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Pharmaceutical Advertising

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Shearn Delamore & Co

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1. Regulatory Framework

1.1 Laws and Self-regulatory Codes

The principal legislation governing advertising of medicines in Malaysia is the Medicines (Advertisement and Sale) Act 1956 (1956 Act), which is an Act to prohibit certain advertisements relating to medical matters and to regulate the sale of substances recommended as a medicine. Section 4B of the 1956 Act requires any publication of an advertisement for medicine "for the purpose of treatment or prevention of diseases or conditions of human" to be approved by the Medicine Advertisements Board (MAB). Overseeing the approval of medicine advertisement is the MAB, an agency of the Pharmaceutical Services Division of the Ministry of Health, which is chaired by the Director-General of Health.

In addition to the 1956 Act, the Medical Devices Act 2012 (MDA 2012) seeks to implement a regulatory framework for medical devices, which includes the introduction of the requirement to register medical devices as well as regulation of advertisements relating to medical devices. Malaysia also has the following legislation that contains provisions that may be applicable to the advertising of medicines:

- The Trade Descriptions Act 2011 (TDA) – Section 5 of the TDA provides that any person who:
  - (a) applies a false trade description to any goods;
  - (b) supplies or offers to supply any goods to which a false trade description is applied; or
  - (c) exposes for supply or has in his possession, custody or control for supply any goods to which a false trade description is applied, commits an offence.
- The Indecent Advertisements Act 1953. Section 6 prohibits advertisements on treatments or remedies in relation to venereal diseases.
- The MAB has issued the Guideline on Advertising of Medicines and Medicinal Products to General Public 2015 (2015 Guidelines), which governs the advertising practices of medicines and medicinal products aimed at the general public. The 2015 guidelines are intended to complement the provisions of the 1956 Act and the MAB Regulation 1976.

The codes of conduct regulating advertising and promotion of medical products include:

- the Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (PhAMA Code) by the Pharmaceutical Association of Malaysia (PhAMA);
- the OTC Code by PhAMA;
- the Code of Medical Ethics issued by the Malaysian Medical Association;

- general advertising codes, which include the Code of Advertising Practice (Advertising Code);
- the Communications and Multimedia Content Code (Content Code), which the Communications and Multimedia Content Forum of Malaysia has adopted for the purpose of statutory duty, and which sets out the guidelines and procedures for good practice and standards of content disseminated to audiences by service providers in the communications and multimedia industry in Malaysia;
- the Cosmetic Advertising Code, which was drawn up with the intention to provide guidance to the cosmetics industry in developing advertising message in an ethical manner; and
- the Advertising Guidelines for Healthcare Facilities and Services (Private Hospitals, Clinics, Radiological Clinics and Medical Laboratories).

1.2 Application and Legal Value of Regulatory Codes

In Malaysia, promotion for prescription medicines is jointly regulated through government legislation and pharmaceutical companies' codes of conduct. Advertisements on medicines, remedies, appliances, skill and services relating to diagnosis, prevention and treatment of diseases or conditions affecting the human body are under the authority of the MAB and Ministry of Health Malaysia. The role and tasks of the MAB are as follows:

- approve or reject any medicine advertisements application in any media;
- withdrawal or cancellation of approved advertisement whenever necessary; and
- approve/amend any guidelines pertaining to advertisements.

The 2015 Guidelines apply to anyone advertising medicine and medicinal products aimed at the general public. It does not apply to anyone advertising medicine and medicinal products to doctors, dentists, nurses, pharmacists or any advertising done by the Federal Government or State Government.

The PhAMA Code sets out the standards with which its members are required to comply to ensure ethical promotion of pharmaceutical products to healthcare professionals and that member companies' interactions with healthcare professionals are appropriate and perceived as such.

The OTC Code is separately administered by PhAMA to regulate over-the-counter (OTC) products used in self-medication to treat ailments that do not require a doctor's prescription. The OTC Code is more focused on the interaction of pharmaceutical companies with the consumers through advertisements.

Self-regulation of advertising in Malaysia is carried out through the Malaysian Advertising Standards Authority, whose members, all experienced in advertising, are drawn from the Malaysian Newspapers' Publishers Association, the Association of Accredited Advertising Agents Malaysia, the Malaysian Advertisers Association and the Media Specialist Association. The Malaysian Code of Advertising Practice (MCAP) governs print advertisements. The Advertising Standards Advisory Malaysia administers the MCAP, which applies to all advertisements in any print media.

Responsibility for observing the MCAP rests primarily with the advertiser although it also applies to any advertising agency or medium involved in publication of the advertiser's message to the public.

The Communications and Multimedia Content Forum has also issued general industry guidelines in the form of the Content Code. The Content Code governs advertisements via electronic means and includes television, radio, online services and audio text-hosting services otherwise referred to as premium rate services. The main objective of the Content Code is to ensure continued reliable standards of advertisements through self-regulation in accordance with expectations of consumers and internationally recognised good practice governing advertisement content disseminated by the electronic media.

While compliance with the Content Code is entirely voluntary and the Malaysian Communications and Multimedia Commission (MCMC) encourages self-regulation by the content providers, the Communications & Multimedia Act (CMA) provides that compliance with the Content Code provides a valid legal defence against any legal proceedings arising as a result of a contravention of the Content Code. As such, while observance of the Content Code is not mandatory, compliance is desirable as a good market practice.

Responsibility for observing the Cosmetic Advertising Code rests primarily with the advertiser.

Advertising Guidelines for Healthcare Facilities and Services (Private Hospitals, Clinics, Radiological Clinics and Medical Laboratories). The purpose of these Guidelines is to provide information to private hospitals, clinics, radiological clinics and medical laboratories regarding the regulations governing advertisements of healthcare services offered by these facilities that are disseminated to the general public.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

Under the 1956 Act, the word 'advertisement' is inclusive of all forms of communication methods that intend to promote

a particular product or service. It describes an advertisement as "including any notice, circular, report, commentary, pamphlet, label, wrapper or other documents, and any announcement made orally or by any means of producing or transmitting light or sound." The 2015 Guidelines provide a non-exhaustive list of what amounts to advertising and include the following:

- advertising on electronic ordering systems;
- aerial promotion, such as hot air balloons and/or blimps;
- aisle, ceiling, 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, giant mock-up boxes;
- gondola end advertising;
- indoor displays such as at airports, washrooms, 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;
- website and other internet materials including brand home pages and banner advertising; and
- any other form or means of advertising.

Advertising is defined under the Trade Description Act 2011 as "every form of advertising (whether or not accompanied by or in association with spoken or written words or other writing or sounds and whether or not contained or issued in a publication) by the display of notices or by means of catalogues, price lists, circulars, labels, cards or other documents or materials or by the exhibition of films or of pictures or photographs, or by means of radio or television, or in any other way including through electronic means".

2.2 Difference Between Information and Advertising

The 2015 Guidelines provide that advertisements give notice and public information with the intent to draw attention and inform. As such, advertisements attract consumers to buy products or services and have a direct impact on business. The 2015 Guidelines further provide that advertising is understood to encompass written or spoken words, and any pictorial representation or design, used or appearing to be used to promote the sale of medicines or medicinal products, generally by highlighting product claims.

The word 'information' is not defined in the 1956 Act or the 2015 Guidelines but it has been defined under the Guideline Of The Malaysian Medical Council (MMC) as referring to the factual information on public health promotion and specifically on prevention, control and treatment of diseases, and any other aspects related to these modalities, which a registered medical practitioner as a healthcare provider is permitted to disseminate to the public, without the practitioner contravening the ethical codes of professional conduct, and without any designs to obtaining patients, profiting financially or materially, or, appearing directly or indirectly, to promoting his or her own professional advantage or a product, or appearing to be for these purposes. Further, the 2015 Guidelines provide that advertorials that describe the historical use or current research of herbal ingredients or vitamins (such as ginseng, garlic, *tongkat Ali*, vitamin C, etc) without reference to the registered pharmaceutical product may be used without approval from the MAB subject to the following:

- the product brand name, pictorial representation or any reference to the product website should not be included as this would be considered as indirect advertisement of the product;
- there should also be certain statements or disclaimers in these advertorials that the consumer should seek appropriate professional healthcare advice; and
- any advertisements featuring registered products containing the active generic ingredients mentioned in the advertorials or others should not be tied in with these advertorials, and thus should not be placed on the same page or facing page, to comply with this requirement.

Disease awareness campaigns will not qualify as advertising if the campaigns merely provide information, promote awareness of a disease (or diseases) and educate the public about health, diseases and their management. Paragraph 10.2 of the 2015 Guidelines provides that the focus of the campaigns should be on health and disease education and where to get appropriate advice. It should not promote the use of a particular medicinal product.

Further, the 2015 Guidelines provide that the product brand name, pictorial representation or any reference to the product website should not be included and that the source(s) of the information material should be identified. If, however, the information provided makes product claims, uses brand names, restricts the range of management options described

and draws attention to the use of specific medicines, this can be considered promotional in nature and thus fall within the definition of an advertisement. The emphasis of the material should therefore be on the condition and its recognition rather than on treatment options in order for it not to fall within the definition of an advertisement.

The 1956 Act allows prescription medicines advertising if it is intended to provide information to the relevant parties such as doctors, pharmacists, nurses and members of the local authority or the governing body of a hospital and the like. Advertising by the government is also not subject to these rules. Further, the PhAMA Code permits the direct advertising of prescription drugs to healthcare professionals. 'Healthcare professionals' are defined 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.

2.3 Restrictions on Press Releases

Paragraph 10.3 of the 2015 Guidelines states that press releases for medicine product launches can be made but the information provided must be factual and comply with the Guidelines. It should be analysed, therefore, on a case-by-case basis, whether a press release is or is not an advertising activity. The 2015 Guidelines provide that press releases for New Chemical Entities (NCE) are allowed ONCE only for products which comply with the following criteria:

- new drugs that are available in Malaysia for the first time or within 18 months after being marketed/launched and no other similar drug is available in Malaysia;
- new combinations of active pharmaceutical ingredients; or
- new approved indications.

Further, the 2015 Guidelines provide that the use of brand names should be kept to a minimum and the tone and content of the press release must be factual and not sensationalised.

2.4 Comparative Advertising

Comparative advertising is allowed subject to restrictions. Paragraph 5.6 of the 2015 Guidelines governs comparative guidelines and provides a list of what comparative advertisements should comply with. The Guidelines provide that comparative claims 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 made clear what comparison(s) is being made;
- 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;
- where appropriate, be supported by documentary evidence that is easily understood; and
- not involve the use of 'baseless' hanging comparatives that merely claim that a product is, eg, 'longer-acting', 'quicker' or 'stronger'.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The Guidelines to Advertising of Medicines and Medicinal Products to General Public provide that all medicines must be registered with Drug Control Authority (DCA) before they are sold or marketed in Malaysia. Both pharmaceutical products that contain scheduled poisons as defined in the Poisons Act 1952 (ie prescription drugs) and pharmaceutical products that do not contain scheduled poisons (ie OTC products) are required to be registered. Cosmetic products, traditional medicines and veterinary medicines are also required to be registered.

Only registered products (with valid MLA registration number) are allowed to be advertised, as those products are assured safe for consumption. Further, the PhAMA Code provides that no pharmaceutical product shall be promoted in Malaysia until the requisite approval for marketing for such use has been given. The compassionate-use programme in Malaysia is available as an extension to an approved clinical trial protocol.

Through this programme, only subjects enrolled in the approved clinical trial are allowed to continue the use of the unregistered medicinal product with the approval of the DCA. As the compassionate use programme is an extension of a completed clinical trial and subjects will be provided with continued treatment with the unregistered product, all serious, unexpected adverse drug reactions should be reported to the Centre for Investigational New Products. In the event that the product to be used by the subjects of the completed clinical trial is registered with the DCA and commercially available, all suspected local adverse reactions should be reported to the Pharmacovigilance/ADR/MADRAC Unit, Centre for Post Registration of Products in accordance with their established procedures. Meanwhile, for named patient programmes involving compassionate use of unregistered product and that fall under the following applications where CTIL and/or CTX are not applicable, any Suspected Unexpected Serious Adverse Reactions (SUSAR) should be reported to the Pharmacovigilance/

ADR/MADRAC Unit, Centre for Post Registration of Products in accordance with their established procedures.

In Malaysia, the use of off-label medication is permitted subject to procedural guidelines. Doctors can inform patients on off-label usage (unregistered indication) with the informed consent of the patient, approved in each instance by the Director-General of Health and reported via a standardised form. Before prescribing the medication for off-label use, doctors must sign a consent form stating they have explained to the patient:

- that the medication/indication prescribed is not registered with DCA Malaysia;
- all the risks involved;
- that it is an alternative for their treatment and give patients the opportunity to ask all questions; and
- that they must ensure that the medicine is used according to the recommended procedure during the treatment period.

A consent form must be signed by patients stipulating they understand the usage of the medicine for their treatment and that they accept full responsibility for all the risks related to the use of the medicine during the course of the treatment.

3.2 Provision of Information During a Scientific Conference

The PHAMA Code provides that "no pharmaceutical product shall be promoted in Malaysia until the requisite regulatory approval for marketing for such use has been given." The PHAMA Code further provides that this provision is not intended to prevent the right of scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences.

According to the Pharma Code, dissemination of information of unapproved product or indication is permitted at local meetings inclusive of Continuing Medical/Professional Education (CMEs) and at international meetings. To the extent allowed by local laws and regulations, dissemination of scientific information for a pharmaceutical product or indication that has not been approved for marketing by the Malaysian DCA, or for a registered product with a new unapproved indication, can be undertaken by a member company provided:

- no brand name is mentioned;
- there is a declaration that it is still unapproved in Malaysia;
- it is organised under the auspices of a professional body or hospital-based CME committee;
- it is based on verifiable (eg, poster/abstract/publication) data or peer-review reprints as a CME event endorsed by a professional body; and
- relevant permission is obtained from authorised bodies (if required).

Information provided at international meetings/symposia/congresses held in Malaysia, which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia, may refer to pharmaceutical products that are not registered in Malaysia, or which are registered under different conditions, provided that the following conditions are observed:

- the meeting should be a truly international scientific event with a significant proportion of the speakers and attendees from countries other than Malaysia;
- information (excluding promotional aids) for a pharmaceutical product not registered in Malaysia should be accompanied by a suitable statement indicating that the product/indications/dosage form is not registered and must make clear that the product/indication/dosage is 'still unapproved in Malaysia'; and
- information that refers to the prescribing information (indications, warnings, etc) authorised in a country or countries other than Malaysia, but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

3.3 Provision of Information to Healthcare Professionals

As mentioned in **3.2 Provision of Information During a Scientific Conference**, the PHAMA Code sets forth that healthcare professionals can be kept informed of unauthorised medicines and/or indications in order to be kept up to date with scientific and medical progress to allow full and proper exchange of information between healthcare professionals. This will include information on unauthorised medicines or unauthorised indications.

3.4 Provision of Information to Healthcare Institutions

The PHAMA Code does not prevent information on unauthorised medicines or unauthorised indications being sent to healthcare institutions to prepare budgets, etc. Care should however be taken to ensure that such communications are not, in effect, advertisements for an unlicensed medicine or use. At private hospitals, medical consultants who need the medicines will initiate the procurement process and submit their recommendation for purchase supported by relevant clinical literature.

4. Advertising to the General Public

4.1 Main Restrictions on Advertising to the General Public

As mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, any advertisement of medicines including OTC medicine or controlled medicine must first apply for approval from the Medical Advertisement Board. Once approval is granted, an approval serial number will be given. No product that is a controlled medicine, poison or contains poisons as specified in the Poisons List set out in the First Schedule to the Poisons Act 1952 (Revised 1989) may be advertised unless exempted.

PhAMA, which represents pharmaceutical companies, administers a code of conduct as a guide for the advertising of prescription medicines. The OTC Code is separately administered by PhAMA to regulate OTC products used in self-medication to treat ailments that do not require a doctor's prescription. The OTC Code is more focused on the interaction of pharmaceutical companies with the consumers through advertisements.

General Principles on Advertising of Medicines/Medicinal Products to General Public

- advertisements should contain information that is reliable, accurate, truthful, informative, fair, objective, unambiguous, balanced, up-to-date, capable of substantiation and in good taste;
- they should not contain any misleading or unverifiable information either directly or by implication that is likely to induce unjustifiable medical use or to give rise to undue risks;
- it is important that advertisements do not abuse the trust or exploit lack of knowledge among the general public, and that they should not lead to self-diagnosis or inappropriate treatment of potentially serious diseases;
- advertisements should not, without justification, show or refer to dangerous practices or manifest a disregard for safety, and special care should be taken in advertisements directed towards or depicting children or young people;
- advertisements should not contain any statements or visual presentations that might lead to or support acts of violence;
- advertisements should not contain statements or visual presentations that are likely to be interpreted to be, contrary or offensive to the standard of morality or decency prevailing in the Malaysian society or in any way defamatory or humiliating to any segment of the public;
- the products, advertisers or advertisements of other companies should not be disparaged either directly or by implication; and
- advertisements should not:

  (a) contain any statement(s) that either explicitly or by implication disparage the medical profession, the value of professional attention and treatment, or another product; or

  (b) discredit or unfairly attack other products, advertisers or advertisements directly or by implication.

However, comparisons of products from the same registration-holder is allowed if substantiated.

4.2 Information Contained in Advertising to the General Public

The following is information that the advertising must contain:

- the brand name of the product;
- the active ingredients, using approved names where they exist;
- the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- the date of production of the advertisement;
- abbreviated prescribing information that should include an approved indication together with the dosage and method of use and a succinct statement of the contraindications, precautions and side effects (minimum font size of 6pt is to be used for printed materials);
- the approval serial number from the MAB must be displayed in the advertisement;
- claims made in an advertisement must be in accordance to the product indication and/or label as approved by the DCA;
- a translation if the advertisement is only in the Chinese or Tamil languages; and
- if required, special/cautionary statements such as "this preparation contains X% of alcohol" must be included in the advertisement.

Advertisements should not contain any claims either directly or indirectly referring to:

- the prevention, treatment alleviation, cure or diagnosis of diseases and conditions as listed in Schedule 1 of the Medicine (Advertisements and Sales) Act 1956;
- practising contraception among human beings;
- improving the condition or functioning of the human kidney or heart or improving the sexual function or sexual performance of human beings; or
- procuring miscarriage in women.

Advertisements should not make specific claims to suggest or imply that any product offered will prevent and/or treat:

- sexual weakness, ageing, loss of virility;
- loss of hair, baldness, etc;
- the use of comparison, either direct or by implication, between one hospital, clinic, radiological clinic or medical laboratory and another is prohibited; the use of superlatives (eg, 'the best') in describing the available services or facilities is also not permitted;

- in reference to publication of brochures or pamphlets there should be no overemphasis on doctors associated with the hospital, clinic, radiological clinic or medical laboratory by way of touting for customers (testimonials from patients shall not be published or printed);
- unsolicited communication with potential clients for the purpose of touting and enticing patients is prohibited; and
- announcement over the radio, television, rediffusion or cinema is prohibited.

As for pricing, the Medical Advertisements Board's Policy and Decision (Product) Guidelines state that pricing of medicines in an advertisement does not fall under the MAB's purview. Rather, it falls under the jurisdiction of the Ministry of Domestic Trade and Consumer Affairs.

Currently, only those selling price-controlled goods must display prices of the goods that can be easily read by consumers as per s.9 of the Price Control and Anti-Profiteering Act 2011.

As medicine is not yet a controlled good based on the Ministry's portal (https://www.kpdnhep.gov.my/list-of-controlled-goods/?lang=en), advertisements technically speaking do not have to contain prices. However, it is best practice to do so in order for consumers to not be deceived because s.14 of the TDA makes it an offence for anyone to offer to supply any goods if they make false or misleading indications as to the price of the goods.

Additionally, the Ministry of Health does have plans to make medicine a controlled price good as of November 2018 (https://www.thestar.com.my/news/nation/2018/11/15/ministry-aims-to-control-prices-of-medicines/).

Advertisements may include Halal certifications for medicines that already have Halal certification.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Interactions with Patient Organisations (PhAMA Code)

All interactions with patient organisations should be ethical and the independence of patient organisations must be respected. When working with patient organisations, companies must ensure that the involvement of the company and the nature of that involvement is clear from the outset. Moreover, no company may claim that it is the sole funder of the patient organisation or any of its programmes.

Companies that provide financial support or 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 that the primary purpose of the meeting is professional, educational and scientific in nature or otherwise supports the mission of the patient organisation. When companies hold meetings for patient organisations, companies must ensure that the venue and location are appropriate and conducive to informational communication.

Requests from individual members of the public for information or advice on personal medical matters must always be refused and the inquirer recommended to consult his or her own doctor.

The MMC, which is the governing body of doctors in Malaysia under the Medical Act 1971, does generally restrict interactions between doctors and patients and also doctors and the general public when it comes to advertising in particular. In general, paragraph 4.1 of the MMC's Code of Professional Conduct states that advertising by doctors, whether directly or indirectly, for the purpose of getting patients or promoting their professional position is generally contrary to the public interest and doctors can be liable to disciplinary punishment.

The Malaysian Dental Council (MDC), which is the governing body of dentists in Malaysia under the Dental Act 1971, also has general restrictions on interactions between dentists and patients and also dentists and the general public in terms of advertising. The MDC's Code of Professional Conduct states at paragraph 8 that dentists must not use advertising or publicity materials that draw undue attention to them or are likely to bring the profession into disrepute amongst others.

4.4 Restrictions on Endorsements by Healthcare Professionals

There are restrictions on endorsements by healthcare professionals in the advertisement of medicines under the 2015 Guidelines. Under **5.2 Reference to Data Not Included in the Summary of Product Characteristics**, it is stated advertisements should not have anything amounting directly or indirectly to an impression of endorsement by doctors, dentists, pharmacists, nurses and paramedics, etc. However, endorsement by professional bodies may be allowed with the consent from the respective professional bodies.

Authorisation from the said bodies should be given in writing and produced on demand. Further, the PHAMA Code provides that no financial benefit or benefit-in-kind (including grants, sponsorships, gifts, scholarships, subsidies, support, consulting contracts or educational or practice-related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. The MCAP by Advertising Standards Authority (ASA) 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.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

In Malaysia, pharmaceutical promotion of prescription medicines is self-regulated by pharmaceutical companies. The PhAMA Code is designed to complement the requirements dictated by government legislation. The PhAMA Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals, patient organisations and medical institutions are appropriate and perceived as such.

The PhAMA Code covers interactions with healthcare professionals and the promotion of pharmaceutical products. The PhAMA Code provides that 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. Further, 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).

Promotion should be capable of substantiation either by reference to the approved labelling or by scientific evidence. In addition, 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 are appropriate to the source of the enquiry. All printed promotional materials, other than 'reminder advertisements', must include:

- the brand name of the product;
- the active ingredients, using approved names where they exist;
- the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- the date of production of the advertisement;
- 'abbreviated prescribing information', which should include an approved indication together with the dosage and method of use; and
- a succinct statement of the contraindications, warnings, precautions, side effects and dosage.

A minimum font size of 6 points is to be used for printed materials. All Printed Promotional Material, other than 'reminder advertisements', should also fulfil the following requirements:

- promotional material, such as mailings, journal advertisements and loose inserts, must not be designed to disguise its real nature;
- advertisements in journals should not be designed so as to resemble editorial material;
- promotional material should conform, both in text and illustration, to canons of good taste and should recognise the professional standing of the recipient;
- all printed promotional material, including advertisements should include the name of the product (normally the brand name), the generic name of the product and the date of production of the advertisement;
- doctors' names or photographs must not be used in a prominent manner in promotional material or in any way that is contrary to the ethical Code of the medical profession;
- promotional material should not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse;
- material and articles from the lay press should not be used as promotional material; and
- the disclaimer statement "For Healthcare Professionals only" is to be added to printed materials for the HCP-targeted audience.

The PhAMA Code states that promotions must be ethical, accurate, balanced and not misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

The PhAMA Code provides that companies are committed to the transparency of clinical trials which they sponsor and that it is recognised that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and regulatory agencies. The PhAMA Code provides that such disclosures, however, must maintain protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

5.3 Restrictions on Reprints of Journal Articles

The PhAMA Code provides that reprints of scientific and medical articles, when used as standalone documents, are not developed by pharmaceutical companies and as such will not be considered as promotional materials. Such reprints are acceptable to be presented if they are disease education articles only. If, however, they are presented to a healthcare

professional together with other company-originated documents, they then become promotional materials.

In all cases, where promotion refers to, includes or is presented together with scientific or medical articles or studies, clear references should be provided. Any reprint of artwork (including graphs, illustrations, photographs or tables) taken from articles or studies and included or presented with promotional materials should clearly indicate the source of the artwork and be faithfully reproduced. Any article on promotional/branding prescription product is however not allowed.

Only full text is allowable – ie publish it as it is. Abstracts are not allowed. Article reprints are not acceptable.

Scientific general papers from the lay press are also acceptable. Those from medical publications, ie, *Medical Tribune* are not acceptable.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Under s.4B of the Medicines (Advertisement and Sale) Act 1956, any publication of an advertisement for medicine is to be approved by the MAB, which is the competent authority. Advertising to the public is only allowed for a product that is registered with the DCA and healthcare services (handled by Medical Practitioners), namely private hospitals, private clinics, private radiological clinics and private medical laboratories. All advertisements approved by the MAB will be given approval numbers.

The requirements for approval are as follows:

- submit Form B;
- submit five copies of advertisement formats (if it's an internet website, three copies only);
- a bank draft/money order/postal order worth MYR300 made payable to 'Ketua Setiausaha, Kementerian Kesihatan Malaysia';
- certificate of incorporation;
- one copy of the translation of the advertisement, if advertisement only involves Chinese or Tamil language;
- for advertisements on medical products ONLY:
  (a) indication certificate approved by the DCA;
  (b) product formula (ingredients) with complete content percentages up to 100%;
  (c) labels and package inserts that have been approved by the DCA; and
- any other relevant documents/certificates.

In the issuance of an approval for any advertisement relating to a medical product, the MAB requires an applicant to ensure that the advertisement which it seeks to publish to the public complies with the 2015 Guidelines and is subjected to the conditions mentioned in **4.1 Main Restrictions on Advertising to the General Public** and **4.2 Information Contained in Advertising to the General Public**, above, in order to obtain approval from the MAB.

6.2 Compliance with Rules on Medicinal Advertising

The Medical Act provides that the MMC shall have disciplinary jurisdiction over all persons registered under this Act. In the exercise of its function under section 29(2) of the Medical Act, the MMC relies upon its Code of Professional Conduct (the 'Code') and its guidelines which supplement the Code, in particular, 'The Duties of a Doctor', which contains 'Good Medical Practice' and 'Confidentiality'. The MMC's Code and its guidelines do not prescribe ideal behaviour, but the minimum standards of conduct expected of a registered medical practitioner.

7. Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

All types of dissemination of information about products and health services including on the internet are classified as advertisements. Therefore, MAB approval is required before it can be published to the public. A KKLIU number must be clearly displayed on every page that has been approved by the MAB.

The name, address and contact number of the advertiser must also be clearly stated on the page. In a situation where medicine is advertised together with other healthcare products, care must be taken to avoid misleading so that it clearly distinguishes between MAB-approved advertisements and advertisements that do not require the MAB's approval.

7.2 Advertising of Medicines on Social Media

The PhAMA Code provides that all social media communication for business purposes should be communicated from a company profile and not associated to a personal account. Further, all information shared in social media for business purposes needs to be appropriate, accurate and fair for public viewing and understanding.

The following information should be shared in the social media platform for transparency:

- a product name/logo (either brand or generic) is not allowed as direct to consumer promotion is prohibited;

- any description that could refer only to a specific product (eg a therapeutic class in which there is only one product) is not allowed as well;
- a disease area/indication will need to be reviewed and approved by the relevant function in accordance with the approval process of the respective member company; and
- company branding.

If required, the information shared should be accompanied with referencing, scientific disclosure, possible conflicts of interest and a privacy statement. Member companies are responsible for the information uploaded onto their website. In a decision by MAB 3/2012 (19 July 2012), the MAB decided not to allow links to social networking sites (eg, Facebook, Twitter and blogs) in the advertisement of medical products and healthcare facilities and services. The MAB also agreed that the advertiser shall be liable for all of the information displayed in these social networks.

As for the restrictions that apply, they are the same ones as contained in **7.1 Regulation of Advertising of Medicinal Products on the Internet**.

7.3 Restrictions on Access to Websites

Websites containing advertisements or information whose nature and content are directed at health professionals (eg where non-exempted controlled medicine is advertised) must be access-restricted and clearly labelled as intended for health professionals.

8. Inducement/Anti-bribery

8.1 General Anti-bribery Rules

Under s.16 of the Malaysian Anti-Corruption Commission Act 2009 (MACC Act), it is an offence for someone either to give, promise, offer, solicit, receive or agree to receive any gratification as an inducement to or a reward for another to do or not to do anything in respect of any matter or transaction be it actual, proposed or likely to take place.

Gratification is defined under the MACC Act to include money, donation, gift, reward, property, any valuable consideration, any service or favour, etc. It is likely this may apply to interactions between pharmaceutical companies and healthcare professionals or healthcare organisations to prevent a pharmaceutical company providing a gift of some kind to healthcare professionals in order to obtain something in return from the healthcare professionals, such as preferring one drug over another when it comes to prescription. Section 24 of the MACC Act provides that those who commit an offence under s.16 are liable on conviction to imprisonment for a maximum term of 20 years and a fine of not less than five times the sum or value of the gratification.

The MACC Act does not make a distinction between private sector bribery and bribery of public officials. The provision dealing with the offence of accepting gratification has a general application and, therefore, it applies to any person regardless of whether the bribery was between two private individuals or whether a public officer was involved.

8.2 Legislative or Self-regulatory Provisions

In relation to this point, the MMC Guideline on the Relationship between Doctors and the Pharmaceutical Industry 2006 (2006 Guidelines) provides that *"practitioners are expected to prescribe a particular pharmaceutical agent to his patient based on his own clinical judgment without any influence from the industry."* Doctors must exercise their independent judgement and decide whether what they are receiving is acceptable. Nonetheless, the 2006 Guidelines does ask doctors to err on the side of rejecting gifts.

The 2006 Guidelines also discusses hospitality offered to doctors and states hospitality provided to the doctors must be simple and modest and interactions with doctors should successfully withstand public and professional scrutiny. The 2006 Guidelines also consider drug samples from manufacturers under Part 7. It does not prohibit doctors from receiving them but does state that only a sufficient quantity of the relevant drug to enable the particular need to be met should be accepted.

It is also recommended for doctors to not ask for drug samples or accept free samples, which may influence their prescribing choices.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Malaysian law does not specifically govern interactions with HCPs, but, in certain circumstances, the MACC Act may apply. The PhAMA Code provides that no financial benefits or benefits-in-kind may be provided or offered to HCP in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Providing or offering cash, cash equivalents or personal services is also prohibited. Gifts for the personal benefit (such as sporting or entertainment tickets, electronic items, social courtesy gifts, etc) of HCPs are prohibited.

Items of medical utility may be offered or provided by member companies if such items are of modest value, do not exceed MYR500/item/HCP, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care. Items such as stethoscopes, surgical gloves, blood pressure monitors and needles are examples of routine business expenses, and as such

they are expected to be supplied by the HCPs themselves or their employers. They should not be offered on more than an occasional basis, even if each individual item is appropriate.

Educational medical material such as journals, textbooks, anatomy models and subscriptions not exceeding a limit of MYR1,500 (approximately USD370) a year per institution or HCPs are allowed. Gifts of cultural courtesy are not allowed.

Providing or offering promotional aids to HCPs in relation to the promotion of prescription-only medicines is prohibited. Examples of banned promotional aids include sticky notes, mouse pads, calendars, etc. Pens and notepads can be provided to HCPs in the context of company organised events or third-party scientific events for the purpose of taking notes during the meeting.

They must not bear the name of any medicine, campaign names, tag lines and logos of therapeutic area but may bear the name of the company providing them. In addition, they must be of minimal value – ie no more than MYR15 (USD4) per item and only the necessary quantity is distributed.

9.2 Limitations on Providing Samples to Healthcare Professionals

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 provides that samples of products given out should be no larger than the smallest commercial pack of each strength and clearly labelled as "Samples – Not for Sale" or similar wording allowed by the law.

Where samples of products restricted by law to supply on prescription are distributed by a representative, the sample must be handed direct to the doctor or given to a person authorised to receive the sample on his behalf. Samples must be delivered conforming to the Postal and Poisons Regulations governing it and must be packed so as to be reasonably secure against the package being opened by children. Samples must not be used as unofficial bonus and an inducement to purchase.

They must also not be used for clinical trials. Samples of medicines should not be sold by anyone.

The 2006 Guidelines provide that asking for drug samples is not recommended. The acceptance of free samples that may influence the choice of prescribing is not recommended. Requesting samples for personal use is also not acceptable.

They do not prohibit doctors from receiving them but do state that only a sufficient quantity of the relevant drug to enable the particular need to be met should be accepted. It is also not recommended for doctors to ask for drug samples or accept free samples which may influence their prescribing choices.

9.3 Sponsorship of Scientific Meetings

Part 4 of the 2006 Guidelines discusses sponsored meetings by pharmaceutical companies. Part 4.1 states that " *The pharmaceutical industry provides sponsorship both for organising meetings and to doctors for attending them.*" Therefore, it does seem to appear that pharmaceutical companies are allowed to sponsor scientific meetings or congresses and attendance by doctors to these events.

However, it does provide that the ideal manner for pharmaceutical companies to provide such sponsorship is through an independently organised scientific meeting for which the costs of bringing in invited speakers are defrayed by the funds provided by industry; the cost of travel and attending such a meeting is met by doctors because of its value to their continuing professional development.

PhAMA Code of Pharmaceutical Marketing Practices

Interactions with healthcare professionals

The PhaMA Code provides that the purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organised or sponsored by a company should be to provide scientific or educational information and/or inform healthcare professionals about products. Any financial support of medical societies, hospitals and clinics' social events eg annual general meeting, annual dinner, family day, sports day, etc in the form of donation and/or gifts is not allowed. The PhAMA Code further provides that no company may organise or sponsor an event for healthcare professionals that takes place outside Malaysia, where the majority of the attendees are Malaysians.

International scientific congresses and symposia that derive participants from different countries are therefore justified and permitted to be hosted in any of the countries that are represented by the delegate (all sponsorship and meeting criteria still apply). For external international events/meetings, sponsorship by pharmaceutical companies should be limited to basic economy travel (if travel time is less than six hours), meals, lodging and registration fees.

Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

Relationship between Doctors & Pharmaceutical Industry

Pharmaceutical industry sponsored travel and attendance at meetings

The 2006 Guidelines provide that the ideal manner for pharmaceutical companies to provide sponsorship is through an independently organised scientific meeting for which the costs of bringing in invited speakers are defrayed by the

funds provided by industry; the cost of travel and attending such a meeting is met by doctors because of its value to their continuing professional development.

The 2006 Guidelines provide that in accepting sponsorship outside these arrangements, the main issues with ethical implications that need to be considered by a doctor are that:

- the sponsorship must be clearly linked to education;
- there should be no loss of professional independence through accepting the sponsorship offered;
- the doctor should have no reservations regarding the sponsorship being publicly scrutinised;
- the criteria to select invited speakers and delegates can be made available to organisations invited to contribute to the event; and
- leisure activities must be kept to the minimum and must not interfere or coincide with the main educational activities.

The 2006 Guidelines further provide that if any sponsorship is offered to the doctor to travel to a meeting where he or she is making a formal contribution, any actual payments should be made by the organisers of the meeting and not by the sponsor.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Part 5.4 of the 2006 Guidelines provides that doctors can approach pharmaceutical companies to support scientific meetings such as supplying dinners, programmes or satchels as well as taking part in exhibitions of pharmacological or other products. Such support is appropriate provided that there are no contingencies upon alterations in the programme, speakers or other aspects of the meeting. In these circumstances, appropriate acknowledgement generally should be given, but this should be by general reference to the company without reference or endorsement of a single product.

The doctor should not accept or acknowledge sponsorship that could in any way damage the public standing or reputation for independence of the profession in the eyes of:

- peers, colleagues and co-workers;
- the media;
- patients and their relatives; and
- the general public.

The question should always be asked: "Can this presentation stand on its own without the financial support and influence of an outside body?"

PhAMA Code of Pharmaceutical Marketing Practices

Companies should not organise events nor provide financial support including sponsoring HCPs to any event at renowned venues or those that are not appropriate for the purpose of scientific education, being instead associated with leisure, golf, spa, island resorts (not accessible by land transport) and gaming activities. The PhaMA Code provides that no entertainment or other leisure or social activities should be provided or paid for by member companies.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

This issue is addressed by Part 3.2 of the 2006 Guidelines. There is no distinction between monetary donations and donations of equipment or services. The 2006 Guidelines state that it is generally acceptable for financial grants or equipment to be provided by pharmaceutical companies to hospitals, healthcare centres and universities specifically for the purposes of research. However, they should be appropriately acknowledged in the research and other publications.

Also, there should be in a place a formal contractual arrangement, which is open to scrutiny, where the donation is linked to or contingent upon a clinical trial or specific research project.

As a general rule, grants and donations should not be provided for the purpose of supporting a recipient's ordinary business expenses, eg for infrastructure or overhead (such as the purchase, construction, expansion or modification of facilities or equipment and paying of salaries). Institutions or organisations must ensure that the recipients use the donations and grants in accordance with the intended purposes independent from the companies providing the grants and donations.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

The PhAMA Code does not restrain or regulate commercial trade terms for the supply of pharmaceutical products and therefore does not prohibit pharmaceutical companies from giving its customers discounts or other favourable trade terms for the supply of pharmaceutical products. However, any rebates or discounts could fall within the wording "any valuable consideration" and constitute a gratification under the MACC and lead to the possibility of an offence being committed as discussed in **8.1 General Anti-Bribery Rules**.

9.7 Payment for Services Provided by Healthcare Professionals

The PhAMA Code provides that healthcare professionals may be engaged as consultants and advisers for services, such as speaking at and/or chairing meetings and events, involvement in training services and participation at advisory board meetings where such participation involves remuneration. The arrangements that cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services, which specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine;
- the fair market value of the services provided is MYR1,500/engagement/day with up to maximum MYR3,000/multiple engagement/day;
- if it concerns local speakers at international events held locally or outside Malaysia, members are advised to refer to their own company's internal code. The same proposal on a signed contract remains; and
- if it concerns international speakers, then members are advised to check with the speaker's home country code and apply accordingly. The same proposal on a signed contract remains.

Under Part 8 of the 2006 Guidelines, doctors are entitled to remuneration for services they provide to the pharmaceutical industry. It also goes on to say that such a relationship should be within public knowledge. Doctors are also able to act as consultants for pharmaceutical companies, obtain reward for developing new drugs and be employed in the pharmaceutical industry.

Doctors should not request or accept a fee equivalent consideration from pharmaceutical companies in exchange for seeing them in a promotional or similar capacity. An individual doctor may act as a consultant for a pharmaceutical company. This may be in general terms or in relationship to a particular product.

The arrangement should be like that of any business undertaking. If a doctor acts as a consultant to the industry, this information should be public knowledge, and be appropriately reported to and recognised by all relevant committees.

9.8 Prior Authorisations or Notifications

Malaysian laws do not provide for such requirements.

10. Transparency

10.1 Requirement to Disclose Details of Transfers of Value

There is no legislation or clear guidelines explaining this point. However, the 2006 Guidelines provide that there is a need for openness and transparency in dealings between doctors and pharmaceutical companies. In many cases this will require disclosure of financial or other arrangements to institutions, ethics committees, patients, potential research subjects and others.

Such disclosures do not in themselves imply the existence of conflicts of interest, but merely allow public scrutiny of possible dualities of interest to ensure that such conflicts do not develop and do not cloud the primary clinical objectives.

10.2 Foreign Companies and Companies that Do Not Yet Have Products on the Market

We are not aware of any such requirements.

11. Enforcement

11.1 Enforcement Bodies

Enforcement of Medicines Advertising Rules

Medicines (Advertisement and Sale) Act 1956

Section 7 provides that the Minister may establish the MAB. The Minister may also provide the procedure and manner of submitting advertisements for approval and impose fees for submission and approval of such advertisements. Section 4b provides that advertisements of medicines must be approved by the MAB, which has been established for this purpose by the Minister.

The MAB may, at its discretion, issue or refuse to issue any approval for advertisements of registered product to be publicised or may cancel any approval that was previously issued. The MAB reserves the right to delete from any advertisements, acts which could bring about undesirable thoughts and impression to the viewers.

PhAMA Code of Pharmaceutical Marketing Practices

Infringements, complaints and enforcement

Each member company is strongly encouraged to adopt procedures to assure adherence to the PhAMA Code. While strong legal and regulatory mechanisms and vigorous government enforcement may obviate the need for compliance mechanisms, member companies are encouraged, where appropriate, to include provisions intended to assure compliance with PhAMA Code.

Enforcement of rules on inducements

As for enforcing the rules on inducement, the appropriate body would be the Malaysian Anti-Corruption Commission as their functions under Section 7 of the MACC are to detect

and investigate any suspected offence, suspected attempt to commit any offence and suspected conspiracy to commit any offence under the 2009 Act. This would fall within the scope of **8.1 General Anti-bribery Rules**. Here, Section 7 of the MACCA 2009 provides that the functions of the officers of the Commission are to:

- receive and consider any report of the commission of an offence under this Act and investigate such of the reports as the Chief Commissioner or the officers consider practicable;
- detect and investigate any suspected offence, attempt or conspiracy to commit any offence under this act;
- examine the practices, systems and procedures of public bodies in order to facilitate the discovery of offences under this Act and to secure the revision of such practices, systems or procedures as in the opinion of the Chief Commissioner may be conducive to corruption;
- instruct, advise and assist any person on ways that corruption may be eliminated by a person;
- advise heads of public bodies of any changes in practices, systems or procedures compatible with the effective discharge of the duties of the public bodies as the Chief Commissioner thinks necessary to reduce the likelihood of the occurrence of corruption;
- educate the public against corruption; and
- enlist and foster public support against corruption.

11.2 Initiating Proceedings for Advertising Infringements

MAB Guideline on Advertising of Medicines and Medicinal Products to General Public

A competitor may file a complaint to the MAB. If the advertisement has breached the Guidelines, the MAB will revoke its approval for that advertisement under Paragraph 3.1 of the 2015 Guidelines. If the advertisement has breached the provisions under the Medicines (Advertisement and Sale) Act 1956, then the Attorney General Chambers under s.6F of the 1956 Act will prosecute the infringing company.

This can be seen in two cases prosecuted under the 1956 Act, PP v Twenty First Century Product Sdn Bhd [1994] 1 CLJ 108 (High Court) and PP V Oze Marketing Sdn Bhd [2016] 1 LNS 457 (High Court).

PhAMA Code of Pharmaceutical Marketing Practices

Infringements, Complaints and Enforcement

Genuine complaints relating to infringements of the PhAMA Code are encouraged. Detailed procedures for complaints and the handling of complaints (including the respective roles and jurisdiction of PhAMA and member associations) can be found in Appendix A of said document. But, generally, any complainant company should first initiate contact with the company alleged to be in breach, in order to discuss the issue and endeavour to settle the dispute/disagreement of any subject matter, prior to forwarding such complaints in writing to the Ethics Committee for deliberation.

The complainant should provide proof or evidence that the parties concerned have communicated but were unable to come to a decision, when lodging a complaint.

11.3 Penalties for Violating Advertising Rules and Rules on Inducements to Prescribe

As for violating medicines advertising rules in the 2015 Guidelines, the MAB can revoke its approval of the advertisement under Paragraph 3.1 the 2015 Guidelines.

As for violating medicines advertising rules in the Medicines (Advertisement and Sale) Act 1956, Section 5 of the 1956 Act provides that anyone contravening the specific offences under the Act can be liable to either a maximum MYR3,000 fine or a maximum one-year imprisonment term, or both if it is their first conviction. If it is a subsequent conviction, then that person can be liable to either a maximum MYR5,000 fine or a maximum two-year imprisonment term or both.

As for violating inducements to prescribe, as explained in **8.1 General Anti-bribery Rules**, Section 24 of the MACC Act provides that those who commit an offence under Section 16 are liable on conviction to imprisonment for a maximum term of 20 years and a fine of not less than five times the sum or value of the gratification.

11.4 Relationship Between Regulatory Authorities and Courts

Self-regulatory authorities such as the PhAMA and the MAB have formal procedures that will be carried out if there is a breach of relevant advertising rules. As mentioned above, the MAB have the power to cancel any such approval previously issued. Any violation of the laws, such as offences under the Medicines (Advertisements and Sale) Act 1956 and the MACC, is criminal in nature and thus, will be heard and decided by a court. If guilty, the offender can be fined and imprisoned.

11.5 Recent Enforcement Trends

There does not appear to be recent enforcement trends per se as there does not appear to be data showing advertisements that have breached the rules. It does however appear that there have been two cases in the Malaysian High Court regarding enforcement under the Medicines (Advertisement and Sale) Act 1956.

PP v Twenty First Century Product Sdn Bhd [1994] 1 CLJ 108 (High Court)

In this case, the Company was accused of issuing advertisements in relation to medicines being able to cure certain diseases, which under the Medicines (Advertisement and Sale) Act 1956 it was prohibited from doing so. The High Court dismissed the prosecution's appeal because the Com-

pany had not "advertised" to the general public. It had only advertised to pharmacies, which it was allowed to do so under Section 3(2) of the 1956 Act.

PP v Oze Marketing Sdn Bhd [2016] 1 LNS 457 (High Court)

In this case, the respondent advertised his products claiming to "increase memory levels by 95%." This advertisement did not receive prior approval from the MAB and, thus, the main point in dispute is whether "increasing memory levels" would constitute as treatment or prevention of disease or conditions of human beings. As seen in Section 4b Medicines (Advertisement and Sale) Act 1965, such advertisements are prohibited unless they have been approved by the MAB.

It was held that the product was not for the purpose of treating an illness but rather as an enhancer, or a product to boost the body's immune system, which does not fall within the definition of s.4b. Further, the court stated that the respondents had previously received permission to advertise "Memo Plus Gold" products from the Ministry of Health of Malaysia where respondents did not have to apply for advertising permission from the Medicine Advisory Board.

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