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MALAYSIA

Law and Practice

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Contents

1. Regulatory Framework

1.1 Legislation and Regulation

Pharmaceuticals and medical devices in Malaysia are governed by the following main legislation and regulations:

- the Sale of Drugs Act 1952 (SODA 1952);
- the Control of Drugs and Cosmetics Regulations 1984 (CDCR 1984);
- the Dangerous Drugs Act 1952 (DDA 1952);
- the Poisons Act 1952 (PA 1952);
- the Medicines (Advertisement and Sales Act) 1956 (MASA 1956); and
- the Medical Device Act 2012 (MDA 2012).

The main regulatory bodies for pharmaceuticals and medical devices are the:

- Drug Control Authority (DCA);
- Pharmacy Board (PB);
- National Pharmaceutical Regulatory Agency (NPRA);
- Medicine Advertisement Board (MAB); and
- Medical Device Authority (MDA).

All of the above legislation and regulatory bodies are under the purview of the Malaysian Ministry of Health (MOH).

1.2 Challenging Decisions of Regulatory Bodies

Appeals may be made against the decisions of the regulatory bodies in accordance with the procedure set out in the applicable Act or Regulations.

Under Regulation 18, CDCR 1984:

- any person aggrieved by the decision of the Authority or the Director of Pharmaceutical Services may make a written appeal to the Minister of Health for Malaysia;
- all notice of appeals shall be made within 14 days from the date of notification from the Authority; and
- any decision of the Minister made on an appeal shall be final.

Nevertheless, a person who is adversely affected by a decision, action or omission in relation to the exercise of a public duty or function shall also be entitled to make an application to the court for judicial review, pursuant to Order 53 of the Rules of Court 2012. The remedies which may be sought under the judicial review application are:

- mandamus (peremptory or mandatory order);
- certiorari (quashing order);
- prohibition (prohibition order); and
- damages.

1.3 Different Categories

Pharmaceutical products are categorised into:

- those containing the scheduled poison(s) listed in the PA 1952;
- those containing active ingredients which are not listed in the PA 1952 and not categorised as health supplements or natural products or cosmetics which may be freely available over the counter.

Pharmaceutical products which contain scheduled poison(s) under the PA 1952 may be categorised into different groups: Group A for products with high toxicity, Group B for prescription medicines, Group C for non-prescription medicines and Group D for products for laboratory use and with different registration requirements for each category of products.

The wholesale and retail sale of pharmaceutical products are governed by s.15 and s.16 of the PA 1952 respectively.

Medical devices are classified into four Classes, ie, Class A, B, C and D based on the risk associated with the vulnerability of the human body, the technical design and the manufacture of the medical device with different registration requirements and registration fees. The classification rules are based on:

- intended use;
- duration of use (transient, short-term and long-term); and
- the part of human body (non-invasive or invasive with respect to body orifices, surgically invasive interventions, central circulatory system, central nervous system).

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials are regulated in Malaysia by the NPRA or the MDA and are reviewed by Institutional Review Boards/Independent Ethics Committees (IRBs/IECs) of the organisation conducting the trials. Approvals from the Medical Research & Ethics Committee (MREC) for trials are required for trials using MOH's facilities.

The NPRA ensures the quality, efficacy and safety of pharmaceuticals in Malaysia prior to release in the Malaysian market and acts as a Secretariat to the DCA.

The MDA implements and enforces the MDA 2012 to address public health and safety issues related to medical devices and to facilitate the medical device trade and industry.

The DCA is empowered to review matters related to product registration and to approve or reject applications for a clinical trial import licence (CTIL) or a clinical trial exemption (CTX).

A CTIL is a clinical trial import licence issued to import any product for purposes of clinical trials.

A CTX is the authorisation to manufacture any product(s) solely for the purpose of producing samples for clinical trials.

Guidelines
The applicable clinical trial guidelines in Malaysia are as follows:

- the Malaysian Guideline for Good Clinical Practice, Fourth Edition, which adopts the basic principles outlined by the International Committee on Harmonisation of Good Clinical Practice, but with appropriate modifications to suit local requirements, effective since January 2018;
- the Malaysian Guideline for Application for Clinical Trial Import Licence and Clinical Trial Exemption in Malaysia, edition 6.4, effective since August 2017;
- the Malaysian Guideline for Independent Ethics Committee Registration and Inspection, First Edition, effective since May 2016;
- the Guidelines for Good Clinical Practice (GCP) Inspection, Second Edition;
- the Malaysian Guideline for Phase I Unit Inspection and Accreditation Programme;
- the Malaysian Guideline for Independent Ethics Committee Registration and Inspection, First Edition;
- the Malaysia Guideline for BE Inspection, First Edition; and
- the Malaysian Guideline for Safety Reporting of Investigational Products, First Edition.

Directives
Directives from the Director of Pharmaceutical Services (DPS) of the PB on the regulation of clinical trials include the following:

- all ethics committees that approve clinical trials in Malaysia must be registered with the DCA to regulate the quality, safety and efficacy of pharmaceutical products;
- all clinical trials requiring a CTIL/CTX must be registered with the National Medical Research Register (NMRR);
- all bio-equivalence (BE) research made for the purpose of registering a product in Malaysia must be carried out in a BE research centre that has been listed in the NPRA's Compliance Programme.

2.2 Procedure for Securing Authorisation

Before commencing any clinical trial involving product(s), the investigator/sponsor/contract research organisation (CRO) must have secured the approval of the relevant IRB/IEC and the CTIL/CTX for the importation/manufacturing of the product locally for the study.

The following products will require a CTIL/CTX:

- a product, including a placebo, which is not registered with the DCA and is intended to be imported for clinical trial purposes;
- a product with a marketing authorisation when used or assembled (formulated or packaged) in a different way from the approved form and when used for an unapproved indication/when used to gain further information about an approved use for clinical trial purposes;
- a traditional product with a marketing authorisation with an indication for "traditionally used" when used for unapproved indication/therapeutic claims for clinical trial purposes;
- an unregistered product, including a placebo, which is manufactured locally for the purpose of the clinical trial.

IRB/IEC
The committees to whom the application should be submitted will depend on the location or facility where the clinical trial will be conducted:

Government health facilities under the MOH
Under the Malaysian National Institute of Health's Guidelines for Conducting Research in MOH Institutions and Facilities, all clinical trials involving MOH facilities must register with the NMRR and obtain prior approval from the MOH.

- a government employee intending to act as an investigator for the clinical trial must sign an investigator agreement and obtain approval from the head of his or her department and the organisational or institutional director of the relevant government department. Permission must be obtained to conduct research at the respective facilities/institutions;
- where a private institution undertakes collaborative research with the MOH, a formal letter of agreement between the related MOH institution or division and the private institution is required;
- the NMRR will review the documents submitted. If it is satisfied with the registration application, the NMRR will forward them to the MREC for its review and approval.

Universities or private institutions
Applications are to be submitted to the respective IRB/IEC of the university or institution, which will review and approve the trial proposal as per the functions of the MREC.

If the university or institution concerned does not have its own IRB/IEC, applications can be submitted to the MREC or any such committees of other universities or private institutions.

All ethics committees must be registered with the DCA.

The application to the IRB/IEC is made by the investigator, that is, the person responsible for the conduct of the trial, or where conducted by a team, the person who is the leader of the team (principal investigator), subject to the particular policies of that IRB/IEC.

Section 3.1.2 of the Guideline for Good Clinical Practice provides for the list of documentation to be submitted to the IRB/IEC for approval, which includes the following:

- trial protocol;
- written informed consent form;
- consent form updates;
- subject-recruitment procedures and other written information to be provided to subjects;
- investigator's brochure, which is a compilation of the clinical and non-clinical data on the trial drug relevant to its study in human subjects.

2.3 Public Availability of Databases

There are no statutory requirements for clinical trials, nor for the results to be made publicly available.

Nonetheless, some organisations have voluntarily published their data, eg, Novartis providing technical results and trial summaries for patients from Phase 1 through 4 interventional trials for innovative products within one year of trial completion, at their website https://www.novctrd.com/CtrdWeb/trial-results.nov.

2.4 Restriction for Using Online Tools

There are no restrictions for using online tools to support clinical trials. Volunteers may be recruited through various online portals, such as https://clinicalresearch.my/iamaware/fact/ and https://my.gsk.com/en-gb/research/trials-in-people/become-a-clinical-research-volunteer/.

2.5 Use of Resulting Data

The resulting data from the clinical trials would be considered as "sensitive personal data" under s.4 of the Personal Data Protection Act 2010 (PDPA 2010), which defines sensitive personal data as any personal data consisting of information as to the physical or mental health or condition of a data subject.

Under s.40 of the PDPA 2010, any disclosure or processing of sensitive personal data may only be made if the data subject has given his or her explicit consent to do so, or if any of the special circumstances set out in s.40(1)(b) of the PDPA 2010 is satisfied.

2.6 Further Requirements for the Creation of a Database

Creation of a database containing personal or sensitive data constitutes "processing" of data under the PDPA 2010 and thus would be subject to the seven Personal Data Principles, namely (a) the General Principle; (b) the Notice and Choice Principle; (c) the Disclosure Principle; (d) the Security Principle; (e) the Retention Principle; (f) the Data Integrity Principle; and (g) the Access Principle, as set out in s.5 to s.12 of the PDPA 2010.

Further, a data user/processing body which falls under any of the classes under the Personal Data Protection (Class of Data Users) Order 2013 would also need to obtain a certificate of registration in accordance with s.12 to s.20 of the PDPA 2010 prior to processing of personal data.

3. Marketing Authorisations

3.1 Assessment Process and Criteria

The NPRA uses the following criteria to assist in the classification of products as to whether a product is pharmaceutical or a medical device:

- the primary intended purpose of the product;
- the primary mode of action/the principal mechanism of action by which the claimed effect or purpose of the product is achieved; a drug is based on pharmacological, immunological or metabolic action in/on the body, whereas a medical device does not achieve its primary mode of action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its intended function by such means;
- the active ingredient, indication and pharmaceutical dosage form (these are the main criteria for classification of the drugs); and
- the classification of the products in reference countries.

3.2 Granting a Marketing Authorisation

The NPRA's requirements for the registration of biologics/biopharmaceuticals products are aligned with the scientific guidelines and recommendations for quality, clinical efficacy and safety and non-clinical of the World Health Organization (WHO), the European Medicines Agency (EMA) and the International Conference of Harmonisation (ICH).

Every biologic is regulated as a new product and also considered "high risk"; both substance and drug-product production must comply with Good Manufacturing Practice strictly and

in accordance with the ASEAN Common Technical Dossier (ACTD) format.

3.3 Period of Validity

The registration/marketing authorisations shall be valid for five years or any such period as specified in the Authority database (unless sooner suspended or cancelled by the Authority). The renewal of product registration should be submitted within six months prior to the expiry of the validity period of a product registration, together with the appropriate fee.

3.4 Procedure for Obtaining a Marketing Authorisation

To obtain a marketing authorisation for both pharmaceuticals and medical devices, the product must be registered with the relevant authorities.

The registration process may be summarised as follows:

Pre-submission of Application

The applicant needs to determine the category of the product, ie, whether it is a:

- new drug product;
- biologic;
- generic;
- health supplement; or
- natural product.

Method of Evaluation

There are four methods of evaluating the application, ie:

- full evaluation;
- full evaluation (conditional registration): this is for a product which must be registered in at least one Drug Control Authority (DCA) reference agencies. A conditional registration is valid for two years. Thereafter, the conditional registration may be renewed twice (with the possibility of two extensions of two years each);
- full evaluation via abbreviated and verification review: This is for a product that has been evaluated and approved by one reference drug regulatory agency. The verification review applies to a product that has been evaluated and approved by two reference drug regulatory agencies;
- abridged evaluation.

The following general requirements for full evaluation which are in accordance with ASEAN ACTD/ ACTR or ICH guidelines:

- Part I Administrative data and product information;
- Part II Data to support product quality (Quality Document);
- Part III Data to support product safety (Non-clinical Document); and
- Part IV Data to support product safety and efficacy (Clinical Document).

For an abridged evaluation, a bio-availability study and a bio-equivalence study are required.

Submission of Application

Application for product registration shall be submitted only via the online QUEST system at http://bpfk.moh.gov.my/. To conduct transactions via QUEST system, the applicant must first register a membership for the QUEST system with the NPCB and purchase a USB Token that contains a User Digital Certificate, from MSC Trustgate.com Sdn. Bhd., which shall be installed to the applicant's computer.

Decisions of the Authority

A regulatory decision shall be made based on the outcome of the evaluation of the submitted documentation, and samples (if applicable). An application may be approved or rejected by the Authority, and the Authority decision will be sent via email/ official letter to the product registration-holder.

Post-registration Process

The registration status of a product shall be valid for five years or any such period as specified in the Authority database (unless the registration is suspended or cancelled by the Authority). Upon approval for product registration by the Authority, applicants shall fulfil all commitments and conditions imposed during approval of the product registration and shall be responsible for the maintenance of the product in terms of quality, safety and efficacy throughout the validity period of registration. Failure to do so may result in rejection of an application for renewal of product registration. The Authority shall be notified of any changes to the product's efficacy, quality and safety.

Rejected Application

Any person who is aggrieved by the decision of the Authority or the Director of Pharmaceutical Services may make a written appeal to the Minister of Health Malaysia. Re-submission for the product registration of a rejected application due to reason of safety and efficacy shall not be accepted within two years after the rejection. However, if the product is registered in the reference countries, submission of application can be made earlier.

Variation of Marketing Authorisation

There are two types of variations which may be made to a marketing authorisation:

- major variation (MaV): variation to a registered pharmaceutical finished product is a variation that may affect

significantly and/or directly the aspects of quality, safety and efficacy and it does not fall within the definition of minor variation and new registration: for example, change-of-content of product labelling, change of batch site of sterile drug product, etc;
- minor Variation (MiV-N & MiV-PA): variation to a registered pharmaceutical finished product is a variation in terms of administrative data and/or changes with minimal/no significant impact on the aspects of efficacy, quality, and safety: for example, change of product name, the specification of drug substance, etc.

Transfer of Marketing Authorisation
It is permissible to transfer the market authorisation from one marketing authorisation-holder to another. The requirements for transfer are found in Directive (3)dlm.BPFK/PPP/07/25 and also on the NPRA's website at https://npra.gov.my/index.php/en/change-of-product-registration-holder-coh. Upon the approval of the transfer of marketing authorisation, the former product registration-holder shall no longer have marketing authorisation over the registered product.

3.5 Access to Unauthorised Products
The licence required to manufacture or supply a product does not apply to the dispensing of any drug for the purpose of it being used for medical treatment of a patient or animal by a pharmacist, a fully licensed medical or dental or veterinary practitioner or a person employed in a governmental hospital or dispensary to dispense drugs.

Under Regulation 15(6) of the CDCR 1984, 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 may on application be exempted from having to obtain marketing authorisation.

3.6 Ongoing Obligations
Product registration-holders of pharmaceutical products are required to carry out pharmacovigilance. Pursuant to the CDCR 1984, product registration-holders shall inform the Director of Pharmaceutical Services immediately of any adverse reaction arising from the use of the registered product.

All product registration-holders must ensure that a pharmacovigilance system is in place by the company and appropriate action is taken, when necessary.

Product registration-holders are required to monitor and report any product safety issues that arise locally or internationally to the NPRA and comply with all safety-related directives issued by the NPRA.

The product registration may be cancelled if the product registration-holder fails to inform the NPRA of any serious adverse reactions upon receipt of such reports. For further information, reference may also be made to the Malaysian Pharmacovigilance Guidelines available at https://npra.gov.my/images/Guidelines_Central/Guidelines_on_Reporting_and_Monitoring%20_(MADRAC)/Malaysian_Pharmacovigilance_Guidelines_2nd_Edition_2016.pdf.

In relation to medical devices, s.38 MDA 2012 requires the holder of a marketing authorisation to monitor the safety and performance of the medical device and put in place a post-market surveillance system.

3.7 Third-Party Access to Pending Applications
All information declared in the registration form for marketing authorisations of pharmaceuticals are confidential and are not accessible to third parties.

In relation to medical devices, the applicant must apply to the MDA for confidentiality of any information relating to the application. The grant of confidentiality is at the discretion of the authority and consideration will be given to the criteria stated in s.68(3) of MDA 2012. If confidentiality is not granted, s.69 of MDA 2012 stipulates that,subject to the discretion of the authority, the public may have access to such information relating to the application.

Information relating to individuals is governed by the PDPA 2010. Any disclosure or processing of sensitive personal data may only be made if the data subject has given his or her explicit consent to do so. Notwithstanding the requirement for explicit consent from the data subject, s.40 of the Act also allows the processing of sensitive personal data where:

- the processing is necessary:
  (a) to exercise or perform any right or obligation which is conferred or imposed by law on the data user in connection with employment;
  (b) in order to protect the vital interests of the data subject or another person, in a case where consent cannot be given by or on behalf of the data subject or the data user cannot reasonably be expected to obtain the consent of the data subject;
  (c) in order to protect the vital interest of another person, in a case where consent by or on behalf of the data subject is unreasonably withheld;
  (d) for medical purposes and is undertaken by a healthcare professional;
  (e) for any legal proceeding;
  (f) to obtain legal advice;
  (g) for the administration of justice;

(h) for the exercise of any functions conferred by law; or
(i) for any purpose as the Minister thinks fit; or

- the information contained in the personal data has been made public as a result of steps deliberately taken by the data subject.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Pharmaceutical Products

Regulation 7 and Regulation 18A of the Control of Drugs and Cosmetics Regulations 1984 prohibits the illegal distribution of drugs and cosmetics products.

Medical Devices

S.5(2) of the Medical Devices Act 2012 provides that any person who imports, exports, or places in the market an unregistered medical device commits an offence, and shall be liable to a fine not exceeding MYR2,000,000 or to imprisonment for a term not exceeding three years, or to both.

3.9 Border Measures

Issues relating to counterfeiting are dealt with under the Trademarks Act 2019.

Under s.82(1) of the Trademarks Act 2019, any person may file an application to the Registrar, stating:

- that he or she is the registered proprietor, or the licensee having the power to file such application;
- that, at a time and place specified in the application, goods which, in relation to the registered trade mark, are infringing goods are expected to be imported for the purpose of trade; and
- that he or she objects to that importation.

Upon approval by the Registrar, the importation of any infringing goods into Malaysia for the duration of the period specified in the approval shall be prohibited. An approval shall remain in force until the end of the 60-day period commencing on the day of the approval, unless withdrawn earlier by the applicant. Where goods have been seized pursuant to the application, the applicant must take action for infringement within the retention period, otherwise the goods shall be released back to the importer and the applicant may be further liable for loss or damage suffered by the importer as a result of the seizure.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Manufacturing Plants

Pharmaceutical Products

Under the Regulation 7(1) of the CDCR 1984, except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import or possess or administer any product unless the product is a registered product and the person holds the appropriate licence required and issued under these Regulations. The Director of Pharmaceutical Services grants the authorisation.

In relation to a licence application for pharmaceutical products, an online application can be made through Quest3+. Borang BPFK-413: Application for Licence for Registered Products (Manufacturer's Licence, Import Licence, and Wholesaler's Licence). The forms can be found in https://www.npra.gov.my/index.php/en/appformscomplicense.html. Once the Manufacturer's Licence is granted, he or she can manufacture registered products in their premises and can sell by wholesale or supply the registered products.

The Manufacturer's Licence for pharmaceutical products is valid for one year, starting from January 1st to December 31st of the same year.

Medical Devices

All establishments, ie, manufacturer, authorised representative (AR), importer and distributor must apply for an establishment licence. However, only manufacturers and ARs need to apply for medical device registration under s.15 of the MDA 2012. The MDA grants the authorisation of an establishment licence.

The application for an establishment licence can be made by sending an email to MeDC@St2.0, according to MDA's Official Website (https://portal.mda.gov.my/industry/establishment-licence/how-to-apply-for-establishment-licence.html) There is a flow chart of the application process provided on the website. With the establishment licence, the manufacturer can import, export or place any registered medical device in the Market.

The validity of the establishment licence is three years and an establishment can start to renew the licence one year prior to the expiry date.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Pharmaceutical Products

The establishments engaged in wholesale of pharmaceutical products are subject to licensing requirements under the CDCR 1984. Any company carrying out the manufacture, import, or wholesale of any registered products needs to have a Manufacturer's Licence, Import Licence, or Wholesale Licence. The Licensing Unit, Centre for Compliance and Licensing (CCL) is involved in the activity of issuance of the relevant licence.

For licences on the wholesale of poisons, they are issued by The Director-General of Health, or the Director of Pharmaceutical Services or the Director of Medical and Health Services of any State, duly appointed in writing by the Director General of Health to be a Licensing Officer of any State or the Federal Territory pursuant to S.28 of the Poisons Act 1952.

A licence application for pharmaceutical products is by online application made through Quest3+. Borang BPFK-413: Application for Licence for Registered Products (Manufacturer's Licence, Import Licence, and Wholesaler's Licence). The forms can be found in https://www.npra.gov.my/index.php/en/appformscomplicense.html.

Once the Wholesaler's Licence is granted, the licence-holder can sell by wholesale or supply registered products from their premises. The Wholesaler's Licence for pharmaceutical products is valid for one year starting from January 1st to December 31st of the same year.

Medical Devices

For Medical Devices, a distributor shall obtain an establishment licence to conduct its activity. The MDA grants the authorisation for establishment licences. The application for an establishment licence can be made by sending an email to MeDC@St2.0, according to Medical Devices Authority's official website at https://portal.mda.gov.my/industry/establishment-licence/how-to-apply-for-establishment-licence.html with a flow chart of the application process.

With an establishment licence, a distributor can import, export or place any registered medical device in the market. For Medical Devices, the validity of the establishment licence is three years and an establishment can start to renew the licence one year prior to the expiry date.

5.2 Different Classifications

The classifications of drugs can be found in the First Schedule of Poisons Act 1952 where drugs are classified into Group A Poison, Group B Poison, Group C Poison, and Group D poison.

Group A Poison

High-toxicity medicines, eg, alclofenac, amidopyrine, avoparcin.

Group B Poison

Used in treatment where the doctor's diagnosis is needed to recognise the symptoms. Can be dispensed only against prescription, eg, nifedipine, olanzapine, ramipril.

Group C Poison

Used in treatment where the symptoms are easily recognised. Can be dispensed without prescription, eg, ibuprofen, piroxicam, mefenamic acid.

Group D Poison

Chemicals for laboratory, eg, cetyl chloride, ethylidene diacetate, methyl bromide.

6. Import and Export of Pharmaceuticals and Medical Devices

6.1 Governing Law and Enforcement Bodies

The CDCR 1984 governs the import and export of pharmaceutical and medical devices. Under the Regulation 7(1) of CDCR 1984, except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import or possess or administer any product unless the product is a registered product and the person holds the appropriate licence required and issued under these Regulations.

S.12 of the Customs Act 1967 further prohibits the importation and exportation of any dangerous drugs specified in Parts III, IV, and V of the First Schedule of the Customs Act 1967, unless otherwise authorised by the Minister.

Medical Devices

The Medical Devices Act 2012 governs the import and export of medical devices.

At the point of entry, import regulations are applied and enforced by the Royal Malaysian Customs Department, specifically the Import Management & Enforcement Unit and Export Management & Enforcement Unit under the Customs Division. Thereafter, they are then enforced by the NPRA and Ministry of Health.

6.2 Importer of Record

There are no specific requirements to apply for and hold an Import Licence (for the import and sale by wholesale or supply of registered products).

However, in relation to a Clinical Trial Import Licence (for the import of any product for purposes of clinical trials, notwithstanding that the product is not a registered product), only an investigator or an authorised person from a locally registered pharmaceutical company/sponsor/CRO with a permanent address in Malaysia can act as an importer of record of pharmaceuticals and medical devices in the country.

An application for a CTIL/CTX containing a "poison/drug" should be made by a Poison Licence Type A holder for a pharmacist in the private sector or an ARC holder for a public pharmacist. However, it should be noted that the holder of a CTIL/CTX for a particular product need not necessarily conduct the clinical trial himself or herself.

6.3 Prior Authorisations

The importation of pharmaceuticals and medical devices are subject to prior authorisations stated in Regulation 7 of the CDCR 1984, s.8 Poisons Act 1952, and s.15 Medical Devices Act 2012.

There are exemptions regarding those authorisations. Special exemptions for the importation of products that are not registered with the DCA may be granted for the treatment of life-threatening illnesses, as provided under Regulation 15 (6) of the CDCR Regulations 1984.

6.4 Non-tariff Regulations and Restrictions

Licences are required prior to the importation of any poison into Malaysia under s.8 of the Poisons Act 1952.

The categories of licences can be found in s.26(2)(a) of the Poisons Act 1952:

- Type A licence issued to a pharmacist to import, store and deal generally by wholesale and retail or by wholesale only or by retail only, subject to this Act, in all poisons;
- Type B licence issued to any person who is deemed fit or a responsible officer of a company to import, store and sell by wholesale any such poisons (not being a Group A Poison) as may be specified in such a licence;
- Type C licence issued to any person (in this Act referred to as "a listed seller"), whom the Licensing Officer may consider to be a fit and proper person to hold such a licence, to store and sell by retail Group F Poisons only;
- Type D licence issued to any person, whom the Licensing Officer may consider to be a fit and proper person to hold such a licence, to store and sell by retail any such Part II Poisons as may be specified therein; and
- Type E licence issued to any person who, in the course of his or her business, uses Sodium Hydroxide in such a substantial quantity that the Licensing Officer deems it appropriate to issue to him or her a licence to import, store and use Sodium Hydroxide.

S.30 of the Poisons Act 1952 further states that any psychotropic substances listed in the Third Schedule of the Act cannot be imported, exported, manufactured, compounded, mixed, dispensed, sold, supplied, administered, possessed or used unless it is in accordance with the regulations applicable under the Poisons Act 1952.

S.12 of the Customs Act 1967 further prohibits the importation and exportation of any dangerous drugs specified in Parts III, IV, and V of the First Schedule of the Customs Act 1967, unless otherwise authorised by the Minister.

6.5 Provisions on Trade/Regulatory Facilitation

Malaysia has already signed and implemented seven bilateral FTAs with Japan, Pakistan, India, New Zealand, Chile, Australia and Turkey. At the ASEAN level, Malaysia has six regional FTAs with the ASEAN Free Trade Agreement (AFTA), China, Korea, Japan, Australia, New Zealand and India.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control

Prices of pharmaceuticals and medical devices are not regulated in Malaysia. Nonetheless, in the public sector, the MOH indirectly controls and reduces medicine price with bulk purchases through concession supply and national tenders to provide accessible and affordable medicines.

7.2 Price Comparison

Currently, the price level of a pharmaceutical or medical device does not depend on the prices for the same product in other countries.

In the Medicine Price Monitoring Report 2017 issued by the MOH, a comparison of price based on the international reference price was made against the procurement price in the public and private sector in Malaysia. Pursuant to this, there have been discussions on the introduction of drug price regulations; however, no concrete actions have been taken to date.

7.3 Reimbursement from Public Funds
In Malaysia the government-based and publicly funded sector provide health services which are tax-funded and administered by the Ministry of Health through its central, state and district offices. The policies and programmes are centrally formulated, funded and administered.

7.4 Cost Benefit Analysis
There is no formal reimbursement system in Malaysia for pharmaceuticals or medical devices.

Although health technology assessments (HTA) in Malaysia play a role in the formulation of drug policies, cost-effectiveness evidence is currently not mandatory, but is of interest to the decision-makers.

7.5 Prescriptions and Dispensing
In Malaysia, the prescription and dispensing of pharmaceuticals are currently governed by the Poisons Act 1952 (Revised 1989), the Poisons Regulations 1952 and the Poisons (Psychotropic Substances) Regulations 1989.

Where any poison is sold or supplied as a dispensed medicine or as an ingredient in a dispensed medicine, the seller or supplier shall, on the day on which that poison or medicine is sold or supplied, enter or cause to be entered in a Prescription Book certain information, eg, the date of sale, the serial number of the entry, the name of the poison and the ingredients of the medicine, quantity supplied, etc.

8. Digital Healthcare

8.1 Rules for Medical Apps
There are no specific rules that govern medical apps in Malaysia. However, the definition of medical devices under s.2 of the MDA 2012 includes:

- any software for the purpose as specified in paras (i) to (vii) 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 or;
- any software 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 an order published in the Gazette.

As such, the MDA 2012 shall apply to medical apps used for the purposes which fall within the definition of a medical device under the Act. The application for the registration for medical device is in turn governed by s.6 of the MDA 2012.

8.2 Rules for Telemedicine
Telemedicine in Malaysia is governed by the Telemedicine Act 1997. Telemedicine is defined as the practice of medicine using audio, visual and data communications.

S.3 of the Telemedicine Act provides that only a fully registered medical practitioner holding a valid practising certificate or a medical practitioner who is registered or licensed outside Malaysia and holds a certificate to practise telemedicine issued by the council and practises telemedicine from outside Malaysia through a fully registered medical practitioner holding a valid practising certificate is authorised to practise in Malaysia.

8.3 Promoting and/or Advertising on an Online Platform
S.2 of the MASA 1956 defines an advertisement to include any notice, circular, report, commentary, pamphlet, label, wrapper, or other document, and any announcement made orally or by any means of producing or transmitting light or sound. The Guideline on Advertising of Medicines and Medicinal Products to General Public lists online advertising as an example of advertisement under the definition in S.2.

The MASA 1956 governs any online advertising of medicines and medical devices in Malaysia. As advertising on online platform is regulated, conditions imposed by the MASA 1956 shall be followed. Accordingly, online advertisement is subject to approval from the Medical Advertisement Board.

8.4 Electronic Prescriptions
Currently, there is no legislation on electronic prescriptions in Malaysia. However, in 2019, there was a proposal to include electronic prescriptions via the Poisons Act (Amendment) Bill 2019.

8.5 Online Sales
Under S.13 of the Poisons Act 1952, it is against the law to sell or supply medicine without a licence. A seller can be fined up to RM3,000 or receive one-year term of imprisonment for the first offence.

The sale of medicines and medical devices online is not regulated by any specific piece of legislation but the seller must comply with the Consumer Protection (Electronic Trading Transaction) Regulations 2012.

In short, online sales of medicines and medical devices is permitted in Malaysia as long as the seller has a licence and complies with the Consumer Protection (Electronic Trading Transaction) Regulations 2012.

8.6 Electronic Health Records

Health-related information is regulated as sensitive personal data as defined in S.4 of the PDPA 2010. Sensitive personal data includes personal data consisting of information as to the physical or mental health or condition of a data subject.

The processing of such information is governed by S.40 of the PDPA 2010. It is stated that sensitive personal data may only be processed if the data subject has given his or her explicit consent or that the processing is necessary under certain circumstances set out in the PDPA 2010.

In terms of the storing of information in cloud platforms, the Malaysian Department of Personal Data Protection issued a Personal Data Protection Standard 2015, which states that transfer of personal data through cloud platforms is not permitted unless with written consent by an officer authorised by the top management of the data user organisation. It is a requirement that transfer of personal data through cloud platforms must comply with personal data protection principles in Malaysia, as well as with personal data protection laws of other countries.

9. Licensing

9.1 Customary Deal Structures

For licence agreements, deal structures are generally royalty-based and triggers of royalty payment would commonly be tied to sales. Licences are usually non-exclusive and limited by territories or by field-of-use, as licensors would like to keep open the options of venturing into different territories/fields either by themselves or with another licensee.

For early-stage businesses, it is also common for parties to enter into a collaboration/research agreement prior to licensing. In this case, development of the product may be done by one party (in consideration of payment usually tied to satisfactory results), or the parties may co-develop the product.

9.2 Dispute Resolution Provisions

Legal provisions for the resolution of disputes should be drafted in a manner to facilitate speedy resolution. Provisions for good-faith discussions, compelled mediation, and subsequently arbitration with fixed timelines are commonly used for dispute resolution.

9.3 Diligence Obligations Provisions

"Commercially reasonable effort" clauses are recommended and "best-endeavour clauses" are often used and are recognised by the courts to be a contractual obligation, albeit not an absolute one. In practice, parties to an agreement should set out the scope of work, timelines, milestones and service levels to be met, if applicable.

9.4 Change of Control

Given that the licence agreement is entered into between the entities, a change in control of one party would not affect the licence as the entity remains the same (albeit under a different ownership). To avoid this, clauses permitting a party adversely affected by a change of ownership/control of the other party to terminate the agreement should be included in the agreement.

9.5 Termination

The parties may contractually agree for the licensor to obtain rights to clinical data and IP generated pursuant to the licence agreement. Otherwise, the default positions in the various IP legislation, in particular the Patents Act 1983 and the Copyright Act 1987 in relation to the ownership of the IP created, will apply.

Where the rights to a patent for an invention made by an employee have not been dealt with by agreement, then an invention made by an employee is to belong to his or her employer or the person who commissioned the work. Where the employee is not required to engage in any inventive activity in the contract of employment and the employee had used data or means placed at his or her disposal by his or her employer, the right to the patent for any such invention shall be deemed to accrue to the employer.

Similarly, in the case of a copyrighted work, where the copyrighted work is made in the course of the author's employment, or is commissioned under a contract of service, the copyright is deemed transferred to the author's employer or to the person who commissioned the work, as the case may be, subject to any agreement between the parties excluding or limiting such transfer.

10. Patents

10.1 Applicable Laws

Patent rights in Malaysia are governed by the Patents Act 1983, together with the Patents Regulations 1986.

The issue most commonly encountered by pharmaceutical and medical devices products under the legislation is patent infringement.

There is no specific patentability requirement for pharmaceuticals or medical devices.

10.2 Second and Subsequent Medical Uses

The patenting of second and subsequent medical uses are expressly permitted under s.14(4) of the Patents Act 1983. Inventions in relation to new dosage regimes or selected patient

populations are patentable in Malaysia if they satisfy the novelty and inventiveness patentability requirements.

A patent is infringed when a product or process falling within the scope of the protection of the patent, as defined by the claims in the patent, is exploited without the patentee's consent.

10.3 Patent Term Extension

S.35 of the Patents Act states that terms of protection of a patent shall be for 20 years. There is currently no provision that provides for patent-term extension in Malaysia.

10.4 Patent Infringement

The patentee's exclusive right to exploit a patent is the exclusive right to use the patented product or patented process and the right to make, import, offer for sale or sell the patented product and any product obtained directly by means of the patented process. A patent is infringed when there is any unauthorised exploitation of a patent.

However, s.37(1A) of the Patents Act 1983 provides that "the rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority which regulates the manufacture, use or sale of drugs." Accordingly, applications for marketing authorisation for drugs (but not medical devices) will not infringe the patent.

A cause of action for "imminent infringement" is also available in Malaysia and is provided for under s.59(1) of the Patents Act 1983, which states that: "The owner of the patent shall have the same right against any person who has performed acts which make it likely that an infringement will occur, which in this Part is referred to as an "imminent infringement". It is arguable an application for marketing authorisation constitutes "imminent infringement" of a subsisting patent in relation to the product.

10.5 Defences to Patent Infringement

In Malaysia, the Bolar exemption is encapsulated in s.37(1) of the Patents Act 1983, which limits the rights under the patent only to acts done for industrial or commercial purposes and not to acts done only for scientific research. S.37(1A) further states that "the rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority which regulates the manufacture, use or sale of drugs." As such, applications for marketing authorisation of drugs will not infringe the patent. It should be highlighted that the applicability of s.37(1A) is limited to drugs and thus does not cover medical devices.

Defences

The following are defences to a patent-infringement action:

- the claims of the patent allegedly infringed are invalid;
- the product complained of was not obtained by the patented process or, at any rate, not directly;
- the patentee has exhausted his or her rights, that is to say, the patented product or product obtained directly by means of the patented process was produced in Malaysia or elsewhere by, or with consent, conditional or otherwise, of the owner of the patent or his or her licensee;
- the acts complained of were done privately either for purposes which are not industrial or commercial, or for scientific research relating to the subject-matter of the invention;
- the acts complained of were reasonably related to the development and submission of information to the relevant authority which regulates the manufacture, use or sale of drugs – Bolar exemption;
- the acts complained of were done in connection with a foreign vessel, aircraft, spacecraft or land vehicle temporarily in Malaysia;
- the acts were done after notification in the Gazette that the patent has lapsed and before notification in the Gazette that the patent has been reinstated;
- the rights were done pursuant to a compulsory licence;
- the act was authorised by the Government;
- the "Gillette" defence. This ground of defence is that the alleged infringement is old or obvious, that is to say, what the defendant is doing differs from that what was known before the date of the patent only in non-patentable variations.

Compulsory Licences

Under s.49 of the Patents Act 1983, an application for a compulsory licence may be made to the Registrar on two grounds:

- that there is no production of the patented product or application of the patented process without any legitimate reason; or
- that there is no product produced under the patent for sale in any domestic market, or there are some but they are sold at unreasonably high prices or do not meet the public demand without any legitimate reason.

A compulsory licence may be granted when an invention cannot be worked in Malaysia without infringing a patent granted on the basis of an application benefiting from an earlier priority date.

Under s.84 of the Patents Act 1983, the Government may exploit a patented invention under a government-use licence, even without the consent of patent-owner where there is national

emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires.

10.6 Bringing Proceedings

A patentee may bring a civil action against an infringer at the High Court. A patent-infringement action generally begins by filing a writ of summons against the infringer. The procedure to be complied with for an action by Writ is governed by Order 6 and 10 of the Rules of Court 2012.

Remedies

A plaintiff in an infringement action may claim and obtain:

- an injunction (including a quia timet, interlocutory injunction and permanent) restraining the defendant from any act of infringement or imminent infringement;
- an order for the delivery up or destruction of any patented product in relation to which the patent is infringed or any article in which that product is inextricably comprised;
- damages in respect of the infringement;
- alternatively, an account of the profits derived by the defendant from the infringement;
- a declaration that the patent has been infringed by the defendant and (if validity has been successfully contested) that the patent is valid;
- interest on any sum found payable; and
- further or other relief and costs.

Invalidation

A defendant in an infringement action may counterclaim for an invalidation of the patent on the following grounds:

- not an invention. The alleged invention is not an invention, that is to say, not an idea that permits, in practice, a solution to a specific problem in the field of technology;
- not patentable. The alleged invention is excluded from being patentable with reference to the following:
  - (a) discoveries, scientific theories and mathematical methods;
  - (b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, microbiological processes and the products of such micro-organism processes;
  - (c) schemes, rules or methods for doing business, performing purely mental acts or playing games; and
  - (d) methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body.
- contrary to public policy; the performance of any act in respect of the claimed invention would be contrary to public order or morality;
- not new. The alleged invention is not patentable because it is not new since it has been anticipated by prior art. Prior art is defined as everything disclosed to the public, anywhere in the world, by written publication, by oral disclosure, by use or in any other way, before the priority date of the claim;no inventive step. The invention is obvious, having regard to what was known or used before the priority date;
- not industrially applicable. The invention cannot be made or used in any of kind of industry;
- description or claim does not comply with the Patents Regulations 1986.The specification is ambiguous or does not sufficiently and fairly describe the invention and the method by which it is to be performed, or does not disclose the best method known to the applicant for the patent and for which he or she was entitled to claim protection;
- no drawings. The drawings that are necessary for the understanding of the claimed invention have not been furnished;
- patentee not entitled. The right to the patent does not belong to the person to whom the patent was granted;
- incomplete or incorrect information. False or incomplete information has been deliberately provided, or caused to be provided, to the Registrar when filing a request for substantive examination by the patentee or his or her agent.

10.7 Available Procedures

At the pre-submission stage of the application to the NPRA, the potential generic entrant shall provide the NPRA with a declaration that it shall comply with all legal provisions in Malaysia, and conform to the Patent Act 1983 and shall not market, sell, offer for sale, or store any registered product containing any patented active ingredient(s) of which the patent duration has yet to expire.

A potential generic entrant who qualifies as an interested person shall have the right to apply for a declaration from the court against the owner of a patent that the performance of a specific act does not constitute an infringement of the patent, provided that the act in question is not already the subject of infringement proceedings. These proceedings for a declaration of non-infringement may be instituted together with the invalidation proceedings.

11. IP Other Than Patents

11.1 Counterfeit Pharmaceuticals and Medical Devices

Issues of counterfeits are generally dealt with under the Trademarks Act 2019. In addition to civil remedies pursuant to trade-

mark infringement, any person who counterfeits a registered trade-mark commits an offence and would be liable to criminal sanctions as well.

Issues of counterfeiting may also involve intellectual property rights regarding the packaging/container of the pharmaceutical and medical device, which are in turn governed by the Industrial Designs Act 1996. An infringement proceeding for industrial designs is by way of a civil action taken by the owner against any person who has infringed the rights conferred by the registered industrial design, as provided under S.33 of the Industrial Designs Act 1996.

11.2 Restrictions on Trade Marks

The Trademarks Act 2019 does not impose any restrictions on trade marks that can be used for pharmaceuticals and medical devices.

In the now-repealed Trade Marks Act 1976, parallel imports were allowed on the principle of exhaustion of rights which is encapsulated in s.40(1)(d) and s.40(1)(dd), which reads:

"(1) Notwithstanding anything contained in this Act, the following acts do not constitute an infringement of a trade mark

(d) in relation to goods connected in the course of trade with the registered proprietor or a registered user of the trade mark if, as to those goods or a bulk of which they form part, the registered proprietor or the registered user in conforming to the permitted use has applied the trade mark and has not subsequently removed or obliterated it or has at any time expressly or impliedly consented to the use of the trade mark;

(dd) the use by a person of a trade mark in relation to goods or services to which the registered proprietor or registered user has at any time expressly or impliedly consented to…"

However, in the new Trademarks Act 2019, only s.40(1)(dd) was retained in s.55(3)(c) of the Trademarks Act 2019, hence it is unclear as to whether the previous case laws discussing s.40(d) and s.40(dd) remains applicable.

11.3 IP Protection for Trade Dress or Design

The Trademarks Act 2019 allows for the shape of goods or their packaging to be registered as a trade mark, as long as it fulfils the general requirements for registration. Hence, a registered mark for the shape or packaging will be granted trade-mark rights.

Unregistered trade dress or design for pharmaceuticals, medical devices or their packaging may be protected in Malaysia under the common law tort of passing off. To establish a claim for passing off, the following elements must be satisfied:

- that the plaintiff has sufficient reputation or goodwill in the mark;
- that the defendant has misrepresented to the relevant members of the trade/public as a result of which they are misled or likely to be misled into believing that their goods are endorsed, permitted and/or licensed by the claimant or affiliated with the claimant; and
- that the plaintiff has suffered or is likely to suffer damage or injury to its business or goodwill by reason of the defendant's misrepresentation.

Furthermore, trade dress or design of pharmaceuticals and medical devices such as tablets may further be registered and protected under the Industrial Design Act 1996, as they fall under the definition of "features of shape, configuration, pattern or ornament applied to an article by any industrial process or means".

11.4 Data Exclusivity

In Malaysia, protection of undisclosed, unpublished and non-public domain pharmaceutical test data is protected under the Directive No 2 on Data Exclusivity 2011 (the Directive) which was issued by the Director of Pharmaceutical Services under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984. The Directive provides data exclusivity only for new chemical entities and second indications.

The data-exclusivity period runs from the date the new drug or the second indication is first registered or granted marketing authorisation and data exclusivity or test data protection in the country of origin or any country recognised by the Director of Pharmaceutical Services. The period for data exclusivity granted is determined on a case-by-case basis by the Director of Pharmaceutical Services and it shall not be more than five years for a new drug product containing a new chemical entity and three years for second indication of a registered drug product.

Data exclusivity is not automatically conferred upon approval of a drug. The interested party must make a separate application for data exclusivity.

An application for data exclusivity can be made via a Letter of Intent in conjunction with the application for registration of a new drug product containing a new chemical entity or application for a second indication of a registered drug product.

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