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Indonesia

PHARMACEUTICAL ADVERTISING

Contributing firm

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Indonesia.

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INDONESIA
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

Advertising on medicine in Indonesia is regulated by several regulations and decrees. The main source of regulation is Minister of Health ("**MOH**") Decree No. 386/MEN.KES/SK/IV/1994 of 1994 dated April 21, 1994, regarding Guidelines on the Advertising of Over-the-Counter Medicines, Traditional Medicines, Medical Devices, Cosmetics, Household Health Supplies, and Food and Beverages. That decree has been partially revoked and amended by MOH Regulation No. 76 of 2013, Head of Food and Drug Supervisory Board (*Badan Pengawas Obat dan Makanan* or "**BPOM**") Decree No. HK.00.05.3.02706 of 2002 dated August 30, 2002, regarding Promotion of Medicines ("**BPOM Decree 2002**") and Head of BPOM Regulation No. 8 of 2017 dated May 31, 2017, regarding Guidelines for the Supervision of the Advertising of Medicines ("**BPOM Reg. 8/2017**"). In additions, advertisements for medicines must comply with the consumer protection provisions under Law No. 8 of 1999 dated April 20, 2000, regarding Consumer Protection ("**Consumer Protection Law**").

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

The Indonesian Pharmaceutical Association (*Gabungan Perusahaan Farmasi Indonesia* or "**GP Farmasi Indonesia"**) has a code of ethics for pharmaceutical marketing that it enacted on December 19, 2016 ("**GP Farmasi Indonesia Code of Ethics**"). And the Association of International Pharmaceutical Manufacturers Group ("**IPMG**") has a code of ethics for the marketing of pharmaceutical products in Indonesia, which was revised in September 2019 ("**IPMG Code of Ethics**").

a. If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The GP Farmasi Indonesia Code of Ethics applies to the members of GP Farmasi Indonesia, which are companies/businesses engaged in the production, distribution and servicing of medicines, the raw ingredients for medicines, phytopharmaca or herbal medicines, and medical supplies. GP Farmasi Indonesia members may also be pharmaceutical supporting businesses such as distributors, pharmacies, drugstores, etc.

The IPMG Code of Ethics is applicable to IPMG members, which comprise 25 research-based multinational pharmaceutical companies operating in Ib.

b. What is the legal status of the self-regulatory codes?

The codes of ethics of GP Farmasi Indonesia and IPMG are legal instruments issued by the associations that serve as guidelines applicable only to their respective members.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

"Medicine Advertisement" or "Advertisement" is defined in BPOM Reg. 8/2017 as any information or description of medicines in the form of pictures, writing or any other form presented in various manners for the marketing and/or trading of medicines.

a. What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

"Advertisement" as defined by BPOM Reg. 8/2017 covers print media (i.e. newspapers, leaflets, booklets, pamphlets, etc.), electronic media (i.e. television and radio), and outdoor media (i.e. billboards, signboards, banners, etc.) (BPOM Reg. 8/2017, Article 4).

b. Does the definition apply equally to all target audiences?

The definition of "advertisement" applies equally to all target audiences. However, please note that Article 3(1) of BPOM Reg. 8/2017 provides that for prescription medicines, advertising is allowed only through medical or scientific publications targeted at medical and pharmaceutical professionals.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Yes, press releases on medicines are allowed in Indonesia. Such press releases would be considered advertising medicines through print media. As such, the general requirements and restrictions on advertisements for medicines are applicable to press releases. Please refer to our answer in Question 9 below.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

The advertising of medicines requires the approval of BPOM ("**Advertising Approva**l"). The holder of a Marketing Authorization (*Izin Edar)* for medicines can submit an Advertising Approval application to BPOM by completing the application form and the required supporting documents as provided in the Attachment to BPOM Reg. 8/2017. A team from BPOM will evaluate the content of the advertisement and may require the applicant to revise or supplement the content of the advertisement. BPOM shall issue or deny the Advertising Approval within 60 working days after receiving an application that is deemed complete (BPOM Reg. 8/2017, Articles 10 – 16). Note that it is not necessary to obtain an Advertising Approval for medicine advertisements that only contain the names of the medicine and the pharmaceutical company (BPOM Reg. 8/2017, Article 8(2).

6. Do companies have to have material approved by regulatory bodies prior to release?

The material or content of medicine advertisements must be approved by BPOM prior to its release or publication (BPOM Reg. 8/2017, Article 13).

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Medicine advertisements are prohibited from containing any comparative statement referencing other medicines or products, unless such claim is for the benefit of consumers, is not misleading and does not imply that the advertised medicine is better than other medicines or products (BPOM Reg. 8/2017, Section A 2 letter f of Attachment IV).

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

Any information regarding a certain medicine may only be disseminated if the relevant medicine Marketing Authorization (*Izin Edar*) has been obtained for medicine (BPOM Reg. 8/2017, Article 8). This also applies to scientific conferences for healthcare professionals or any other form of information distributed to healthcare professionals.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

Prescription only medicines are only permitted to be advertised in medical or scientific publications for the pharmaceutical industry. Over-the-counter medicines can be advertised to the general public. In general, information contained in a medicine advertisement must be objective, complete and not misleading. Medicine

advertisements must be made and disseminated using the Indonesian language or a local language (*bahasa daerah*) (BPOM Reg. 8/2017, Article 9 paragraphs (1) and (2). The use of a foreign language such as English in medicine advertisements is permitted provided that an Indonesian equivalent version of the medicine advertisement is included. There are several restrictions applicable to the information and educational materials contained in a medicine advertismenet, the people who appear in the advertisement and the advertisement setting (background, location, scene etc.) . For example, a medicine advertisement cannot contain any guarantee on the efficacy/safety of the medicine or superlative statements, promote or allow any form of discrimination, use health professionals or actors actresses who act as health professionals, use any settings displaying health services, laboratories, schools, etc. Specific medicines require the inclusion of certain information, such as “may cause drowsiness” for cold and cough medicines, “a healthy diet may reduce the symptoms of gastric problems” for ulcer medications, etc. (BPOM Reg. 8/2017, Attachment IV).

The Consumer Protection Law provides a general rule that advertisements must not be misleading by promising and then failing to deliver a certain price, time or amount (Consumer Protection Law, Article 12). For medicine advertisements specifically, business actors are not allowed to offer, promote or advertise medicines by promising gifts in the form of goods and/or other services (Consumer Protection Law, Article 13(2)).

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

Interactions between the pharmaceutical industry and patients or patient organizations are regulated in the GP Farmasi Indonesia Code of Ethics and IPMG Code of Ethics. Any program organized with any patient organization must be based on a written agreement, in accordance with the code of ethics, respect the independence of the patient organization and have a clear nature of engagement. Financial assistance may be provided to support meetings of patient organizations organized for professional, educational or scientific purposes, or which support the mission of the relevant patient organization.

IPMG members are specifically prohibited from becoming the sole provider of funds for a patient organization or its programs, except when the relevant patient organization requests so, provided that the support of such IPMG member is not a requirement for its appointment as the sole fund provider. Non-healthcare professional representatives of patient organizations are prohibited from attending any meetings or promotional or scientific events as a participant (IPMG Code of Ethics, Article 6; GP Farmasi Indonesia Code of Ethics, Article 11).

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

The content of medicine advertisements directed at healthcare professionals must comply with the provisions of the Attachment of BPOM Reg. 8/2017. Please refer to our answer to Question 9 above.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

Gifts and donations can only be given to institutions, not to healthcare professionals (BPOM Decree 2002, Article 8(2)). Pharmaceutical companies are specifically prohibited from granting any bonus/gift in the form of money and/or goods to prescribers who prescribed their medicines (BPOM Decree 200, Article 9(c)).

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

The practice of pharmaceutical companies providing samples to healthcare professionals in Indonesia is prohibited under MOH Decree 437/MEN.KES/SK/VI/1987 dated June 11, 1987, regarding Prohibition on the Production, Import, Distribution, Delivery and Giving of Medicine Samples. The GP Farmasi Indonesia Code of Ethics and IPMG Code of Ethics also prohibit the practice.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Article 4 of MOH Regulation No. 58 of 2016 dated November 29, 2016, regarding Sponsorship for

Healthcare Professionals ("**MOH Reg. 58/2016**") provides that the sponsorship of healthcare professionals is permitted, provided that:

a. it does not affect the independence of the healthcare professionals in providing healthcare services;

b. it is not given in the form of money or its equivalent (i.e. cheque, giro or *bilyet*, which is a payment instrument with the same function as a cheque);

c. it is not granted directly to individuals but through a health institutions;

d. it is in accordance with the relevant field of expertise;

e. it is given and managed transparently.

Sponsorship in the form of money or some equivalent is only allowed as an honorarium for speakers and/or moderators (MOH Reg. 58/2016, Article 4(2)). The maximum sponsorship amount is specifically regulated in each association's code of ethics (i.e. GP Farmasi Indonesia Code of Ethics and IPMG Code of Ethics). There is no additional restriction applicable to events taking place aboard. All sponsorships received by healthcare professionals through their respective healthcare institutions must be reported to the Corruption Eradication Commission (Komisi Pemberantasan Korupsi or "KPK") within 30 working days following the granting or receipt of such sponsorship (MOH Reg. 58/2016, Article 10). Please refer to our answer to Question 18 below.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

There is no restriction on the organization of non-scientific events in relation to scientific conferences by pharmaceutical companies. However, any educational materials delivered at scientific conferences must be separated from medicine advertisements to avoid any confusion between advertisements, general information materials or public service advertisements that might result in the appearance of bias.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Healthcare professionals, such as doctors, may receive payment for their services. The Indonesian Doctors Association (*Ikatan Dokter Indonesia* or "**IDI**") issued Guidelines on Medical Services Fees for Doctors (*Acuan Tarif Jasa Medik Dokter* or the "**Guidelines**"), which provides recommendations on the fees for specific medical services. Note that as the Guidelines are merely a recommendation, doctors are not obligated to adhere to the fees stipulated therein. To date, there is no binding legal instrument that regulates restrictions or caps on service fees for healthcare professionals.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Please see our answer to Question 12.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

The obligation to report is applicable to the granting of sponsorships to healthcare professionals and/or institutions under MOH Reg. 58/2016. This reporting obligation is incumbent upon the grantor and receiver of such sponsorship. The report from the receiver of the sponsorship shall be submitted to the KPK within 30 working days following the grant or receipt of such sponsorship. The report from the grantor of the sponsorship shall be submitted to the KPK in the form of a recapitulation of the sponsorship granted during the relevant month at the latest on the 10th day of the following month. The content of the reports shall be in accordance with the Attachment of MOH Circular Letter No. HK.02.01/MENKES/66/2017 of 2017 dated February 10, 2017, regarding Mechanisms for Sponsorship Reporting ("**MOH CL 2017**"). The reports must at least include the event's name, location and date, the amount of the sponsorship (i.e. transportation, accommodation, registration, etc.), and details on the sponsorship grantor or receiver. MOH Reg. 58/2016 does not specify whether foreign pharmaceutical companies are subject to the above reporting obligations. However, noting that MOH CL 2017 was addressed to Indonesian pharmaceutical

companies, we may assume that it does not apply to foreign pharmaceutical companies that do not have any physical presence in Indonesia.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

All medicine advertisements must be approved by BPOM prior to their dissemination and/or broadcast. It is expressly prohibited to advertise medicine through social media (BPOM Reg. 8/2017, Article 19(c)).

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

Article 9 of BPOM Decree 2002 prohibits pharmaceutical companies from entering into a cooperation with any pharmacy and/or prescriber to increase the sale of certain medicines. The same Article prohibits pharmaceutical companies from granting any bonus/gift in the form of money (cash, bank draft, loan, voucher, ticket) and/or goods to prescribers (doctors) of the medicines produced by the pharmaceutical companies.

In addition, if a prescriber (doctor) is a civil servant or state administrator and receives money from a pharmaceutical company, the payment may also be subject to bribery charges as regulated under Law No. 31 of 1999 dated August 16, 1999, regarding the Eradication of Corruption, as amended by Law No. 20 of 2001 ("**Anti-Corruption Law**"). Pursuant to Article 12B of the Anti-Corruption Law, any gratuity granted to civil servants or state administrators may be considered bribery if it is related to their job responsibilities and is contrary to their duties or obligations. The elucidation of Article 12B of the Anti-Corruption Law defines gratuity broadly to cover the giving of money, goods, discount, commission, interest-free loan, travel ticket, accommodation and other facilities. The grantor of the gratuity (pharmaceutical company) and the receiver (healthcare professional) would accordingly be subject to criminal sanctions under the Anti-Corruption Law. Note that if the receiver (healthcare professional) of the gratuity reports the gratuity to the KPK within 30 working days of its receipt they many not be subject to criminal sanctions.

Self-regulatory bodies, such as GP Farmasi Indonesia and IPMG, also prohibit the granting or offering of any transfer of value by pharmaceutical companies to healthcare professionals as compensation for the prescription, recommendation, purchase, supply or management of their products or the commitment to continuously perform the same (IPMG Code of Ethics, Article 4; GP Farmasi Indonesia Code of Ethics, Article 5)

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

Please refer to our answer to Question 20 above.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

The regulatory authorities responsible for the enforcement of the rules on advertising and inducements are BPOM and the KPK, respectively. In addition, GP Farmasi Indonesia and IPMG, as associations in the pharmaceutical industry, are authorized under their respective codes of ethics to enforce the rules on advertising of medicine and inducements. For bribery cases, the Corruption Court (*Pengadilan Tindak Pidana Korupsi*) has the absolute authority to adjudge and decide such matters.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

The GP Farmasi Indonesia Code of Ethics provides an avenue for members of GP Farmasi Indonesia to report violations of the GP Farmasi Indonesia Code of Ethics to the Ethics Commission of the GP Farmasi Indonesia, which will assess such reported violations. If any violation is proven, the Ethics Commission shall issue a decision to request the violating member to provide a written guarantee that they will cease from committing such violation and provide restitution. Within 14 days, if the relevant member is unwilling to provide such guarantee and/or the violation persists, the Ethics

Commission may notify BPOM of such violation.

The IPMG Code of Ethics provides that members may report violations of the IPMG Code of Ethics to the IPMG Marketing Practices Sub-Committee. If the IPMG Marketing Practices Sub-Committee finds that:

a. there is not enough proof that there has been any violation, the case shall be closed and the result shall be delivered to the relevant IPMG members;

b. there has been a minor violation of the IPMG Code of Ethics, such finding shall be delivered to the relevant members of the IPMG and reported to the Executive Committee.

c. there has been a major violation of the IPMG Code of Ethics, such finding shall be delivered to the accused member:

i. if the accused member accepts such finding, it shall be delivered to the reporting member and the Executive Committee.

ii. if the accused member rejects such finding and intends to seek a second opinion, they may request a panel trial. The panel shall consist of five company representatives who understand the IPMG Code of Ethics and represent these functions – medical, legal, compliance, regulation and general manager. The panel will issue a final decision regarding the existence of a major violation, which will be further assessed by the Executive Committee. The Executive Committee may accede to the final decision of the panel or adopt an independent decision regarding such major violation.

As provided in our answer to Question 24 below, the sanctions imposed for an advertising infringement may take the form of administrative sanctions imposed by BPOM or criminal sanctions. BPOM administrative sanctions may be triggered if the Ethics Commission of GP Farmasi Indonesia reports any advertising infringement to BPOM or if BPOM finds such infringement independently in conducting its supervision function.

Criminal sanctions under the Consumer Protection Law are usually triggered by a report from an affected consumer or the National Committee for the Protection of Consumers and Business Actors (*Komite Nasional Perlindungan Konsumen dan Pelaku Usaha*) on behalf of the affected consumer. A competing pharmaceutical company may also report such infringement to the police. Criminal proceedings under the Consumer Protection Law shall be under the competence of the District Court (*Pengadilan Negeri*) which jurisdiction covers the domicile of the offending pharmaceutical company.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Advertising

Article 22 of BPOM Reg. 8/2017 provides that any violation of the provisions on advertising as contained in BPOM Reg. 8/2017 shall be subject to administrative sanctions in the form of:

a. suspension of advertisement publication;

b. suspension of advertisement activities for 6 months; and/or

c. cancellation of Marketing Authorization (*Izin Edar*).

Article 61(2) of the Consumer Protection Law provides that any offer, promotion or advertisement of medicine by any business actor by promising gifts in the form of goods and/or services shall be subject to criminal sanctions in the form of imprisonment for a maximum of five years or a maximum fine of two billion rupiah. In addition, Article 62(2) of the Consumer Protection Law provides that any false advertising carried out by business actors shall be subject to criminal sanctions in the form of imprisonment for a maximum of two years or a maximum fine of five hundred million rupiah.

Inducement to Prescribe

Article 10 of BPOM Decree 2002 provides that any violation of the provisions of Article 9 of BPOM Decree 2002 (as referred to in our answer to Question No. 20) shall be subject to administrative sanctions in the form of:

a. written warning;

b. temporary suspension of activities;

c. freezing and/or revocation of Marketing Authorization (Izin Edar) for the relevant medicine; and

d. other administrative sanctions in accordance with the prevailing laws and regulations.

Article 12B(2) of the Anti-Corruption Law provides that civil servants or state administrators who receive any bribe shall be subject to criminal sanctions in the form of imprisonment for at least four years and a maximum of 20 years, and a fine of at least two hundred million rupiah and a maximum of one billion rupiah.

In addition to the above sanctions, Attachment I of the IPMG Code of Ethics provides that any violation to the IPMG Code of Ethics shall be subject to a written warning and fine. And Chapter III of the GP Farmasi Indonesia Code of Ethics provides that any member of GP Farmasi Indonesia that is proven to have violated the GP Farmasi Indonesia Code of Ethics shall be subject to the following sanctions:

a. revocation of membership;

b. notification to BPOM or other authorized institutions of its violation;

c. notification to the parent company or headquarters of the violating company;

d. announcement of the violation in the GP Farmasi Indonesia bulletin; or

e. all of the above.

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

The procedures before or measures taken by the self-regulatory authorities (i.e. GP Farmasi Indonesia and IPMG) are only applicable for violations of their respective codes of ethics and do not extend to violations of statutory provisions. However, as provided in our answer to Question 24 above, GP Farmasi Indonesia may report violations of its code of ethics to BPOM, which may take further measures if such violations amount to a violation of either BPOM Reg. 8/2017 or BPOM Decree 2002. In addition, the GP Farmasi Indonesia Code of Ethics provides that any procedures before or measures taken under the GP Farmasi Indonesia Code of Ethics shall be suspended if any investigation and/or examination by BPOM has commenced in relation to the relevant violation.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

In 2019, BPOM reported that between 2016 and 2018 there had been an increase in the number of medicine advertisements not in compliance with the advertising requirements. Violations included failure to secure approval for the advertisements, advertisement content not in accordance with the approved content, and failure to show the Marketing Authorization (*Izin Edar*). In response to these violations, BPOM issued warnings to the relevant companies and made site visits to the relevant companies' premises. There is no other publicly available information related to the above.

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