medical Code of Ethics. However, it is acceptable to use names and photographs in scientific meetings (eg, if a healthcare professional conducts a presentation), but it is not acceptable to do so in promotional brochures, journal advertisements and so on.

Advertising medical devices

Like those advertising pharmaceuticals, advertisements for medical devices may not include or show healthcare professionals or actors portraying healthcare professionals or use the attributes of healthcare professionals, unless they are only published in health magazines, health service advertisements or professional scientific forums. Further, as explained in the response to Question 5, testimonials are also prohibited in advertisements for medical devices.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

No, it is prohibited. MOH Decree No 437/MEN.KES/SK/VI/1987 on the Prohibition of Production, Imports, Distribution, Dispensing, and Medicine Samples, stipulates that pharmaceutical businesses and manufacturers are prohibited from providing samples of drugs to doctors, healthcare workers and/or other healthcare facilities. The IPMG and GPFI Codes also provide that sending samples of pharmaceutical products to members of the health professionals is prohibited. Therefore, companies are not allowed to send product samples to health professionals, unless they obtain special permission from the competent authority.

Further, BPOM Regulation 2/2021 prohibits advertisements promising gifts in the form of goods or services of any kind in connection with the sale or use of drugs/medicines. The Consumer Protection Law also prohibits businesses from offering, promoting or advertising either pharmaceuticals or medical devices by promising prizes in the form of other goods or services.

In line with the above, the IPMG Code provides that IPMG members are prohibited from offering any kind of inducement, door prize, incentive or financial reward to healthcare professionals.

More specifically, under the IPMG Code:

- providing free samples of pharmaceutical products to healthcare professionals is prohibited, unless exceptional approval has been granted by the BPOM or MOH (the relevant authorities);
- donations are also strictly prohibited and may not be given directly to healthcare professionals (see Question 15 below); and
- grants may not be given for promotional purposes; they may only be given to healthcare organisations in response to unsolicited requests for the purpose of supporting healthcare or medical education, or scientific research.

The GPFI Code also prohibits the offering of gifts, awards, incentives, donations, financial support and similar forms to health professionals associated with prescribing or recommending the use of the company's drugs or products. Gifts and donations are permitted only for institutions and must benefit patients or contribute to the education of health professionals at the institution. Additionally, they must not be linked to product standardisation or the purchase, prescription or use of the company's drugs or products at the institution.

14. What rules govern the offering of hospitality to healthcare professionals?

The general principles that apply to offering hospitality and interactions with healthcare professionals are provided in the IPMG Code. They include the following:

- Interactions between IPMG members and healthcare professionals must be intended to benefit patients and enhance the practice of medicine. They should focus on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.
- No transfer of value may be provided or offered to healthcare professionals in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on the healthcare professionals' prescribing practices.
- IPMG members must report any sponsorship given to healthcare professionals to the relevant government institutions. To ensure transparency, advance written approval must be obtained for any sponsorship or service agreement with an individual healthcare professional. The authorised officer of the healthcare professional's employer must obtain written approval. The details of the sponsorship or service agreement must be stated clearly in written documentation signed by both parties.
- Member companies are prohibited from offering any kind of inducement, door prize, incentive or financial reward to healthcare professionals.
- A written agreement must be entered into in advance before engaging a healthcare professional as a speaker, moderator, adviser, consultant and so on. The agreement must at least state the

healthcare professional's role and responsibilities, compensation and obligation to describe him/herself as a speaker, moderator, adviser, consultant and so on to the member company when writing or speaking, and to maintain confidentiality, data privacy protection and a transparency report.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

The advertising platforms acknowledged under BPOM Regulation 2/2021 are only visual, audio and audio-visual media, and MOH Regulation 76/2013 only acknowledges advertisements published in print, electronic, informational technology and outdoor media. The IPMG Code contains specific provisions on making donations to healthcare institutions and organisations.

The IPMG Code defines donations as financial or physical contributions given typically for charitable purposes or to benefit patients. The following provisions apply to donations:

- donations can only be given to government or non-profit organisations in response to unsolicited requests, except in the event of a catastrophe, when IPMG members may voluntarily make donations to eligible third parties;
- donations may not be given directly to healthcare professionals or to charities nominated by healthcare professionals;
- donations should provide a benefit for patients; and
- donations may not be made in return for products purchased or product standardisation, or the prescription or use of an IPMG member's product by employers of healthcare professionals (government or private).

As elaborated in the response to Question 13, offering donations and similar forms to health professionals associated with prescribing or recommending the use of the company's drugs or products is prohibited under the GPFI Code. Furthermore, donations are permitted only for institutions and must benefit patients or contribute to the education of health professionals at the institution.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

Under MOH Regulation 76/2013, medical devices that require professional assistance can be advertised in scientific or educational meetings in the health sector.

IPMG members can sponsor scientific events in the health sector for pharmaceuticals, as long as the purpose is to provide balanced scientific or educational information or inform healthcare professionals about products. IPMG members can only sponsor scientific events if they comply with the following requirements:

- their agenda includes valid scientific content;
- IPMG members are prohibited from providing or financing entertainment events or other social activities (concerts and tourism packages), or providing free lunch boxes without having any scientific discussions and so on; and
- the meetings or discussions are held in appropriate locations and venues appropriate to the scientific or educational objectives and purposes of the events.

In addition to the above, under the GPFI Code, any support provided to a health professional to attend a scientific meeting should not be conditioned/associated with an obligation to promote or prescribe a product.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

As an overview, the IPMG Code requires the following principles to be complied with when interacting with patient organisations:

- All interactions and programmes with patients, caregivers and patient organisations must be ethical; conducted with integrity and mutual respect; protect the right to privacy, and appropriately manage and protect personal information; and ensure full transparency.
- The independence of patients, caregivers and patient organisations must be respected.

- Interactions between patients and IPMG members must not interfere with the physician-patient relationship and must be voluntary.
- Patient support provided by IPMG members can never be an inducement to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.

If IPMG members wishes to engage with patient organisations, the following requirements also apply:

- IPMG members may provide financial support for patient organisation meetings, provided that the primary purpose of the meeting is professional, educational and scientific in nature, or otherwise supports the mission of the patient organisation.
- IPMG members must ensure that the venue, location and any meals or refreshments provided by a company comply with the IPMG Code.
- An IPMG member may not require a company to be the sole funder of the patient organisation or any of its programmes, unless this is offered or required by the patient organisation itself, as long as the company does not make its support conditional on it being the sole funder.
- IPMG members should avoid being the majority annual funder of a patient organisation and patient organisations should be encouraged to seek financial support from a wide variety of sources. In some circumstances, such as rare diseases afflicting small patient populations and with limited treatment options, it may not be possible for IPMG members to avoid being the majority or sole funder of a patient organisation.
- It may be appropriate for IPMG members and patient organisations to partner or collaborate on specific projects in which IPMG members provide all the financial support needed for the project.
- The support provided by IPMG members for patient organisations should be disclosed in a manner that provides reasonably sufficient information about the IPMG members' support or collaboration on the occasion of the relevant event. IPMG members and patient organisations are encouraged to voluntarily disclose the support on their websites.
- Interactions between IPMG members and patient organisations should be structured to enable knowledge sharing, unless legitimate intellectual property, competitive or regulatory restrictions apply that may restrict public dissemination of the collaboration.
- Non-healthcare professionals' representatives of patient organisations may not attend as participants in promotional or scientific meetings or events.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

This is not specifically prohibited. Therefore, we believe that this is allowed, as long as advertising approval has been obtained.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

The IPMG Code defines the transfer of value as the provision of any benefit to healthcare professionals, including, but not limited to, healthcare professionals' sponsorship to attend meetings, healthcare professionals' engagement by IPMG members as speakers/moderators/consultants/the advisory board, business meals, items of medical utility and promotional reminders.

If the transfer of value is based on sponsorship provided to a healthcare organisation or healthcare professional, the IPMG member must report such sponsorship to the relevant bodies.

This obligation is also outlined in MOH Regulation No 58 of 2016 on Sponsorship to Healthcare Professionals ('MOH Regulation 58/2016'), as well as MOH Circular Letter No HK.02.01/MENKES/66/2017 of 2017 on the Mechanisms of Sponsorship Reports in line with MOH Regulation 58/2016, whereas the sponsorship providers (which includes pharmaceutical and medical device producers) and receivers must report such sponsorship to the Corruption Eradication Commission and forward the report to the MOH. Sponsorship providers must submit the recapitulation report of all sponsorship given in a one-month period, at the latest, on the tenth day of the following month. Meanwhile, the recipient must submit the report, at the latest, 30 business days after receiving sponsorship.

Note that sponsorship given to healthcare providers must:

- not affect independence in providing health services;
- not be in the form of money or other forms equivalent to money;

- not be granted directly to individuals;
- be openly granted; and
- be managed in an accountable and transparent manner.

Sponsorship in the form of cash may only be given if it is for the fee of the speaker or moderator.

In addition to the above, the following provisions of the IPMG Code on transfers of value must be complied with:

- No transfer of value may be provided or offered to healthcare professionals in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on the healthcare professional's prescribing practices.
- Transfers of value to healthcare professionals or others in connection with patient programmes should be commensurate with the work performed, and payments should never constitute an inducement (or have the appearance of an inducement) to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

Pharmaceuticals

The following progressive administrative sanctions may be imposed for violating BPOM Regulation 2/2021:

- a warning;
- a stern warning;
- a temporary suspension of advertising activities;
- the suspension of marketing authorisation; and
- the revocation of the holder's marketing authorisation.

Under the IPMG Code, violations are categorised as either minor or major violations. Minor violations include, but are not limited to, providing cultural courtesy gifts, undermining another company's sponsored scientific event and providing door prizes, while major violations include making untrue claims in promotional materials, off-label promotions, sponsoring spouses of healthcare professionals, providing extravagant facilities to healthcare professionals and paying cash for prescriptions.

The sanction depends on whether the offence is the first or subsequent offence.

First offence

If the violation is the company's first offence, the following sanctions will be imposed:

- the IPMG Ethics and Compliance Task Force will serve a written warning on the General Manager concerned under a final and binding decision (cc the IPMG secretariat); and
- for a major violation, the violating company must pay a US$2,000 fine.

Second offence

For a second offence, the following sanctions will be imposed:

- the IPMG Executive Committee will send a written warning to the general manager concerned, if the violation is categorised as minor; or
- send an official letter to the senior management at the global headquarters of the violating company, if the violation is categorised as major; and
- the IPMG Executive Committee will invite the general manager to a meeting with the Executive Committee to explain the company's behaviour; and

- the violating company must pay a fine of up to US$2,000 for a minor violation or US$5,000 for a major violation.

Further offences

If the violation is a further offence, the following sanctions will be imposed:

- the IPMG Executive Committee will send an official letter to the senior management at the global headquarters of the violating company; and
- invite the general manager to a meeting with the Executive Committee to explain the company's behaviour; and
- the violating company must pay a fine of US$5,000 for a minor violation or US$20,000 for a major violation.

Medical devices

For violating the requirements and restrictions under MOH Regulation 76/2013, the advertiser must rectify, withdraw, delete or cease publishing the advertisement within seven working days of receiving notice. Failure to do so may result in the Directorate General of Pharmaceutical and Medical Devices taking the following action:

- issuing written notification of a warning notice;
- revoking approval for the advertisement; and
- revoking the medical devices' marketing authorisation.

In addition to the above, under GR 72/98, for advertising medical devices and pharmaceuticals that can only be purchased with a doctor's prescription in print media, other than in scientific print media or scientific pharmaceutical print media, a criminal fine of IDR 10m may be imposed.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

Pharmaceuticals

The Head of the BPOM is responsible for the enforcement and imposition of sanctions. The supervisory team of the BPOM supervises advertising activities. In addition, the general public (which includes competitors) can report potentially non-compliant advertisements electronically to the BPOM through:

- the BPOM's official email address for public complaints at halobpom@pom.go.id; and
- the hotline number for public complaints, 1500533.

Reports can also be submitted in writing to the Director of the Security, Quality and Import-Export of Drugs/Medicines, Narcotics, Psychotropics, Precursors and Addictive Substances.

Complaints can also be submitted to the IPMG Ethics & Compliance Task Force. Complaints must provide the complainant's details; the company involved; reference materials; and the date, location and name of the event; as well as a summary of the allegation for it to be processed by the IPMG Ethics & Compliance Task Force.

Regarding GPFI, complaints can be submitted to the Chairman of the Board of Advisors of the GPFI Code.

Medical devices

The administrative sanctions described in the response to Question 20 are imposed by the Directorate General of Pharmaceuticals and Medical Devices. For a medical device advertising infringement, the competitor can first report the infringement through the MOH's 'Mobile Alkes' application, available at **https://mobilealkes.kemkes.go.id**. The MOH's supervisory team will then follow up on the report.

FUTURE DEVELOPMENTS
22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?
The Indonesian Government recently issued the New Health Law. While the government is currently preparing its implementing regulations, it remains to be seen whether significant changes will be made to the regulations on the promotion of pharmaceuticals and medical devices as the New Health Law does not contain any relevant provisions.