LEXOLOGY
Getting The Deal Through

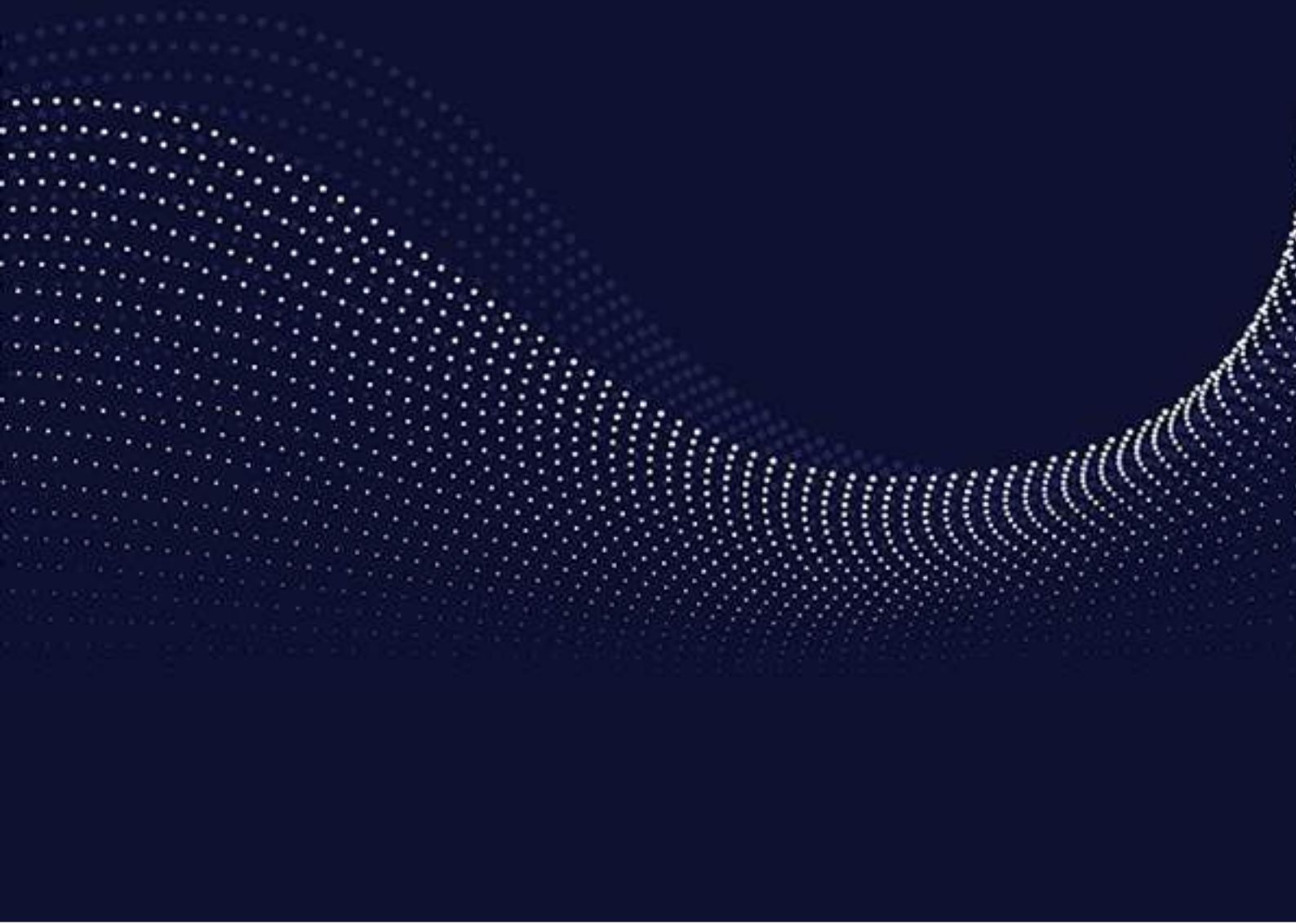
PHARMA & MEDICAL DEVICE REGULATION

Malaysia

Contributing Editor

Geoffrey Levitt

DLA Piper



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Contributors

Malaysia

Raja, Darryl & Loh

RAJA, DARRYL & LOH
advocates and solicitors

Latifa Haiqa latifahaiqa@rdl.com.my
Meagan Soo meagansoo@rdl.com.my

REGULATORY FRAMEWORK

Competent authorities for authorisation

Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

In Malaysia, there are pieces of legislation and regulations that apply to activities relating to the marketing or distribution, or both, of various products and services in the healthcare industry, including but not limited to medicinal products and medical devices. For medical devices, the Medical Device Authority is tasked with the supervision and governance of, among others, the marketing and distribution of medical devices in Malaysia. In this context, the term 'medical device' refers to the definition set out in the Medical Device Act, 2012. A medical device is:

> *(a)any instrument, apparatus, implement, machine, appliance, implant, in-vitro-reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of:*
>
> *i. diagnosis, prevention, monitoring, treatment or alleviation of disease;*
>
> *ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;*
>
> *iii. investigation, replacement or modification, or support of the anatomy or of a physiological process;*
>
> *iv. support or sustaining life;*
>
> *v. control of conception;*
>
> *vi. disinfection of medical device; or*
>
> *vii. providing information for medical or diagnostic purpose by means of in-vitroexamination of specimens derived from the human body, which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; and*
>
> *(b)any instrument, apparatus, implement, machine, appliance, implant,in-vitro-reagent or calibrator, software, material, or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a medical device by order published in theGazette.*

For pharmaceutical and health-related products, the principal regulatory authority in Malaysia is the Drug Control Authority. This authority is an executive body established under the Control of Drugs and Cosmetics Regulations, 1984 (CDCR), which were promulgated under the Sale of Drugs Act, 1952 to ensure the safety, quality and efficacy of, among others, pharmaceutical and health-related products that are marketed or distributed (or both) in Malaysia.

When a product is a combination of the two (being either a drug–medical device or a medical device–drug combination product), such a combination product will be regulated based on the primary mode of action determining whether it is classified as a drug or a medical device. The Drug Control Authority has jurisdiction over combination products that are to be regulated as a drug in accordance with the requirements set forth in the CDCR and other relevant documents published by the National Pharmaceutical Regulatory Agency. The Medical Device Authority has jurisdiction over combination products that are to be regulated as medical devices in accordance with the requirements set forth in the Medical Device Act, 2012 and other relevant documents published by the Medical Device Authority.

Approval framework

Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

The regulatory framework for the marketing of medical devices stems from the Medical Device Act, 2012 and the regulations and guidelines related thereto. As for pharmaceutical and health-related products, the Sale of Drugs Act, 1952, the Poisons Act, 1952 and the Medicines (Advertisement and Sale) Act, 1956 – together with regulations and guidelines related thereto – apply.

There are also approval requirements for the marketing or distribution, or both, in Malaysia of medical devices or pharmaceutical and health-related products, or all of the aforementioned, that fall within the purview of this regulatory framework, as well as regulatory prescriptions and requirements on, among other matters, labelling (including the inclusion of a patient information leaflet), packaging or marking on the packaging (or all of the aforementioned) of such products.

CLINICAL PRACTICE

Applicable rules

What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

The Control of Drugs and Cosmetics Regulations, 1984 and related guidelines issued by the National Pharmaceutical Regulatory Agency (including but not limited to the Malaysian Guideline for Good Clinical Practice (GCP) Inspection and the Malaysian Guideline for Independent Ethics Committee Registration and Inspection) contain various requirements that will have to be considered where applicable when undertaking activities related to clinical trials (including the performance thereof).

Reporting requirements

What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

The fourth edition of the Malaysian Guideline for Good Clinical Practice adopts the International Council for Harmonisation's E6 Good Clinical Practice Guideline. For trials, the Malaysian Guideline for Good Clinical Practice provides that an adequate and accurate source of documents and trial records, which include all pertinent observations on each of the site's trial subjects, should be maintained.

The Malaysian Guideline for Good Clinical Practice also provides that certain essential documents need to be compiled during various stages: before the commencement of the clinical trial; during the clinical trial; and after completion or termination of the clinical trial. These essential documents are usually inspected by the regulatory authority or authorities to confirm the validity of the trial conduct and the integrity of the data collected. Upon completion of the trial, a summary of the results should be provided to the relevant regulatory authority or authorities.

Consent and insurance

Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

The Malaysian Guideline for Good Clinical Practice provides that written, informed consent should be obtained from the trial subject or subjects prior to participation in the trial before a written approval or favourable opinion from the Institutional Review Board or the Institutional Ethics Committee can be awarded. The Malaysian Medical Council also published its Guideline on Clinical Trials and Biomedical Research, which provides that participation of a subject in a trial without prior consent may be grounds for legal action.

The Malaysian Guideline for Good Clinical Practice provides that, if it is required by the relevant regulatory requirements, the sponsor ought to provide insurance or indemnity to the investigator or the institution against claims arising from the trial. However, the insurance or indemnity shall not cover claims that arise from malpractice or negligence, or both.

MARKETING AUTHORISATION

Time frame

How long does it take, in general, to obtain an authorisation from application to grant, what fees are payable and what is the normal period of validity of the authorisation?

The time taken to obtain a marketing authorisation, as well as the fees payable, differ based on the type of product, the applicable legislation and regulatory frameworks issued by the relevant authorities. The relevant pieces of legislation and regulatory frameworks also list the general periods of validity for the relevant authorisations, although this is subject to the discretion of the relevant authorities.

Marketing exclusivity

What protections or exclusivities apply to the marketing period of an approved medicinal product or variation?

Statutorily, there are no specific protections and exclusivities that apply in relation to the marketing period of an approved medicinal product or variation.

Protecting research data

What protections or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

The Director of Pharmaceutical Services issued the Directive on Data Exclusivity (DDE), which came into force on 1 March 2011, with the intent to protect undisclosed, unpublished and non-public-domain pharmaceutical test data for new drug products containing a new chemical entity (new drug product) or a second indication of a registered drug product (second indication drug product) under the data exclusivity regime.

Calculating from the date on which a new drug product or a second indication drug product is first registered, granted marketing authorisation, first approved and granted data exclusivity or test data protection in the country of origin or any country recognised by the Director of Pharmaceutical Services, the period of data exclusivity shall not exceed:

- five years for a new drug product; or
- three years for data concerning a second indication drug product.

However, the DDE stipulates that an application for data exclusivity shall only be considered if the data exclusivity application is made within a certain time frame from the date first registered, granted marketing authorisation, first approved and granted data exclusivity or test data protection in the country of origin or any country recognised by the Director of Pharmaceutical Services.

Data exclusivity protection is not applicable to certain products such as products where compulsory licences have been issued or implemented with the need to protect public health and ensure access to medicine, to ensure national security or to allow non-commercial public use. This is also the case in situations of national emergency or any other circumstances declared by the government.

Freedom of information

To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

Save for any information and data that are publicly available, there are generally no Malaysian laws that expressly allow third parties to make freedom of information applications to obtain copies of research data submitted by applications for authorisation to market medicinal products or medical devices.

However, for medical devices, the Medical Device Act, 2012 stipulates that the public may have access to certain information relating to any application or furnishing of information under the Medical Device Act, 2012 provided that such information has not been granted confidentiality under the Medical Device Act, 2012 or in respect of which the Medical Device Authority has revoked its confidentiality. Pursuant to the Medical Device Act, 2012, an applicant may apply to the Medical Device Authority for the confidentiality of any information relating to the application or furnishing information subject to certain criteria.

Regulation of specific medicinal products

What are the specific requirements and processes for marketing approval of the major categories of regulated products?

There are strict registration and licensing requirements under the Control of Drugs and Cosmetics Regulations, 1984 (CDCR) for pharmaceutical products. Products listed under the CDCR must be further registered with the Drug Control Authority through the National Pharmaceutical Regulatory Agency (NPRA). The specific requirements and processes for marketing approval for medicinal products are listed in the Drug Registration Guidance Document (DRGD).

Further, regarding biologics, health supplements, and traditional herbal and homoeopathic products (natural products) in Malaysia, there are additional requirements and processes for marketing approval. These are listed in the following appendices and read in conjunction with the main body of the DRGD:

- Appendix 4: Guidelines on Registration of Biologics;
- Appendix 6: Guideline on Registration of Health Supplements; and
- Appendix 7: Guideline on Registration of Natural Products.

The specific requirements and processes for the marketing approval of biosimilars in Malaysia are listed in the DRGD and the Guidelines for Registration of Biosimilars in Malaysia. Biosimilars can be approved based in part on an exercise to demonstrate similarity to an already approved reference product. The same reference product should be used throughout the comparability programme to generate coherent data and conclusions. Comparative quality, non-clinical and clinical studies are needed to substantiate the similarity of structure or composition, quality, safety and efficacy between the biosimilar and the reference product. The pharmaceutical form, strength and route of administration should be the same as that of the reference product. Any differences between the biosimilar and the reference product should be justified by appropriate studies on a case-by-case basis.

To obtain marketing approval to market medical devices legally in Malaysia, the medical device must be registered and must satisfy conformity assessment elements assessed by the Conformity Assessment Body. The Medical Device Authority has also released the Good Distribution Practice for Medical Devices, which is applicable to all parties involved in the supply chain of medical devices, including authorised representatives of foreign manufacturers, importers or distributors of medical devices in Malaysia.

Rewards and incentives

What rewards or incentives for approval are applicable to the major product categories, including orphan drugs, drugs for paediatric use, generic drugs and biosimilars?

There is insufficient data available on this topic in Malaysia.

Post-marketing surveillance of safety

What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

Once the product is placed on the market, the product registration holder of any registered product has various pharmacovigilance or device vigilance obligations, including the obligations to:

- inform the regulatory authority or authorities (ie, the NPRA or the Medical Device Authority) immediately of any adverse reactions arising from the use of the registered product;
- ensure that the company has a vigilance system in place and takes the necessary and appropriate actions related to any adverse reactions;
- monitor and report any product safety issues that arise locally or internationally to the regulatory authority or authorities; and
- comply with all safety-related directives issued by the regulatory authority or authorities.

Other authorisations

What authorisations are required to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

For medicinal products, the CDCR stipulates the following licences that are required for the manufacturing, importing, exporting or conducting of wholesale distribution and storage of medicinal products:

- a manufacturer's licence, authorising the licensee to manufacture the registered products in the premises specified in the licence and to sell by wholesale or supply the products;
- a wholesaler's licence, authorising the licensee to sell by wholesale or supply the registered products from the address of the business premises specified in the licence;
-

a clinical trial import licence, authorising the licensee to import any product for the purposes of clinical trials, notwithstanding that the product is not a registered product; and

- an import licence, authorising the licensee to import and sell by wholesale or supply the registered products from the address of the premises specified in the licence.

The processing fee payable for the application for such licences ranges from 500 to 1,000 ringgit. Generally, licences issued under the CDCR – other than the clinical trial import licence – are usually valid for one year. The clinical trial import licence is valid for a period not exceeding three years from the date of issue of the licence, as may be specified in the licence.

The documents, particulars or information required to be provided to the authorities with an application differs from the type of licence and the applicant. If the applicant is not the product owner, the application for registration shall be accompanied by additional documents from time to time as prescribed by the relevant regulatory authority.

For medical devices, a manufacturer, authorised representative, importer or distributor of a medical device is required to apply for an establishment licence under the Medical Device Regulations, 2012. The application fees for all establishments are in the range of 250 ringgit, while the licensing fee for a manufacturer or authorised representative is 4,000 ringgit and the licensing fee for a distributor or importer is 2,000 ringgit. The validity period of the establishment licence is usually three years from the date of issuance of the licence unless the licence is cancelled by the regulatory authority before its expiry.

Sanctions

What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

The relevant authorities may impose sanctions comprising fines or imprisonment on entities or their directors and officers for breach of the requirements concerning controlled activities if the entity is found to have committed an offence under the relevant legislation.

Exemptions

What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

The following may be exempted upon an application to the Director of Pharmaceutical Services:

- a pharmaceutical school or training institution, or any research or training institution that wishes to manufacture any product or cosmetic item for teaching and research;
- any person who wishes to manufacture any product solely for the purpose of producing samples for clinical trials; and
- any person who wishes to import or manufacture any product solely for the purpose of treatment of any person suffering from a life-threatening illness.

Parallel trade

Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide the full particulars normally required to obtain an authorisation to market? What are the requirements?

Parallel imports of finished products already authorised in another jurisdiction are generally only allowed if they are produced by, or with the consent of, the owner of the patent or the licensee. However, an importer of medicinal products is required to apply for an import licence and, if the importer is not the product owner, the application for registration shall be accompanied by a letter of authorisation from the product owner, a letter of appointment of contract manufacture from the product owner and a letter of acceptance from the contract manufacturer.

AMENDING AUTHORISATIONS

Variation

What are the main requirements relating to variation of authorisations for medicinal products and medical devices?

For medicinal products, an applicant is required to inform the National Pharmaceutical Regulatory Agency (NPRA) of any variations or amendments made to the particulars of a registered product. Depending on the type of variation, if it is a major variation, the applicant is required to seek prior approval from the NPRA and submit the necessary documents in accordance with the specified conditions for each type of variation as listed in the Malaysian Variation Guideline for Pharmaceutical Products. If it is a minor variation, the applicant would only be required to inform the NPRA of the variation.

For medical devices, the Medical Device Guidance Document titled Change Notification for Registered Medical Device sets out the obligations in relation to any change to a registered medical device. The changes are categorised based on the principles of safety and performance, and the ability of the regulatory framework to manage the risks of medical devices. The main requirements to be met to continue importing, exporting or placing the medical devices in the market differ according to the types of variations to the registered medical device.

Renewal

What are the main requirements relating to renewal of authorisations for medicinal products and medical devices?

The main requirement for the re-registration of a medicinal product (renewal of product registration) is that the application for re-registration must be submitted within six months prior to the expiry of the validity period along with the applicable non-refundable processing fees. Any appeal for re-registration shall not be considered if the application is not submitted

before the expiry date of the product's registration. Further requirements for product re-registration apply to products in different categories.

In relation to the renewal of a designated medical device permit, the Medical Device Act, 2012 stipulates that a permit holder may apply to the Medical Device Authority for the renewal of its designated medical device permit no later than one year before the expiry of the permit. The Medical Device Authority may request the permit holder to provide any information, particulars or documents as may be required for the renewal application.

Transfer

How easy is it to transfer the existing approvals or rights to market medicines and medical devices? How long does this take in general?

In relation to a change of the product registration holder for the purposes of transferring the market authorisation for a registered medicinal product in Malaysia, an application for a transfer procedure to allow the same product to maintain the registration number is required. Approval for such an application can take up to 45 working days or more to be granted.

For medical devices, the Medical Device Guidance Document titled Change in Ownership for Medical Device Registration provides guidance in relation to changes of ownership for a medical device registration, enabling the transfer of the existing approvals for the registered medical device to the new authorised representative. Approvals for such applications take approximately 30 working days based on complete submissions with all the necessary accompanying information and documents.

RECALL

Defective and unsafe products

What are the normal requirements for handling cases of defective or possibly unsafe products, including approvals required for recall and communication with health professionals?

In relation to medicine and medicinal products, the Control of Drugs and Cosmetics Regulations, 1984 requires every licensed manufacturer, importer and wholesaler to have a product recall procedure for medicinal and pharmaceutical products. The recall may arise from a voluntary decision of the licensee or may be directed by the Director of Pharmaceutical Services.

In relation to medical devices, the Medical Device Act, 2012 stipulates the mandatory reporting obligations relating to any of the following incidents occurring inside or outside Malaysia that have come to the relevant business establishment's attention. As provided in section 40 of the Medical Device Act, 2012, it is mandatory to report any incident that:

> *• is related to the failure of the medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its instructions for use and such report shall be made within thirty days of discovery;*

• has led to the death or serious deterioration in the state of health of a patient, user or other person, or could do so were the incident to recur and such report shall be made within ten days of discovery; and

• is a serious threat to public health and such report shall be made within forty-eight hours from the discovery.

The establishment may undertake a voluntary recall after it has notified the Medical Device Authority and all persons that may be affected by the recall of a medical device within a certain period of time before the recall is made, based on the recall category. After the voluntary recall has been completed, the establishment shall submit a report to the Medical Device Authority.

However, the Medical Device Authority may order an establishment to recall any medical device at any time on the grounds of patient safety and public health. If so ordered, the establishment shall undertake the recall and report the result thereof within a period determined by the Medical Device Authority.

ADVERTISING AND PROMOTION

Regulation

Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?

For medicinal products, the Medicines (Advertisement and Sale) Act, 1956 (MASA) contains requirements and restrictions that apply to activities relating to the advertisement of medicines (including the requirement of prior approval from the Medicine Advertisement Board). This applies to online advertisements as well. For medical devices, the Medical Device (Advertising) Regulations, 2019 contain requirements and restrictions that apply to activities relating to the advertising of medical devices. An advertisement of a medical device shall contain a statement that the medical device is registered under the Medical Device Act, 2012 and the registration number assigned to the registered medical device.

The Medical Device Authority has issued a guideline about online advertising with additional requirements relating thereto, including the requirement that a disclaimer is placed on the same advertisement site and not on different sites. Advertisements are generally also required to comply with the Malaysian Communications and Multimedia Content Code, 2022, the Consumer Protection Act, 1999, the Communications and Multimedia Act, 1998 and the Trade Descriptions Act, 2011.

Inducement

What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?

The Code of Practice, 22nd Edition (2023), as published by the Pharmaceutical Association of Malaysia (PhAMA Code) emphasises the prohibition of inducements to healthcare professionals to prescribe, sell, supply or recommend the use of a particular medicinal product or medical device. Formal complaints may be lodged against pharmaceutical companies to the Pharmaceutical Association of Malaysia ethics committee, which may take appropriate action as it deems fit against pharmaceutical companies found to be in contravention of the PhAMA Code.

Reporting transfers of value

What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?

Not applicable.

Enforcers

Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.

The Medicine Advertisements Board and the Medical Device Authority are among the primary regulators responsible for ensuring compliance with the rules and regulations pertaining to the advertisement of medicinal products and medical devices, as set out under the relevant legislation.

Sanctions

What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?

Any person found to be in contravention of the relevant provisions under the MASA regarding general prohibitions on the advertisement of medicinal products shall, in the case of a first conviction, be liable for a fine not exceeding 3,000 ringgit or imprisonment for any term not exceeding one year, or both. In the case of a subsequent conviction, such a person shall be liable for a fine not exceeding 5,000 ringgit or imprisonment for a term not exceeding two years, or both.

For medical devices, the Medical Device Act, 2012 provides that any person found to advertise an unregistered medical device, or making any misleading or fraudulent claims in respect of a medical device in any advertisement, shall, on conviction, be liable for a fine not exceeding 300,000 ringgit or imprisonment for a term not exceeding three years, or both. The Medical Device (Advertising) Regulations, 2019 also provide that any person who advertises any registered medical device without approval from the Medical Device Authority shall, on

conviction, be liable for a fine not exceeding 200,000 ringgit or imprisonment for a term not exceeding two years, or both.

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

May health professionals prescribe or use products for 'off-label' indications? May pharmaceutical companies draw health professionals' attention to potential off-label uses?

Off-label use – described as prescriptions or use of registered drugs other than for what was originally intended by the product's manufacturer – is not prohibited, provided that the prescription or use is medically indicated or justified, or both. In this regard, the Pharmaceutical Services Division of the Ministry of Health has published a standard consent form for off-label treatment.

The PhAMA Code provides that pharmaceutical products shall not be promoted until the requisite regulatory approval for marketing for the intended use is obtained. As such, pharmaceutical companies cannot and should not draw health professionals' attention to potential off-label uses.

Unlicensed products

What rules apply to the manufacture and importation and supply to healthcare providers of unlicensed medicines or medical devices?

Generally, there cannot be any manufacture, importation or supply to healthcare providers of unlicensed medicines or medical devices without complying with the existing regulatory framework. In certain circumstances, subject to compliance with the applicable guidelines and fulfilment of prescribed conditions related thereto, an application can be made to the Drug Control Authority to import and manufacture unregistered products for the treatment of life-threatening illnesses.

Compassionate use

What rules apply to the establishment of compassionate use programmes for unlicensed products?

A clinical trial import licence and clinical trial exemption are required for the establishment of compassionate use programmes for unlicensed products. The subjects for the use of unlicensed products are restricted to subjects who had previously enrolled in the clinical trial. The Malaysian Guidelines on Good Pharmacovigilance Practices for Products Registration Holders, as published by the National Pharmaceutical Regulatory Agency, also provides that the treatment protocol that includes the use of unlicensed products should clearly describe the responsibility to report the adverse drug reaction or adverse event following immunisation suspected of being related to the use of the product. The PhAMA Code also provides that compassionate use programmes must comply with all applicable laws,

regulations and codes, including ensuring that communications used for compassionate use programmes are not advertisements for an unlicensed medicine or use.

SALE AND SUPPLY

Regulation

Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?

The rules governing the dispensation or sale, or both, of medicine and medicinal products can be found in the Sale of Drugs Act, 1952, the Poisons Act, 1952 and the Poisons Regulations, 1952.

For medical devices, the statutory prescriptions related to the sale of medical devices are found in the Medical Device Act, 2012.

Online supply

What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?

The Sale of Drugs Act, 1952, the Poisons Act, 1952, the Poisons Regulations, 1952 and the Medical Device Act, 2012 contain provisions governing the dispensation, sale and supply of medicinal products in general (which would apply to any dispensation, sale and supply of medicinal products through online media). Similarly, the Medical Device Act, 2012 applies to the online dispensation, sale or supply, or all of the aforementioned, of medical devices that fall within the purview of this act.

Pricing and reimbursement

What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?

The government of Malaysia recently set the maximum retail and wholesale prices for covid-19 vaccines under the Price Control and Anti-Profiteering (Determination of Maximum Price) Order, 2022, and for antigen rapid test kits under the Price Control and Anti-Profiteering (Determination of Maximum Price) (No. 7) Order, 2021. The Pharmaceutical Services Programme of the Ministry of Health published the Consumer Price Guide to serve as a public reference for purchasing medicines in the private sector. The information provides medicine availability and market price guidance for consumers to make informed choices.

UPDATE AND TRENDS

Forthcoming legislation and regulation

Is there any current or foreseeable draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices? What is likely to change, and what steps need to be taken in preparation?

The Pharmacy Bill currently in motion may affect the regulation of pharmaceutical products in the future, potentially replacing the Registration of Pharmacists Act 1951, the Poisons Act 1952, the Sale of Drugs Act 1952 and the Medicines (Advertisement and Sale) Act, 1956. The new Pharmacy Bill was not in force as of August 2023.