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Indonesia

PHARMACEUTICAL ADVERTISING

Contributor

SSEK Legal Consultants

Ira A. Eddymurthy

Partner | iraeddymurthy@ssek.com

Winnie Y. Rolindrawan

Partner | winnierolindrawan@ssek.com

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 medicines in Indonesia is regulated by several regulations and decrees. The main sources of regulation are: (i) 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, which has been partially revoked by MOH Regulation No. 76 of 2013; and (ii) Food and Drug Supervisory Board (*Badan Pengawas Obat dan Makanan* or "**BPOM**") Regulation No. 2 of 2021 dated February 3, 2021, regarding Guidelines on the Supervision of the Advertising of Medicine ("**BPOM Reg. 2/2021**"). In addition, 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?

There are two associations in Indonesia with codes of ethics that apply to the advertising of medicines. These associations are the (i) Indonesian Pharmaceutical Association (*Gabungan Perusahaan Farmasi Indonesia* or "**GP Farmasi Indonesia**"), which is for Indonesian pharmaceutical companies, and the (ii) International Pharmaceutical Manufacturers Group ("**IPMG**"), which consists of multinational pharmaceutical companies.

GP Farmasi Indonesia has a code of ethics for pharmaceutical marketing that it enacted on December 19, 2016 ("**GP Farmasi Indonesia Code of Ethics**"). The IPMG has a code of ethics for the marketing of pharmaceutical products in Indonesia, which was last revised on October 1, 2021 ("**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, phytopharmaceuticals 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 Indonesia.

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. 2/2021 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. 2/2021 covers visual media (i.e. newspapers, leaflets, booklets, pamphlets, billboards, static displays on online media including social media, etc.); audio media (i.e. radio, audio recording on online media including social media, etc.); and audio-visual media (i.e. television, cinema, video recording on online media including social media, etc.) (BPOM Reg. 2/2021, Article 7). Social media as referred to above allows for two-way communication feature services between advertisers and the public, as long as the communication contains information that is objective, complete and not misleading in accordance with the approved advertisement plan. Additionally, BPOM Reg. 2/2021 requires visual media advertisements to include customer service contact information (*kontak layanan informasi masyarakat*).

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

The definition of "Advertisement" applies equally to all target audiences. However, please note that Articles 3 and 9 of BPOM Reg. 2/2021 provide that for potent drugs (*obat keras*), narcotics, and psychotropics, advertising is only allowed through medical or pharmaceutical scientific printed media and directed at healthcare professionals. Furthermore, Article 24 of BPOM Reg. 2/2021 explicitly prohibits the advertising of potent drugs or prescription-only drugs (*obat keras*), narcotics, and psychotropics to the general public.

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 visual media. As such, the general requirements and restrictions on advertisements for medicines are applicable to press releases. Please refer to our answer to 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 the Head of BPOM ("**Advertising Approval**"). The holder of a Marketing Authorization (*Izin Edar*) for medicines can submit an Advertising Approval application to BPOM through the Advertising Approval Application System (*Sistem Aplikasi Persetujuan Iklan* or "**SIAPIK**") website at https://siapik.pom.go.id. The Advertising Approval application must include the Marketing Authorization (*Izin Edar*) approval letter, approved label design or label, advertising design (in the form of print ad for visual media, script for audio media, or storyboard for audio-visual media), the Indonesian translation from a sworn translator of the advertisement if it uses a foreign language other than English, the Indonesian translation of the advertisement if it uses a local language, and supporting documents containing certain information that is not related to the usage of medicine, if required by the BPOM supervisor for the verification process (BPOM Reg. 2/2021, Article 13).

BPOM will evaluate Advertising Approval application documents which are deemed complete within 10 working days for a minor Advertisement and 25 working days for a major Advertisement. Minor Advertisement refers to an Advertisement with a new concept that does not have the potential to cause misinterpretation, or a variation of a previously approved Advertisement with insignificant changes such as changes to included information which was not clear and/or the removal of one or more pieces of information from the Advertisement. Major Advertisement refers to an Advertisement with a new concept that may potentially cause misinterpretation, or a variation of an approved Advertisement with significant changes (BPOM Reg. 2/2021, Article 14). BPOM applies the clock-on and clock-off system in evaluating Advertising Approval application documents, whereby it evaluates the completeness and correctness of the documents, as well as the fulfilment of three main criteria for information in an Advertisement, namely that it be objective, complete, and non-misleading (BPOM Reg. 2/2021, Article 15). Additionally, Article 16 of BPOM Reg. 2/2021 allows the Head of BPOM to form a team to evaluate the Advertisement design. BPOM will issue its approval or rejection of the Advertising Approval application electronically.

Pursuant to Article 18 of BPOM Reg. 2/2021, BPOM also provides notification service through the SIAPIK website for applications to extend the Advertising Approval for the same advertisement or a variation of a previously approved advertisement with changes that would not

change the media type or any meanings, definitions, claims or information relayed in the advertisement. An Advertising Approval will apply as long as the medicine Marketing Authorization (*Izin Edar*) has not expired and the criteria and requirements for the advertisement are still met (BPOM Reg. 2/2021, Article 19).

Note that it is not necessary to obtain an Advertising Approval for medicine advertisements that only contain: (i) the names of the medicine and the pharmaceutical company; (ii) a packshot in accordance with the medicine label design as has been approved by BPOM; (iii) information which is exactly the same as the information on the labeling as has been approved by BPOM; and/or (iv) a price list and/or product catalogue (BPOM Reg. 2/2021, Article 25). Please also note that pursuant to Article 10 of BPOM Reg. 2/2021, an Advertising Approval is only required for advertisements for medicines classified as over-the-counter medicine (*obat bebas*) or restricted-over-the-counter medicine (*obat bebas terbatas*).

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. 2/2021, Article 10). Please refer to our answer to Question 5 above.

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. 2/2021, Section III point 7 of Attachment I).

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 Marketing Authorization (*Izin Edar*) for the relevant medicine has been obtained, and the information disseminated must be in accordance with the approved information contained in the Marketing Authorization (*Izin Edar*) (BPOM Reg. 2/2021, Articles 2 and 4). 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.

Article 2 of BPOM Reg. 2/2021 categorizes medicines into over-the-counter medicines (*obat bebas*), restricted-over-the-counter medicines (*obat bebas terbatas*), potent drugs or prescription-only drugs (*obat keras*), narcotics, and psychotropics. Potent drugs or prescription-only drugs (*obat keras*), narcotics, and psychotropics are only permitted to be advertised through medical or pharmaceutical scientific printed media and directed at healthcare professionals. Over-the-counter medicines (*obat bebas*) and restricted-over-the-counter medicines (*obat bebas terbatas*) 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. Alternatively, the use of a foreign language such as English and/or a local language (*bahasa daerah*) in medicine advertisements is permitted provided that an Indonesian equivalent version of the medicine advertisement is included. However, terms in foreign language may be used if there is no equivalent term in the Indonesian language. Moreover, medicine advertisements may use a local language (*bahasa daerah*) if the advertisements are delivered in a specific area or are intended for consumers from a particular area (BPOM Reg. 2/2021, Article 5).

There are several restrictions applicable to the information and educational materials contained in a medicine advertisement, 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, show any form of discrimination, use and/or contain statements from healthcare professionals,

laboratory officers, government institutions, health profession organizations, religious figures, teachers or public figures, or use any setting displaying health services, laboratories, schools, etc. (BPOM Reg. 2/2021, Attachment I). In addition, specific medicines (i.e. asthma medicines, cough or flu medicines, ulcer (*maag*) medicines, etc.) 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. 2/2021, Article 6 and Attachment II).

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.

The GP Farmasi Indonesia Code of Ethics requires patient relations to be in accordance with the principles of safety, efficacy, and quality, although it does not provide any further stipulations on interaction with patients (GP Farmasi Indonesia Code of Ethics, Article 11).

Meanwhile, the IPMG Code of Ethics requires all interactions and/or programs with patients, caregivers, and patient organizations to be ethical, conducted with integrity and mutual respect, ensure privacy rights by appropriately managing and protecting personal information, and be fully transparent. The interaction between patients and IPMG members must be voluntary and must not interfere with the physician-patient relationship. Moreover, IPMG members also have the obligation to respect the independence of patients, caregivers, and patient organizations and to ensure that their involvement and the nature of such involvement is clear from the outset when working with patients, caregivers, and patient organizations. Any financial support or in-kind contribution provided to any patient organization, or service engagement fees provided to patients, their families, and caregivers by IPMG members must be based on a written agreement which states the nature and purpose of such funding, support, contribution, or service engagement.

The IPMG Code of Ethics allows IPMG members to interact with patients, patient advocates, patient organization representatives, patient experts, and caregivers as individuals in a number of ways, including engaging them as consultants/advisors and/or speakers/panellists. IPMG members are also allowed to provide financial support for patient organization meetings organized for professional, educational, or scientific purposes, or which support the mission of the relevant patient organization.

With regard to patient organizations, IPMG members are specifically prohibited from requiring that they become the sole provider of funds for a patient organization or its programs, except when the relevant patient organization requests or requires so, provided that the support of such IPMG member is not made conditional subject to its appointment as the sole funder. Nevertheless, IPMG members are encouraged to avoid being the majority annual funder of a patient organization, except in certain circumstances where such situation is impossible to avoid. Additionally, the support to patient organizations should be meaningfully disclosed, and preferably also reported on the websites of the IPMG members and patient organizations. Moreover, subject to any restrictions on its public dissemination, the structure of the interactions between IPMG members and patient organizations should enable knowledge sharing. Non-healthcare professional representatives of patient organizations are prohibited from attending any promotional or scientific events or meetings as a participant.

Finally, the patient support and assistance programs of IPMG members must comply with the highest ethical standards, subject to the review and approval of the Medical Department, and be designed solely for the benefit of patients who are treated or will potentially be treated with the products of the relevant IPMG member, including to support the disease outcome management of the patients. IPMG members are also obligated to disclose their involvement in patient programs to patients and healthcare professionals, ensure that such patient programs would not interfere with the relationship between healthcare professionals and patients or undermine decisions on the patients' treatment, as well as ensure the patients' safety through pharmacovigilance procedures and controls by the structuring of the programs. (IPMG Code of Ethics, Article 7).

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 Attachments of BPOM Reg. 2/2021. Please refer to our answer to Question 9 above.

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

The members of GP Farmasi Indonesia and IPMG are strictly prohibited from granting any gifts or donations directly to healthcare professionals. Instead, gifts and donations can only be given to institutions (GP Farmasi Indonesia Code of Ethics, Article 5; IPMG Code of Ethics, Articles 8 and 10). Previously, BPOM Decree No. HK.00.05.3.02706 of 2002 dated August 30, 2002, regarding the Promotion of Medicines prohibited pharmaceutical companies from granting any bonus/gift in the form of money and/or goods to prescribers who prescribed their medicines. The decree has been revoked by BPOM Reg. 2/2021, which is silent on such prohibition.

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 except in the case of an exceptional approval granted by the competent authorities.

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 of 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 institution;
d. it is in accordance with the relevant field of expertise;
e. it is given transparently; and
f. it is managed responsibly and 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 abroad. All sponsorships received by healthcare professionals through their respective healthcare institutions must be reported to the Indonesian 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**") has issued Guidelines on Medical Service 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 Indonesian Corruption Eradication Commission (*Komisi Pemberantasan Korupsi* or "**KPK**") within 30 working days following the 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. The reports shall be submitted by email to the KPK via sponsorship@kpk.go.id, copying the Ministry of Health at sponsorship@kemkes.go.id.

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. Advertising on the internet, including social media, is only allowed for over-the-counter medicines (*obat bebas*) and restricted-over-the-counter medicines (*obat bebas terbatas*). Please see our answer to Question 3.

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

The main regulation for anti-bribery is Law No. 31 of 1999 dated August 16, 1999, regarding the Eradication of Corruption, as amended by Law No. 20 of 2001 dated November 21, 2001, and as partially revoked by Law No. 30 of 2002 dated December 27, 2002, regarding the Corruption Eradication Commission ("**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, discounts, commissions, interest-free loans, travel tickets, accommodation and other facilities. In this regard, 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, thus subjecting the grantor of the gratuity (pharmaceutical company) and

the receiver (healthcare professional) 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 may 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 answers to Questions 12, 14 and 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 the 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 GP Farmasi Indonesia, which will assess 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 impose further sanctions, e.g., notify BPOM of the violation (see our answer to Question 24 below).

The IPMG Code of Ethics provides that members may report violations of the IPMG Code of Ethics to the IPMG Ethics & Compliance Task Force. If the IPMG Ethics & Compliance Task Force 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 the finding, it shall be delivered to the reporting member and the Executive Committee.
    ii. if the accused member rejects the 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 26 of BPOM Reg. 2/2021 provides that any violation of the criteria and requirements of medicine advertisements as contained in Articles 2, 3(2), 4, 5(1), 6(1), 8, 9, 10, 20, and/or 24 of BPOM Reg. 2/2021 shall be subject to the administrative sanctions of the Head of BPOM in the form of:

a. warning;
b. stern warning;
c. temporary suspension of advertisement activities;
d. freezing of Marketing Authorization (*Izin Edar*); and/or
e. revocation of Marketing Authorization (*Izin Edar*).

Administrative sanctions in the form of warning and/or stern warning are followed by an order to revise, cease, and/or retract the published Advertisement.

Article 62(1) 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 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 life imprisonment or 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, 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. 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 and is unwilling to provide a written guarantee within 14 days as of the request by the Ethics Commission and/or the violation persists (see our answer to Question 23 above) 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 relevant healthcare professional organization for their further action;
d. notification to the parent company or headquarters of the violating company;
e. announcement of the violation in the GP Farmasi Indonesia bulletin; or
f. 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 BPOM Reg. 2/2021. 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 2020, BPOM reported that as a result of the COVID-19 pandemic, many advertisements for various medicines, traditional medicines, and supplements have claimed to be effective in healing or preventing COVID-19, while there is no proof of said efficacy. To prevent such false advertising, BPOM is cooperating with the Ministry of Communication and Informatics ("**MOCI**") to block the sites selling such products. BPOM has communicated its findings on medicine advertisements claiming to have COVID-19 healing properties to the Indonesian E-Commerce Association ("**idEA**"), the MOCI, and a number of online e-commerce platforms in order for such advertisements to be taken down. As of September 2021, BPOM has prohibited any claim or medicine advertisement, including for herbal medicines, related to the medicine's efficacy against COVID-19. BPOM also prohibits medicine manufacturers to include testimony as it views such testimony as subjective and biased.

BPOM reported that a total of 286,844 ineligible advertisements for traditional medicines and health supplements have been taken down in 2021, while 126,311 sites have been taken down as of January-April 2022. Most of the violations resulting in such site takedowns were in the form of misleading advertisement and advertising products with no Marketing Authorization (*Izin Edar*).

Based on data from BPOM in 2021, ineligible online advertisements for traditional medicines and health supplements (61.12%) were more common than advertisements for conventional medicines (21.76%). Further, it was reported that 80.21% of the online advertisement violations were committed by non-manufacturer or non-distributor sellers (non-official sellers). And around 61% of the total online advertisement violations by non-official sellers occurred on marketplace platforms and most were committed by micro and small businesses.

In response to the above, BPOM launched the Online Promotion Friendly Zone Program (*Program Zona Ramah Promosi Online)* on May 27, 2022. This is a preventive educational program targeted at micro and small business non-official sellers selling and advertising traditional medicines and/or health supplements on marketplace platforms. The program was introduced in collaboration with a number of marketplace platforms (e.g., Tokopedia, Shopee, Bukalapak) and supported by the MOCI and idEA.
Additionally, in an effort to support the implementation of COVID-19 health protocols, BPOM has urged pharmaceutical companies to include information regarding the implementation of these health protocols on product labels and advertisements, pursuant to BPOM Circular Letter No. HK.02.02.1.2.08.20.23 of 2020 dated August 21, 2020, regarding Health Protocols Implementation Campaign for Medicines and Food Labelling and Advertisements to Prevent and Control the Spread of COVID-19.

Another recent update in the Indonesian pharmaceutical industry is that the Ministry of Health has restricted the distribution and consumption of a number of syrup medicines that contain ethylene glycol and diethylene glycol in excess of the safety threshold. This restriction was introduced in response to the number of Atypical Progressive Acute Kidney Injury cases suffered by children resulting in increasing deaths. As a follow-up action, BPOM, along with the MOCI and idEA, has tracked the online sales of prohibited syrup medicines and, as of October 26, 2022, taken down a total of 6,001 sites identified as selling such products.

Contributors

Ira A. Eddymurthy
Partner
iraeddymurthy@ssek.com

Winnie Y. Rolindrawan
Partner
winnierolindrawan@ssek.com