Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

INDONESIA

Indonesia

Cahyani Endahayu, Reagen L. Mokodompit

In Indonesia, various legislation and guidelines govern the advertisement of medical devices and pharmaceutical products (drugs). Medical devices fall under the authority of the Ministry of Health (**MOH**), while drugs fall under the authority of the MOH and the Food and Drugs Supervisory Agency (*Badan Pengawasan Obat dan Makanan* or **BPOM**).

Click here to access:

1. Medical Devices

2. Drugs

Medical Devices

Introduction

The applicable regulations require any medical device that will be advertised in the Indonesian market to be first registered at the relevant government authorities. Upon being registered, a marketing authorization for each product will be issued.

Regulatory framework

The following are the relevant regulations with regard to advertisement of medical devices in Indonesia:

(i) Law No. 8 of 1999 on Consumer Protection ("**Law 8**")

(ii) Law No. 32 of 2002 on Broadcasting ("**Law 32**")

(iii) Decision of the MOH No. 252/MenKes/SK B/VII/80 on controlling and monitoring drugs, food, beverages, cosmetics, and medical devices advertisement ("**Decision 252**")

(iv) MOH Regulation No. 1184/MENKES/PER/X/2004 on Safety of Medical Devices and Household Healthcare Supplies ("**Regulation 1184**")

(v) MOH Regulation No. 62 of 2017 on the Marketing Authorization for Medical Devices, In Vitro Diagnostic Medical Devices and Household Healthcare Supplies ("**Regulation 62**")

(vi) MOH Regulation No. 76 of 2013 on the Advertisement on Medical Devices and Household Healthcare Supplies ("**Regulation 76**")

(vii) MOH Regulation No. 1189/MENKES/PER/VIII/2010 on the Production of Medical Devices and Household Healthcare Supplies ("**Regulation 1189**")

The following are the applicable codes of ethics with regard to conducting advertisement of medical devices in Indonesia:

(i) Advertorial guidance on medical devices, cosmetics and household medical preparations issued by the Indonesian Advertisement Council or Indonesian Advertisement Code of Ethics (**IACE**)

(ii) Indonesian Medical Code of Ethics (*Kode Etik Kedokteran Indonesia*) (**MCE**)

(iii) Indonesian Advertorial Ethical Guidelines issued by Indonesian Advertising Company Union Association (**EPI**)

Permitted and prohibited practices

General requirements

Advertisement for a medical device can only be shown or included in the designated media once it has been approved by the Directorate General of Pharmaceutical and Medical Devices, which is a division

in the MOH responsible for overseeing pharmaceutical and medical device products.

Target of promotion and advertising

The relevant regulations regarding medical devices do not limit the target of the advertisement. Thus, arguably, advertisement can target the public (including consumers or medical practitioners).

Permitted media and method

Regulation 76 provides that medical devices may be advertised on:

(i) Printed media

(ii) Electronic media

(iii) Information technology media and/or outdoor media

Considering the permitted media for advertisement is quite broad and can be accessed freely by the public, this reinforces the fact that the target of the advertisement of medical device is the public and not limited. Further, Regulation 76 provides that if professional help is needed for the use of a medical device, the advertisement of that medical device can only be done through:

(i) Printed media for physicians and pharmacies

(ii) Scientific forums for healthcare professionals (**HCP**s)

The manner of advertisement of medical devices should also comply with advertising ethics and other applicable regulations.

Advertisement by an HCP

Under Law 36, "healthcare professional" is defined as anyone who serves people in the health sector and has knowledge and expertise gained from medical education and for special purposes. HCPs have

to obtain authorization to conduct medical treatment and are prohibited from advertising and promoting medical devices.

Specific manners in advertising

Pricing display: Under the IACE, medical device companies are permitted to advertise the prices of medical devices. If the price is displayed in the advertisement, it has to be clear and perceptible enough for the consumer to easily determine how much the product is. An asterisk sign (*) on printed media cannot be used to mislead or lie to the public regarding the real price of the advertised medical device.

Email: Advertisement through email should be permitted, given that its method is inseparable from the use of electronic or information technology media, that is, an email (containing an advertisement) can only be accessed or sent using electronic or information technology media.

Advertisement content requirements

Under Law 8, medical device companies must use common words that can be understood by the public and do not mislead consumers. Further, under Law 8 and Regulation 76, medical device companies must provide sufficient information on the products they promote. Medical device advertisement must fulfill the following requirements:

(i) It should contain information that is: (i) objective, (ii) complete and (iii) not misleading.

(ii) It should use Indonesian language, Arabic numbering and Latin letters that are easy to understand and do not lead to multiple interpretations.

(iii) It is not contrary to ethics of decency.

"Objective" means that the advertisement must provide correct information in accordance with marketing authorization. "Complete" means that the advertisement must provide information regarding

benefits, contra indications, side effects and/or other information that must be considered in product use. "Not misleading" means that the advertisement must be truthful, accurate and can be accounted for and must not take advantage of community concerns about health problems.

Scientific data and literature as an advertisement

The definition of "advertisement" based on Regulation 76 is very broad and basically covers any information used to inform the public about the availability of a product. For context, Article 1.1 of Regulation 76 defines "advertisement" as information that is commercial and public service in nature, about the availability of services, goods and ideas that could be utilized by the public, with or without reward to the relevant advertiser.

Accordingly, if scientific data and literature are used in an advertisement, they will most likely be considered as advertisement material. However, the MOH will have the final say on whether or not content could be considered advertising material (i.e., including scientific data and literature that relate to a medical device).

Please note that if the scientific data and literature is published through: (i) electronic media; and (ii) information technology media, the Minister of Communication and Information has the authority to determine whether or not the publication is lawful.

Prohibited advertisement content

Under Regulation 76, the following advertisement content are unlawful:

(i) Misleading through emphasis, striking comparisons or omitting facts

(ii) Comparing with other similar products with intent to degrade

(iii) Directly or indirectly encouraging the use of medical devices that are excessive and unnecessary

(iv) Taking advantage of the ignorance of the community by including scientific data that cannot be validated and verified

(v) Causing fear or taking advantage of myths in the community

(vi) Providing testimonials

(vii) Using names, initials, logos, symbols, and/or references that indicate suggestions

(viii) Using institutions or organizations engaged in the health sector

(ix) Using confusing medical jargon/slogans

(x) Misusing the results of research or using quotes from technical or scientific publications

(xi) Suggesting directly or indirectly that the product can prevent diseases

(xii) Using words, sentences or illustrations that claim that the product can cure abnormalities or diseases

(xiii) Suggesting directly or indirectly that the medical devices can prevent, slow down or restore physiological changes and related degenerative conditions related to the aging process

(xiv) Making various claims or creating the impression that the medical device is complete, guaranteeing that it will provide certainty of healing

(xv) Ignoring the treatments (including the main treatment) and offering specific advice, diagnosis or treatment for serious and chronic diseases

Comparative advertising

Under Regulation 76, comparative advertising is allowed but limited to some extent. If comparison with another product is done in a derogatory manner, then it would be prohibited.

Other promotional activities

Medical device companies providing HCPs or medical institutions with gifts, hospitality, entertainment and discounted products

Under the MCE, HCPs are prohibited from receiving any promotional materials and products from medical device companies or other similar institutions. Further, companies must also observe the reporting obligation required under the prevailing sponsorship regulation issued by the MOH.

Patient information sessions about products, disease and surgery

Regulation regarding this is unclear. To organize patient information sessions and disseminate information about the product, medical device companies have to abide by relevant provisions regarding medical device advertising since such activities can be considered as promotional in nature.

Sponsorship for training, research, employee positions or events

Under the MCE, healthcare professionals are prohibited from receiving any promotional materials and products from medical device companies or other similar institutions. Further, companies must also observe the reporting obligation required under the prevailing sponsorship regulation issued by the MOH.

Sample products from medical devices companies to hospitals

Regulation regarding this is unclear. We believe that no legal issue will arise as long as the medical device companies have no intention of influencing the independence of the hospitals. Considering the sensitivity of the issue, however, we will need to further assess on case-by-case basis.

Contracts with HCPs and medical institutions

There is no specific regulation regarding this matter. However, under the MCE, HCPs are prohibited from attending any direct or indirect promotional activities.

Consequences of breach

Administrative sanctions

If a medical device company does not comply with the rules, it will face administrative or other sanctions under prevailing law.

Professional codes of conduct

Under the IACE, if a medical device company does not comply with the rules, the Indonesian Advertisement Council (**IAC**) will issue a warning letter twice. If the noncompliance continues, the IAC must stop the broadcasting or issue a recommendation of sanction to all relevant parties (e.g., the Indonesian Broadcasting Commission, the MOH, and the Minister of Communication and Information).

If the advertisement of a medical device is deemed to violate the requirements and standards under Regulation 76, the DGPMD has the authority to order the manufacturer of the medical device to either change, withdraw, erase and/or stop the advertisement ("**Rectification Action**") within seven working days after notification is served.

In case the manufacturer fails to perform the Rectification Action within the deadline, the Directorate General of Pharmaceutical and Medical Devices may take the following administrative actions:

(a) Issue a written notification

(b) Revoke the approval on the advertisement

(c) Revoke the marketing authorization

Drugs

Introduction

The promotion and advertising of drugs in Indonesia are highly regulated. The Ministry of Health (**MOH**) first issued a regulation on the advertising of drugs in 1994 (i.e., MOH Decision 386 - please see below). Later on, the Food and Drugs Supervisory Agency (*Badan Pengawas Obat dan Makanan* or **BPOM**) issued specific procedures on drug promotion and advertising.

BPOM has different regulations for drug promotion and drug advertisement. BPOM Decision 05 regulates how drugs can be promoted for the purpose of increasing the volume of prescription, distribution, sale or use of the products. BPOM Regulation 8, meanwhile, regulates how drugs are advertised (especially when making and distributing content through the media).

Based on BPOM Decision 05, "promotion" is defined as any activity of providing information regarding finished drugs, which have marketing authorization by pharmaceutical manufacturers and wholesalers, with the purpose of increasing prescription, distribution, sale and/or use of drugs. Based on BPOM Regulation 8, "advertisement" is defined as any provision of information or statement on drugs in the form of pictures, writing or other forms, in a variety of ways, to market and/or trade drugs.

In other words, promotion encompasses a wider spectrum of marketing activity, while advertising is limited to the media being used. With this logic, marketing that is not done within a medium regulated under the drug advertisement regime can be considered a promotion and should comply with BPOM Decision 05 and would be excluded from obligations set out under BPOM Regulation 8.

In addition, Indonesia is both a civil law country and an emerging market. Laws and regulations here are therefore often principle-based, not descriptive, thus leaving room for wide discretion on the part of the regulators when it comes to policy.

Regulatory framework

The following are the relevant regulations with regard to the advertisement of drugs in Indonesia:

(i) Government Regulation No. 72 of 1998 on Safekeeping of Drugs and Medical Devices Preparations ("**GR 72**")

(ii) Head of BPOM Regulation No. 8 of 2017 on Guidelines on the Supervision of Drugs Advertisement ("**BPOM Regulation 8**")

(iii) MOH Decision No. 386/MENKES/SK/IV/1994 on Advertisement Guidelines for Non-Prescription Drugs, Traditional Drugs, Medical Devices, Cosmetics, Health Equipment for Household, Foods and Beverages ("**MOH Decision 386**")

(iv) Head of BPOM Decision No. HK.00.05.3.02706 Tahun 2002 on Promotion of Drugs ("**BPOM Decision 05**")

Permitted and prohibited practices

General requirements

Published advertisements generally must follow these basic principles:

(i) Objective

(ii) Comprehensive

(iii) Not misleading

BPOM Regulation 8 provides a comprehensive guideline that elaborates on the three principles above. The same level of detail is not provided for the promotion of drugs under BPOM Decision 05, which only mentions that the promotion of drugs must be done "in accordance with the prevailing laws and regulations." The fact that promotional activities could take many forms (e.g., sponsorship) may

be the reason why there is no definitive guideline for promotional activities.

Any type of drugs that will be advertised or promoted must be registered under a marketing authorization. The content of the promotion and/or advertisement of the ethical drug must also be in accordance with the information provided under the marketing authorization, but not all information is suitable to be stated.

Based on BPOM Regulation 8, the content of advertisements for ethical drugs do not require pre-approval from the BPOM before these advertisements can be published. The requirement is only for the advertisement of OTC Drugs.

BPOM pre-approval is not required for ethical drugs probably because, by law, advertisement of ethical drugs is not accessible to the public. Consumer safety has always been BPOM's priority when it comes to supervision of drugs.

Language

Based on Article 9 of BPOM Regulation 8, drug advertisements must use the Indonesian language or a local language in Indonesia (e.g., Javanese). Foreign languages may be used as long an Indonesian version/translation is also available.

The regulation is silent on the language requirement for the promotion of drugs. In our view, promotion through advertising media (i.e., printed, electronic media or outdoor media) would fall under the scope of advertisement and must therefore comply with the language requirement under BPOM Regulation 8.

For other "more direct" types of promotion (e.g., face-to-face marketing), languages other than Indonesian may be used.

Target of promotion and advertising

Article 3 (2) of BPOM Decision 05 and Article 3 (2) of BPOM Regulation 8 mention that ethical drugs cannot be promoted or advertised directly to the public. The government's intentions are to minimize the risks that the public would receive information on the ethical drugs and to provide more benefits for the community (risk and benefit). The word "public" above also extends to patients. They view that information on ethical drugs can only be given to patients through doctors or medical practitioners. Therefore, promotion and advertisement of ethical drugs may be done to doctors or medical practitioners, but not to the public.

The above regulations also mean that only non-ethical drugs (*obat bebas*) and limited non-ethical drugs (*obat bebas terbatas*) (both as "**OTC Drugs**") can be advertised to the public, subject to certain limitations allowed by the prevailing regulations.

Permitted media and method

Based on Article 3 (1) of BPOM Regulation 8, ethical drugs may only be advertised on one of the following media:

(a) Medical scientific printed media

(b) Pharmaceutical scientific printed media

This is in line with the provision under Article 32 of GR 72.

Based on Article 3 (2) of BPOM Regulation 8, OTC Drugs may only be advertised on the following media:

(a) Printed media

Article 4 (1) of BPOM Regulation 8 further elaborates on the types of "printed media" that may be used to advertise OTC Drugs:

(i) Newspaper

(ii) Magazine

(iii) Tabloid

(iv) Bulletin

(v) Calendar

(vi) Poster or broadside

(vii) Leaflet

(viii) Sticker

(ix) Booklet

(x) Pamphlet

(xi) Yellow pages

(b) Electronic media

Article 4 (2) of BPOM Regulation 8 further elaborates on the types of "electronic media" that may be used to advertise OTC Drugs:

(i) Television, including running text

(ii) Radio

(c) Outdoor media

Article 4 (3) of BPOM Regulation 8 further elaborates on the types of "outdoor media" that may be used to advertise OTC Drugs:

(i) Advertisement board (*papan reklame*)

(ii) Billboard

(iii) Neon box

(iv) Name plate

(v) Air balloon

(vi) Car tire holster

(vii) Printed media attached/hanged outdoor

(viii) Banner

(ix) Transit ad (i.e., advertisement put on moving objects)

(x) Videotron

(xi) Gimmick

(xii) Backdrop

However, the regulation is unclear on whether the use of any form of printed media mentioned above (such as booklet, sticker, leaflet) will satisfy the requirement under Article 3 (1) of BPOM Regulation 8 or if, in fact, the pharmaceutical or medical scientific printed media is only referring to one of the abovementioned forms of printed media.

Although there is no clear definition of "medical scientific printed media" and "pharmaceutical scientific printed media," strictly speaking, "scientific printed media" refers to any form of scientific printed media that can only be accessed by healthcare professionals (**HCP**s) and not by the public (i.e., medical or pharmaceutical scientific magazines). Therefore, information should not be provided on any printed media that can be accessed by the public (e.g., yellow pages and calendars).

Further, Article 5 of BPOM Decision 05 specifically prohibits promotion of ethical drugs through audiovisual or electronic media.

We are aware of recent developments regarding how drugs are promoted and advertised, for example, through digital media. However, how the promotion can be conducted and what the boundaries of those activities are remain unclear.

We note that BPOM is quite lenient with the methods of promotion, provided that the information cannot be accessed by the public. We also have had discussions with BPOM officials on the development of BPOM's view on this issue. Based on unofficial confirmation, the promotion and advertisement of ethical drugs through the internet or digital or electronic media in general (e.g., website, email, mobile application / application programming interface) may be done, provided that the information cannot be accessed by the public but only by medical experts or HCPs with some level of protection (e.g., username and password). With regard to promotion in other printed media, such as pamphlets and brochures, a BPOM official informed us that it can be done, provided that the documents are addressed and delivered to the medical experts or HCPs.

Other means of promotion of drugs

Promotion of an ethical drug may also be done through methods that do not require any media, as follows:

Verbal or direct marketing to HCPs (i.e., marketing activity is not done using any media mentioned under BPOM Regulation 8 and therefore cannot be considered as advertisement):

(a) Provision of sponsorship for a scientific event (i.e., for the benefit of an HCP)

(b) Provision of grant or donation to a healthcare institution (i.e., cannot be given directly to an HCP)*

**The grant or donation must not be followed by or related to any request for the institution to influence its HCP employees about prescribing the donator's product.*

Digital promotion and advertising of ethical drugs

The requirement under Article 3 (1) of BPOM Regulation 8 means that ethical drugs can be advertised only in medical scientific printed media and pharmaceutical scientific printed media. Further, based on Article 5 of BPOM Decision 05, promotion through audiovisual and electronic media is only allowed for non-prescription drugs and limited non-prescription drugs. Accordingly, ethical drugs are essentially prohibited from being promoted or advertised through audiovisual and electronic media.

Moreover, advertising of any type of drugs through social media is prohibited under BPOM Regulation 8.

Strictly speaking, the promotion and advertisement of ethical drugs through the internet (e.g., social media and/or web-streaming such as YouTube), which can be accessed by the public, are currently prohibited by BPOM. We understand that this provision is not practicable and will limit the room of promotion. This is in line with the intention of BPOM to limit information regarding ethical drugs directed to the public.

Nevertheless, we note that BPOM is quite lenient with promotion through the internet and any printed media other than medical scientific printed media and pharmaceutical scientific printed media if the information cannot be accessed by the public. We also note that BPOM is still lax with the enforcement of the promotion requirements.

Further, the BPOM official explained that there is an indication that BPOM is currently discussing the possibility of allowing the use of electronic media for the promotion and advertisement of ethical drugs by issuing a new regulation. However, we have no further information on the scope of the regulation and when the regulation is issued.

As we have mentioned above, the provision that pharmaceutical products can only be advertised on medical scientific printed media or pharmaceutical scientific printed media is also stated in Article 32 of

GR 72. Since GR 72 is a higher-level regulation than BPOM Regulation 8, if BPOM would like to issue a new regulation, from a hierarchy of law perspective, the similar requirements must also be amended on GR 72; BPOM Decision 05 and BPOM Regulation 8 must also be amended. Therefore, it still remains to be seen how BPOM will issue regulations regarding digital media.

BPOM strictly prohibits pharmaceutical manufacturers or wholesalers from giving out information on ethical drugs directly to the public or to patients. Information on prescription drugs may only be given to patients through doctors or medical practitioners.

We understand that BPOM and local authorities may still be lax with enforcement. However, clients should be aware that BPOM and local authorities will usually start to check or investigate matters if there is a report or complaint by a disgruntled or ex-employee or a competitor. However, it is also possible that BPOM will start to check matters off its own back, and recently we have been seeing some government authorities taking an increased interest in noncompliance matters.

Prohibited promotion activity

Based on BPOM Decision 05, pharmaceutical manufacturers and wholesalers are prohibited from performing the following promotional activities:

(i) Cooperation with pharmacy and prescriber

(ii) Cooperation on prescription of drugs with pharmacy and/or prescriber in a special program to increase the sale of certain drugs

(iii) Giving of bonus/prize in the form of cash (i.e., cash, bank-draft, loan, voucher, ticket), and/or goods to the prescriber that prescribes the drugs that they manufacture and/or distribute

(iv) Forming of special groups to increase the use of drugs for the purpose of marketing

(v) Carrying out promotions for the sale of OTC Drugs that are done by returning used drugs and/or holding quizzes or similar activities

Consequences of breach

Administrative sanction

Parties who violate the provisions on advertising will be imposed administrative sanctions, including:

(i) Ceasing the publication of the advertisement

(ii) Ceasing the advertisement activities for the particular products within six months

(iii) Revocation of marketing authorization

Criminal sanction

Parties who promote ethical drugs on any platform other than medical and pharmaceutical scientific printed media will be imposed a criminal sanction (i.e., a fine in the amount of IDR 10 million).

Professional codes of conduct

Many pharmaceutical manufacturers are members of the International Pharmaceutical Manufacturer Group (**IPMG**). IPMG has its own code of ethics, which has specific rules on drug promotion and advertising. Failure to comply with the code of ethics may subject the violator to the following institutional actions/sanctions:

(i) First violation:

- Written notification
- Penalty in the amount of USD 2,000

(ii) Second violation:

- Written notification
- Official letter followed by a meeting to discuss the violation (note: a form of internal trial)
- Penalty in the amount of: (1) USD 2,000 for a minor violation; or (2) USD 5,000 for a major violation

(iii) Subsequent violations:

- Official letter followed by a meeting to discuss the violation
- Penalty in the amount of: (1) USD 5,000 for a minor violation; or (2) USD 20,000 for a major violation

Note: Examples of minor and major violations are identified on the IPMG's code of ethics.

Recommendations

Due to the stringent restrictions on advertisements under the prevailing regulations and code, we suggest that an assessment be made in each project to determine whether advertising can be done.

Pharmaceutical manufacturers and wholesalers must put in place appropriate internal codes of conduct and associated guidelines in relation to the advertising and promotion of products in Indonesia, ensuring these are adapted to comply with local regulations.

We also recommend conducting regular training sessions for local company representatives (including sales teams) to ensure awareness and compliance with internal codes of conduct and regulatory requirements.

At a practical level, it is critical to distinguish between advertising and promotional materials that are directed to consumers (where permissible) and those that are directed to HCPs.

The choice of media should also be considered, especially when advertising ethical drugs. As mentioned above, based on our latest discussion, BPOM has begun to accept the use of electronic media (excluding social media) as means to advertise or promote ethical drugs to HCPs, provided that the advertisement cannot be accessed by the public. In some cases, it would be challenging to fully prevent consumers or patients from accessing advertisements of ethical drugs posted on the internet.

In the case of mobile applications, some methods may be used (e.g., using user ID and password) to prevent patients from accessing advertising materials reserved for HCPs.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

www.bakermckenzie.com