PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

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

The main legislation governing the advertising and promotion of pharmaceuticals and medical product is:

- Medicines (Advertisement and Sale) Act 1956;
- Sale of Drugs Act 1952; and
- Medical Device Act 2012.

Other legislation governing the advertising and promotion of pharmaceuticals and medical product is:

- section 5 of the Trade Description Act 2011; and
- section 6 of the Indecent Advertisements Act 1953.

Industry codes governing the advertising and promotion of pharmaceuticals and medical product are:

- Registered Medicinal Product Advertising Approval Guidelines 2022;
- Guideline on Advertising of Medicines and Medicinal Products to General Public 2015;
- Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (the 'PhAMA Code') by the Pharmaceutical Association of Malaysia ('PhAMA');
- Code of Conduct for Non Prescription (OTC) Products (the 'OTC Code') by PhAMA;
- PhAMA Code of Practice for Prescription (Ethical) Products;
- Code of Medical Ethics issued by the Malaysian Medical Association;
- Content Industry Reference: Health Claim Advertisements 2019 by Malaysian Communications and Multimedia Commission (MCMC);
- Medical Device Guidance Document – Code of Advertisement; and
- Medical Device (Advertising) Regulations 2019.

Other codes governing the advertising and promotion of pharmaceuticals and medical product are:

- Code of Advertising Practice; and
- Communications and Multimedia Content Code.

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

Advertising

'Advertisement' is defined under the Medicines (Advertisement and Sale) Act 1956 to include 'any notice, circular, report, commentary, pamphlet, label, wrapper, or other document, and any announcement made orally or by any means of producing or transmitting light or sound'.

Adding to the above, the 2015 Guideline on Advertising of Medicines and Medicinal Products to General Public provides a non-exhaustive list of activities amounting to advertisements, which includes:

- advertising on electronic ordering system;
- aerial promotion, such as a hot air balloon and/or blimps;
- aisle, ceiling and floor advertising, and other signs;
- articles or advertorials in journals, magazines and newspapers;
- brand reminders;
- branded material relating to product sponsorship;
- bulletins and newsletters;
- calendars;
- catalogues;
- consumer brochures, booklets, leaflets, pamphlets and broadsheets;
- consumers promoters;
- counter-top advertising;
- cinema, television and radio/audio commercials;

- direct mail materials;
- directories;
- display packs and giant mock-up boxes;
- gondola end advertising;
- indoor displays, such as at airports, washrooms and shopping centres;
- light box advertising;
- online advertising;
- outdoor displays, such as billboards, banners, bunting and posters;
- point of sale materials;
- sports, art and other sponsorship;
- talk shows;
- vehicle wrappers;
- video recordings; and
- website and other internet materials, including brand home pages and banner advertising.

Under the Code of Advertising Practice, 'advertisement' applies to 'marketing communication or advertising wherever it may appear in the printed form. It includes advertising in leaflets, circulars, posters, billboards, cinemas, advertising claims on packs, labels and point of sale material.'

Promotion

Under the PhAMA Code, 'promotion' is defined as 'any activity undertaken (or material prepared) by a member company or any third party acting on behalf of the company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet'.

Based on the above, it appears that, in Malaysia, the promotion of pharmaceutical/medical devices is carried out through advertising. In other words, the promotion of pharmaceutical/medical devices is the end goal and advertising activity is the means of reaching it.

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

Regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices

In Malaysia, the promotion and advertisement of:

- medical devices are supervised by the Medical Device Authority (MDA) Malaysia, a statutory body under the Ministry of Health Malaysia; and
- pharmaceutical products are regulated by the Medicine Advertisement Board (MAB), an agency under the Pharmaceutical Services division of the Ministry of Health.

However, in general, the MCMC regulates the communications and multimedia industries, which include all promotional/advertising activity. The Advertising Standards Authority (ASA) Malaysia is an independent body that ensures the adherence of the self-regulating advertising industry to the Malaysian Code of Advertising Practice.

Relationship between the self-regulatory process, and the supervisory and enforcement function of the competent authorities

The self-regulatory process, and the supervisory and enforcement function of the competent authorities are conducted independently from each other.

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

'Pharmaceutical products' is defined under the PhAMA Code as 'any pharmaceutical or biological product

(irrespective of patent status and/or whether it is branded or not) which is intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which is intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body'.

Generally, health supplements and nutritional supplement products do not fall within the above definition. Instead, they are categorised as food-drug interphase (FDI) products. 'Health supplement' is defined under the Drug Registration Guidance Document (DRGD) as 'any product that is used to supplement a diet and to maintain, enhance and improve the health function of [the] human body'. The Medicines (Advertisement and Sale) Act 1956 and its guidelines are applicable to health supplements.

CONSUMER MARKETING

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

As a general rule, all advertisements of medical devices and pharmaceutical products must first be approved by the relevant authority before they can be published.

Notwithstanding the above, it is important to bear in mind that not all forms of pharmaceuticals and medical devices can be promoted directly to the public. Certain products are prohibited as stipulated below.

Medical devices

Under the Medical Device Guidance Document – Code of Advertisement, medical devices that are for healthcare professional use only cannot be advertised to the general public.

Pharmaceutical products

Under the Medicines (Advertisement and Sale) Act 1956, it is prohibited to advertise any products in a manner that suggests their use as a medicine or remedy for preventing or treating the diseases outlined in the Schedule to the Medicines (Advertisement and Sale) Act 1956, which includes diseases of the kidney and heart, diabetes, epilepsy, paralysis and tuberculosis.

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

In general, all information shared online for business purposes needs to be appropriate, accurate and fair for public viewing and understanding because companies are responsible for the information they upload online. The identity of the responsible company and the intended audience must be readily apparent.

Internet

- The Kementerian Kesihatan Lembaga Iklan Ubat (KKLIU) number must be displayed on the page, alongside the name, address and contact number of the advertiser.
- Websites containing advertisements for health professionals must be access-restricted and clearly labelled as intended for health professionals.

Social media

- Under the PhAMA Code, all social media communication for business purposes should be communicated from a company profile and not associated to a personal account.
- Company branding should be shared on the social media platform for transparency.

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

Yes, all advertisements of medical devices and pharmaceutical products must first be approved by the relevant authority before they can be used.

Pharmaceutical product

The pharmaceutical product must first be approved by the Drug Control Authority before an application for an advertisement. An application to the Medicine Advertisements Board would entail the following:

1. An application for the Medicine Advertisements Board's advertisement approval can be made by filling in Form B - Advertisement Application Form for Medicine Advertisements Board's Approval. The form can be downloaded at **www.pharmacy.gov.my**.
2. Applicants must submit the completed Form B along with the relevant supporting documents, such as a copy of the company registration certificate of the Companies Commission of Malaysia, product indication certificate and product label by the Drug Control Authority, and the processing fee of MYR 300.
3. The Medicine Advertisements Board will issue a decision on the approval of the advertisement application.

Medical device

The medical device must first be approved by the MDA before an application for an advertisement. An application to the MDA would entail the following.

1. An application shall be submitted by the advertiser to the MDA using the 'Application Form for Medical Device Advertisement', which can be downloaded at **www.mda.gov.my**.
2. The advertisement and/or advertisement script shall be submitted together with the application form. For applications that consist of a recording or video, applicants shall submit a storyboard (frame by frame). However, applicants can submit appropriate media (eg, thumb drive or flash drive) if requested by the authority.
3. Each application shall be submitted together with a MYR 1,000 processing fee.
4. If the authority is satisfied with the advertisement application, it will issue an approval number for the particular advertisement.

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

Under the PhAMA Code, a pharmaceutical product can only be promoted in Malaysia once the requisite regulatory approval for marketing for such use has been obtained. Therefore, off-label information cannot be promoted or advertised.

Notwithstanding the above, off-label use is permissible. According to the Ministry of Health Malaysia, off-label use is allowed, so long as the use/prescription is medically indicated or justified. The healthcare professional seeking to use the pharmaceutical product for off-label usage must thoroughly explain the medicine to the patient before signing the Consent Form for Treatment Using Unregistered Medicine/Indication (Off Label) by the Ministry of Health Malaysia.

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

According to the Guideline on Advertising of Medicines and Medicinal Products 2015 and Medical Device Guidance Document – Code of Advertisement, comparative advertising is allowed. However, it is subject to restrictions. In general, comparisons must be balanced, fair and capable of substantiation.

Any comparative claim should:

- be made on a factual and fair basis, and be capable of substantiation; the intent and connotation of the advertisement should be to inform and not to discredit, disparage, degrade or attack competitors, competing products or services directly or by implication;
- be unambiguous and clearly understandable, and should not mislead by distortion, undue emphasis or omissions;
- be used for honest comparison purposes and not simply to upgrade by association;
- be clear about what comparison(s) is being made;
- not make unjustifiable use of the name or initials of any firm, company or institution nor take advantage of the goodwill attached to the trade name or symbol of another firm or its product(s), or the goodwill acquired by its advertising campaign;

- not explicitly identify the competitive product, whether by name, brand, name, company or any form of identification that clearly exposes the identity of the competition;
- not state that a product does not contain an active ingredient or ingredients used in competitor products other than as permitted by the DCA;
- not involve the selection of subject matter for comparison to confer an artificial advantage on the advertiser or to suggest that a better bargain is offered that is actually the case;
- where appropriate, be supported by documentary evidence that is easily understood;
- when referring to a competitive test, such a test should have been conducted by an independent and objective body; the test must be supportive of all claims made in the advertisements that are based on the test;
- never use or draw on partial results or stress insignificant results to mislead the consumer to draw an improper conclusion; and
- not involve the use of 'baseless' hanging comparatives that merely claim that a product is, for example, 'longer-acting', 'quicker' or 'stronger'.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

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

Definition of healthcare professionals

'Healthcare professional' is defined under the PhAMA Code as 'any member of the medical, dental, pharmacy or nursing professions, or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply or administer a pharmaceutical product'.

The Medical Device Guidance – Code of Advertisement adopts the definition of 'healthcare professional' from the Private Healthcare Facilities and Services Act 1998, wherein 'healthcare professional' is defined as 'a medical practitioner, dental practitioner, pharmacist, clinical psychologist, nurse, midwife, medical assistant, physiotherapist, occupational therapist and other allied healthcare professional as listed in the 2nd Schedule of Allied Health Professions Act 2016 (Act 774)'. This includes:

- audiologist;
- dietitian;
- entomologist (public health);
- physiotherapist;
- medical physicist;
- nutritionist;
- clinical psychologist;
- clinical scientist (biochemist);
- clinical scientist (biomedical);
- clinical scientist (embryologist);
- clinical scientist (medical geneticist);
- clinical scientist (microbiologist);
- occupational therapist;
- speech-language therapist;
- radiation therapist;
- diagnostic radiographer;
- medical laboratory technologist;
- dental technologist;
- environmental health officer;
- health education officer;
- food service officer (healthcare);
- forensic science officer; and
- medical social officer.

Restriction of promotional activities directed towards healthcare professionals

Although promotional activities directed towards healthcare professionals are not prohibited per se, there

are certain restrictions applicable. In general, promotional information directed towards healthcare professionals should be ethical, accurate, balanced and not misleading. Such advertisements shall include a warning statement: 'This webpage content is intended for Healthcare Professionals only, not for [the] general public'.

The advertisement should comply with the following:

- Promotional information should be clear, legible, accurate, balanced, fair and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned.
- Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly (preferably less than five years old). The information must also be supported by a proper assessment of the risks and benefits of the product and its appropriate use.
- Promotion should be capable of substantiation, either by reference to the approved labelling or by scientific evidence.
- Promotion and scientific evidence should be consistent with locally approved product indication. Such evidence should be made available on request to healthcare professionals.
- Companies should deal objectively with requests for information made in good faith and should provide data that is appropriate to the source of the enquiry.

The PhAMA Code also regulates the forms of promotional activities that are acceptable:

- Any promotional activities to healthcare professionals should be focused on information about products, providing scientific and educational information, and supporting medical research and education. Any financial benefit or benefit-in-kind in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so, is prohibited.
- Payment in cash or cash equivalent to healthcare professionals as a promotional activity is strictly prohibited.
- Promotional items for the personal benefit of the healthcare professional are also strictly prohibited under the code.

Inappropriate financial benefit to the healthcare professional in exchange for promotion of the pharmaceutical product is prohibited.

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

In general, all online promotional activities containing advertisements or information whose nature and content are directed at healthcare professionals shall include a warning statement: 'This webpage content is intended for Healthcare Professionals only, not for [the] general public'.

While the regulations governing the promotion of pharmaceutical products and medical devices do not mention 'virtual' meetings specifically:

- sponsorship for healthcare professionals to attend congresses and symposia is not prohibited, so long as they are not conditional on an obligation to prescribe and recommend any product; and
- no compensation should be paid to the healthcare professional for his or her time spent attending the congress/symposia.

It is inferred that a similar regulation would apply for congresses and symposia held online.

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

The Registered Medicinal Products Advertising Approval Guidelines and Medical Device Guidance Document – Code of Advertisement provide that advertisements must not feature healthcare professionals in a manner that suggests that they provide advice, recommendations, endorsements or any form of professional support for the product. This includes avoiding imagery or audio that implies healthcare professional approval, such as white coats or stethoscopes, to prevent the impression of undue authority. Professional body endorsements are permitted, subject to the body's consent and specific conditions.

Such endorsements cannot relate to product indications and must clearly identify the statement being endorsed for advertisement, without implying blanket approval for the product. The use of a professional body's logo in advertisements is allowed only with explicit authorisation.

Further, the PhAMA Code prohibits offering any financial benefit or benefit-in-kind (including grants, sponsorship, gifts, scholarships, subsidies, support, consulting contracts, or educational or practice-related items) to a healthcare professional that would have an inappropriate influence on a healthcare professional's prescribing practices.

The Malaysian Code of Advertising Practice also provides that advertisements should not contain or refer to any testimonial or endorsement, unless it is genuine and related to the personal experience over a reasonable period of time of the person giving it.

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

In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals authorised to prescribe that product in order to enhance patient care.

The PhAMA Code mandates that samples must be the smallest commercial pack size, labelled as 'Samples – Not for Sale', and directly given to the healthcare professional or an authorised individual. Samples must comply with Postal and Poisons Regulations, be child-resistant and not serve as an incentive for purchase or be used in clinical trials. The distribution of unsolicited over-the-counter pharmaceutical samples is restricted.

The MMC Guideline on the Relationship between Doctors and the Pharmaceutical Industry 2006 discourages requesting or accepting drug samples that could influence prescribing decisions or for personal use, except for evaluating a medication's clinical performance in specific instances, without any material benefit to doctors or their institutions.

Regarding gifts and monetary donations, the PhAMA Code asserts that gifts must not incentivise the prescription, recommendation or purchase of pharmaceutical products. Financial donations or gifts for the social events of medical societies, hospitals and clinics are prohibited.

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

Malaysian law does not specifically govern interactions with healthcare professionals, but, in certain circumstances, the Malaysian Anti-Corruption Commission Act 2009 may apply. Benefits are generally prohibited (please refer to the response to Question 12).

In cases where hospitality is permissible, it is regulated with specific limits on the value and type of items offered.

Items of medical utility beneficial for patient care, like stethoscopes or blood pressure monitors, can be provided if they are of modest value (not exceeding MYR 500 per item per healthcare professionals) and given no more than occasionally. Educational materials, such as medical journals or textbooks, are permissible up to MYR 1,500 per year per institution or healthcare professionals. Cultural courtesy gifts are prohibited.

Promotional aids related to prescription-only medicines, like sticky notes or mouse pads, are banned. However, pens and notepads that are devoid of medicine names or therapeutic area logos, but may include the company's name, are allowed if they're of minimal value (no more than MYR 15 per item) and provided in the necessary quantity during company or third-party scientific events for note-taking purposes.

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

Donations to healthcare institutions or organisations are not explicitly classified as promotional tools, but the Registered Medicinal Products Advertising Approval Guidelines defines advertising in a way that includes materials related to product sponsorship and general sponsorship. This suggests that if a donation by permit/authorisation holders to healthcare institutions or organisations is associated with

branded materials or is in some way linked to the promotion of a product, it could be interpreted as a promotional tool rather than a purely philanthropic gesture.

Article 7 of the PhAMA Code outlines the rules concerning donations and sponsorship in various scenarios.

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

Pharmaceutical companies are permitted to sponsor scientific meetings and congresses, as well as support doctors' attendance at these events, as outlined in part 4 of the MMC Guideline on the Relationship between Doctors and the Pharmaceutical Industry. The PhAMA Code reinforces this by emphasising that such events, even when sponsored, should aim to provide scientific or educational information or update healthcare professionals about products.

There is no difference between the two sectors from the perspective of rules on the promotion of products.

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

All interactions with patient organisations must adhere to ethical standards, ensuring that the independence of the organisations is respected. Companies must transparently disclose their involvement and cannot claim sole funding.

Companies that provide financial support or an in-kind contribution to patient organisations must have written documentation in place setting out the nature of the support, including the purpose of any activity and its funding. Companies may also provide financial support for patient organisation meetings, provided the primary purpose of the meeting is professional, educational and scientific in nature or otherwise supports the mission of the patient organisation. When organising meetings for patient organisations, companies should ensure that both the venue and location are appropriate and conducive to informational communication.

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

Pursuant to Article 1.2 of the PhAMA Code, promotion encompasses activities conducted by member companies or third parties on their behalf to promote pharmaceutical products to healthcare professionals. Hence, the delegation of promotional activities through a service agreement is possible, subject to general restrictions.

Co-promotion is not subject to specific regulations in our jurisdiction.

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

No, it is not mandatory. However, the MMC Guideline on the Relationship between Doctors and the Pharmaceutical Industry emphasises the importance of openness and transparency in interactions between doctors and pharmaceutical companies. This often necessitates disclosing financial or other arrangements to institutions, ethics committees, patients, potential research subjects and other relevant parties.

ENFORCEMENT

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

Violations of the Medicines (Advertisement and Sale) Act 1956 shall, on conviction, be liable to fines up to MYR 3,000 or up to one-year imprisonment for the first offence, and fines up to MYR 5,000 or up to two years' imprisonment for subsequent offences.

Under the Medical Device Act 2012, advertising an unregistered medical device or making any misleading or fraudulent claims in respect of a medical device constitutes an offence and shall, on conviction, be liable to a fine not exceeding MYR 3,000, imprisonment for a term not exceeding three years or both. Failure to obtain approval from the MDA to advertise a medical device in compliance with the Medical Device (Advertising) Regulations 2019 shall, on conviction, be liable to a fine not exceeding MYR 2,000 or imprisonment for a term not exceeding two years or both.

The penalties and sanctions under the above acts are occasionally reported by local news agencies. The prosecution of offenders is also recorded as court judgments, which are accessible to the public.

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

For violations of the Medicines (Advertisement and Sale) Act 1956, legal action is pursued by the Public Prosecutor, as seen in significant cases like *PP v Twenty First Century Product Sdn Bhd* [1994] 1 CLJ 108 and *PP v Oze Marketing Sdn Bhd* [2016] 1 LNS 457.

The PhAMA Code provides a framework for handling complaints and infringements related to pharmaceutical marketing practices. Companies are encouraged to resolve disputes amicably before filing a formal complaint to PhAMA's Ethics Committee.

For violations of the Medical Device Act 2012, competitors may lodge a complaint to the MDA, who is authorised to investigate the offence under the said act. The Public Prosecutor has the discretion to institute the prosecution of an offence under the Medical Device Act 2012.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Given the surge in online sales of unregistered pharmaceuticals and medical devices, there has been a noticeable increase in enforcement actions against unauthorised sellers. This includes active raids and the prosecution of offenders in court. At the same time, there has been a heightened effort to alert the public about the risks of purchasing unregistered pharmaceuticals or medical devices.

From the perspective of the enforcement of pharmaceutical or medical device promotion, there has also been a rise in enforcement efforts.