The Life Sciences Law Review

Third Edition

Editor
Richard Kingham

Law Business Research

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CONTENTS

EDITOR'S PREFACE

The third edition of *The Life Sciences Law Review* extends coverage to a total of 36 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. As before, the chapters are arranged to describe requirements throughout the life cycle of a regulated product – from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

Each of the chapters has been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this annual publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2015

Chapter 20

MALAYSIA

Lee Lin Li and Lim Wee Liang[1]

I INTRODUCTION

The life sciences industry in Malaysia comprises a wide range of interdisciplinary fields and therefore falls under a shared purview of the Ministries of Health, Agriculture and Agro-Based Industry, Plantation Industries and Commodities, Natural Resources and Environment as well as Science, Technology and Innovation.

The legislative basis for oversight of new drug products, biologics, generics, health supplements, natural products, veterinary products, poisons and cosmetics (collectively known as 'medicinal products', except for the last two) is the Sale of Drugs Act 1952. Separate regulatory frameworks for the controlled use of substances lie in the Poisons Act 1952 and the Dangerous Drugs Act 1952. The Medical Device Act 2012 regulates the medical devices industry and matters related thereto. Food-related products and pesticides fall under the governance of the Food Act 1983 and the Pesticide Act 1974, respectively. The Protection of New Plant Varieties Act 2004 provides for recognition of the creation of new plant varieties. The release and import of living modified organisms, on the other hand, is regulated by the Biosafety Act 2009.

II THE REGULATORY REGIME

i Classification

The Malaysian regulatory authorities identify the classifications of regulated products on the basis of definitions of each different regulated product found in the relevant legislation and regulations. If the product category is uncertain, an applicant may submit a Classification Form (BPFK – 300) to the Regulatory Coordination Section

1 Lee Lin Li is a partner and Lim Wee Liang is an associate at Tay & Partners.

at the Centre for Product Registration of the National Pharmaceutical Control Bureau (NPCB) for classification.[2]

Classification is of particular difficulty in relation to food-drug interphase products (FDI) and medical device-drug-cosmetic interphase products (MDDCI). The Committee for the Classification of FDI clarified this uncertainty by recently deciding that regardless of the proportion of active food ingredients, all products that are either instant creamed and sweetened beverages, consommé, ready-to-drink beverages, vinegar-based beverages, non-alcoholic fruit drink concentrates or honey-based beverages, are classified as 'food', and therefore fall under the authority of the Food Safety and Quality Division. Products that have medicinal or health benefit claims and contain any ingredients enlisted in the Negative List for Food are regulated by the Drug Control Authority (DCA).[3] Matters related to medical devices are referred to the Medical Device Authority (MDA), whereas drugs and cosmetics are under the supervision of the NPCB. The Committee for the Classification of MDDCI utilises the following criteria to assist in the classification of products:[4]

a the primary intended purpose of the product; and

b the primary mode of action or the principal mechanism of action by which the claimed effect or purpose of the product is achieved:
- a medical device is based on function by physical means such as mechanical action, creation of a physical barrier or replacement or support of organ or body function;
- a drug is based on pharmacological, immunological or metabolic action in or on the body;
- active ingredient, indication and pharmaceutical dosage form; and
- classification of the products in the reference countries.

ii Non-clinical studies

Use of animals

The current Animals Act 1953 is outdated as it does not address the humane treatment of animals for laboratory testing and any uses for scientific purposes.[5] A proposed Animal Welfare Act has been welcome by both animal lovers and researchers alike. Its draft bill reveals that the government takes the stance that the use of animals for research, testing and teaching is prohibited unless the scientific establishment, or a student or member of staff of a scientific establishment, holds a licence and an animal ethics committee of the

2 National Pharmaceutical Control Bureau, Ministry of Health, Malaysia, 'Drug Registration Guidance Document (DRGD)', First Edition – Revised November 2014, Paragraph 8.1.1.

3 NPCB, Ministry of Health, Malaysia, 'Circular for Classification of Food-Drug-Interphase Products' (Bil (19) dlm.BPFK/PPP/01/03 Jld.3), 7 August 2014.

4 Ibid., DRGD, Paragraph 1.4.2.

5 The Malaysian Bar, 'HRC Responds: Should testing on animals be permitted?', www.malaysianbar.org.my/human_rights/hrc_responds_should_testing_on_animals_be_permitted_.html, 10 July 2010 (accessed on 5 January 2015).

scientific establishment approves such use. Section 26(1) of the draft bill provides that no person is allowed to use animals for research, testing and teaching unless:

a all reasonable steps are taken to ensure that the physical, health, and behavioural needs of those animals are met in accordance with both good practice and scientific knowledge;

b when the animals are ill or injured, they shall receive, where practicable, treatment that alleviates any unreasonable or unnecessary pain or distress; and

c where, because of the nature of the research, testing or teaching, the needs referred to in section (a) cannot be fully met or the treatment referred to in section (b) cannot be provided, any degree of pain or distress is reduced to the minimum possible in the circumstances.[6]

Stem cell research and stem cell therapy

The Guidelines for Stem Cell Research and Therapy 2009 provide that all stem cell research and applications must be reviewed by the relevant institutional review board (IRB) or institutional ethics committee (IEC) for approval.[7] Research on human adult stem cells, stem cells derived from foetal tissues from legally performed termination of pregnancies, non-human stem cells and human embryonic stem (HES) cell lines derived from surplus embryos are allowed.[8] This soft law prohibits among others, the following matters:

a creation of human embryos by means such as assisted reproductive technology or somatic cell nuclear transfer for scientific research purposes;

b research involving *in vitro* culture of any intact human embryo for longer than 14 days or until formation of the primitive streak begins;

c research in which HES cells are introduced into non-human primate blastocysts or in which any embryonic stem cells are introduced into human blastocysts;

d no animal into which HES cells have been introduced at any stage of development should be allowed to breed; and

e fusion of human stem cell or other cells of pluripotent nature with cells of non-human origin, longer than 14 days, or until the formation of the primitive streak begins, whichever occurs first.[9]

6 Department of Veterinary Services, Ministry of Agriculture and Agro-Based Industry Malaysia, Animal Welfare Bill 2012.

7 Medical Development Division, Ministry of Health, Malaysia, 'Guidelines for Stem Cell Research and Therapy', MOH/P/PAK/177.08(GU), p. 29, July 2009 (accessed on 5 January 2015).

8 Ibid., p. 30.

9 Ibid., p. 35.

Assisted reproduction[10]

Under the non-binding Guideline of the Malaysian Medical Council (MMC) 'Assisted Reproduction', there are no ethical objections to blastocyst transfer, assisted hatching, cryo-preservation for sperm storage and pre-implementation genetic diagnosis for only severe and life-threatening genetic diseases. The following are some of the practices that are prohibited or unacceptable in Malaysia:

a selection of the sex of embryos for social or personal reasons is prohibited. In exceptional circumstances, sex selection is permitted if a particular sex predisposes to a serious genetic condition such as haemophilia and fragile X syndrome;

b research or experimentation using human oocyte or sperms without the explicit consent of the donors and approval of the appropriate authority;

c developing embryos for any purpose other than for their use in an approved assisted reproductive technology programme;

d experimentation with the intent to produce two or more genetically identical individuals, including development of human embryonal stem cell lines with the aim of producing clones of individuals;

e using fetal gametes for fertilisation;

f embryo splitting with the intention of increasing the number of embryos for transfer;

g placing an embryo in a body cavity other than the human female reproductive tract; and

h alteration of the genetic structure of any cell while it forms part of an embryo.

iii Clinical trials

Clinical trial import licence and clinical trial exemption[11]

Except as otherwise provided in the Control of Drugs and Cosmetics Regulations 1984, no person shall manufacture, sell, supply, import, possess or administer any medicinal product unless the product is registered or notified (for cosmetics) and the person holds a clinical trial import licence (CTIL).[12] Any person who wishes to manufacture any product solely for the purpose of producing samples for clinical trials, for registration or issuance of notification note under the Regulations may on application be exempted from Regulation 7(1) (CTX).[13] Only a person responsible for the conduct of the clinical trial at a trial site or an authorised person from a locally registered pharmaceutical company, sponsor or contract research organisation with a permanent address in Malaysia can apply for a CTIL or CTX. The CTIL or CTX holder need not necessarily conduct the clinical trial him or herself. The NPCB shall not issue the approved CTIL or CTX

10 MMC, Ministry of Health Malaysia, 'Assisted Reproduction', Guideline of the Malaysian Medical Council, MMC Guideline 003/2006, 14 November 2006.

11 NPCB, Ministry of Health Malaysia, 'Sixth Edition Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption', October 2014.

12 Regulations 7(1) and 18A(1), Control of Drugs and Cosmetics Regulations 1984 (CDC).

13 Ibid., Regulation 15(5).

application if the investigator fails to declare that he or she has attended any of the courses or training sessions certified by the National Committee for Clinical Research.[14]

Good clinical practice[15]

The Malaysian Guideline for Good Clinical Practice mandates that all clinical trials in Malaysia should be conducted in accordance with the ethical principles of the Declaration of Helsinki. An IRB or IEC that reviews proposed clinical trials must consist of not fewer than five members with at least one member who specialises in a non-scientific field and one member who is independent of the trial site. Prior to commencing the trial, the investigator should have the IRB or IEC's written approval or favourable opinion of the written informed consent form and any other written information to be provided to the subjects. A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, is responsible for all trial-related medical or dental decisions.

All serious adverse events (SAEs) detected or being notified should be reported immediately to the sponsor except for those SAEs that the protocol or other document identifies as not needing immediate reporting. If the trial is prematurely terminated or suspended, the investigator should promptly inform the subjects and provide them with the appropriate follow-up therapy and inform the regulatory authorities and the IRB or IEC. Upon completion of the trial, the investigator should inform the institution and where applicable provide the IRB or IEC with a summary of the trial's outcome. If required by the applicable regulatory requirements, the sponsor should provide insurance or should indemnify the investigator against claims arising from the trial except for claims that arise from malpractice or negligence.

iv Named-patient and compassionate use procedures

Medicinal products

Any person who wishes to manufacture any product solely for the purpose of treatment of any person suffering from a life-threatening illness may on application be exempted by the Director of Pharmaceutical Services[16] from the required registration of products subject to such conditions or restrictions as the Director may impose. The Director has also directed that extemporaneous preparations for health supplements, homeopathic medicines, herbal remedies, finished herbal products and

14 Director General of Health Malaysia, Ministry of Health, Malaysia, ''Requirement for Attendance of Investigators at Good Clinical Practice (GCP) Courses/Training Certified by the National Committee for Clinical Research (NCCR)', KKM-55/BPF/401/, 8 October 2010.

15 National Committee for Clinical Research, Ministry of Health Malaysia, 'Malaysian Guideline for Good Clinical Practice Third Edition', MOH/S/CRC/22.11(GU), October 2011.

16 Regulation 15(6), CDC.

traditional medicines that have been given directly to the patient by a health-care practitioner during the course of treatment are exempted from registration.[17]

Medical devices

The MDA provides exemptions from registration for medical devices that are custom-made and needed for use by qualified medical practitioners for their patients or for use in emergency situations or in situations where all conventional treatments have failed, are unavailable or unsuitable. Only the Minister of Health has the power to grant exemption from registration.[18] In May 2014, the MDA announced that medical devices exempted from registration for the above-mentioned purposes require approval from the MDA before they can be imported, exported or placed in the market.[19]

v Pre-market clearance

Medicinal products

The applicant for product registration must be a locally incorporated company, corporate or legal entity with a permanent address and registered with the Companies Commission of Malaysia.[20] The name of the applicant shall not reflect the name of a government agency, research institute, quality of the pharmaceutical product, disease or organ.[21] Only web-based online submission of the application is accepted. Prior to filing an application, the applicant must register for membership via an online system with NPCB and purchase a USB token that contains a User Digital Certificate, which has to be installed on the applicant's computer for registration purposes.[22] Compliance with good manufacturing practice (GMP) is a prerequisite for an application for product registration.[23] The official fee for an application for a GMP Certificate is 50 ringgit.[24]

After submitting the online application, the application will undergo an initial evaluation that determines whether the required information is complete. Upon screening approval, the applicant will proceed with making payment and submitting any required hard copy documents. Upon confirmation of payment, the application with the submitted data will be evaluated. Priority review may be granted for a product that is intended for treatment of a serious or life-threatening disease where the likelihood of death is high unless the course of the disease is interrupted. Upon registration of a product by the DCA, a product registration number will be assigned to the registered

17 DRGD, p. 194, 252 & 313.

18 Section 77, Medical Device Act 2012 (MD).

19 MDA, Ministry of Health Malaysia, 'Circular Letter of the Medical Device Authority No. 3 Year 2014 – Policy on Implementation and Enforcement under the Medical Device Act 2012 (Act 737): Exemption of Medical Device from Registration Requirements', (6) dlm. MDA. 100-1/8/5, 22 May 2014.

20 DRGD, p. 65.

21 Ibid.

22 Ibid., p. 66.

23 Ibid., p. 77.

24 Regulation 16, CDC.

product via the online system. The DCA will not issue a certificate of registration for a registered product. The registered product holder will refer to the product registration approval notification sent by the DCA or the Approved Product Registration List on the NPCB website.[25] The processing fees for application for registration of a traditional medicine, and a product other than a traditional medicine, are 500 ringgit and 1,000 ringgit respectively.[26]

Cosmetics[27]

No person shall sell, supply, posses or administer any cosmetic unless the cosmetic is notified.[28] The company or person responsible for placing the cosmetic in the market shall notify the Director of Pharmaceutical Services (DPS). A written authorisation that includes the list of cosmetics from the cosmetic owner is required if the company or person notifying does not own the product. The applicant for notification must be a company incorporated in Malaysia. The applicant should not make claims about the cosmetic that are regarded as medicinal in nature and a notification number will be generated within three days after payment of the processing fee of 50 ringgit. The notification shall be valid for two years.

Medical devices

The person responsible for registering a medical device is the manufacturer. If the medical device is manufactured abroad, it is the authorised representative in Malaysia, either an importer or a distributor, who is responsible for registration.[29] Besides determining the class and group of medical device, an applicant has to gather the necessary evidence to demonstrate its conformity to the requirements of the medical law.[30] The applicant must appoint a registered conformity assessment body (CAB) to conduct the conformity assessment.[31] The CAB will issue a report and certificate of CAB if it is satisfied that all the requirements have been satisfied. The requirements are for conformity of the quality management system, post-market surveillance system and technical documentation, and a declaration of conformity by the manufacturer.[32] Upon completion of the conformity assessment procedure, the applicant may apply to register its medical device by utilising the prescribed online application. The fees for product registration are stipulated in the Fifth Schedule of the Medical Device Regulations 2012 (MDR).

25 DRGD, p. 98.

26 Regulation 13(1), CDC.

27 Cosmetic Technical Working Group, NPCB, 'Guidelines for Control of Cosmetic Products in Malaysia', May 2009, p. 7, 8.

28 Regulation 18A, CDC.

29 Section 6(1), MD.

30 Third Schedule, Part II(2), Medical Device Regulations 2012 (MDR).

31 Ibid., Regulation 4.

32 Ibid., Third Schedule, Part III(5)(1).

vi Regulatory incentives

The MD provides confidentiality to any particular information relating to the application or furnishing of information, subject to the fulfilment of the criteria or confidentiality.[33] An application for data exclusivity can be made via a letter of intent for application for second indication of a registered drug product or registration of a new drug product containing a new chemical entity. A second indication of a registered drug product means a single or cluster of therapeutic indications applied subsequent to the first indication approved at the point of registration of the product.[34] Pharmaceuticals and medical device-related products are listed as 'promoted products' by the Malaysian Investment Development Authority.[35] There are various investment incentives offered to businesses in these industries.

Pursuant to the National Biotechnology Policy, a BioNexus Status is conferred on qualified companies undertaking value-added biotechnology and life science activities. A BioNexus Status company enjoys fiscal incentives, funding assistance and other guarantees to promote the development of its company. Tax incentives granted to a BioNexus Status company include, among others, tax exemption on distributed dividends, double deduction on expenditure incurred for research and development, and exemption of import duty and sales tax on imported raw materials and machinery and equipment.[36]

vii Post-approval controls

Medicinal products

Application for variation of the products shall follow the Malaysian Variation Guideline.[37] The product registration holder is required to report any adverse reaction (ADR) arising from the use of the registered product to the National Adverse Drug Reaction Centre of the DCA by utilising a prescribed format. An initial ADR report that does not consist of at least the named suspected drug, suspected reaction, identifiable patient and identifiable reporter will not be entered into the ADR database. The requirement for ADR reporting applies in situations such as post-registration studies, published scientific literature, periodic safety update review and ADR occurring outside and within Malaysia, as well as ongoing pharmacovigilance evaluation.[38]

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33 Section 68, MD.

34 DRGD, p. 60.

35 Malaysian Investment Development Authority, 'Official Website of Malaysian Investment Development Authority', www.mida.gov.my, 9 January 2015 (accessed 12 January 2015).

36 Malaysian Biotechnology Corporation, Ministry of Science, Technology and Innovation, 'BioNexus: A special award for an exceptional group', www.biotechcorp.com.my/bionexus-new/, 9 January 2015 (accessed 12 January 2015).

37 National Pharmaceutical Control Bureau, Ministry of Health Malaysia, 'Directive for the Implementation of the Malaysian Variation Guideline (MVG)', BPFK/PPP/07/25(2), 29 March 2013.

38 NPCB, Official Portal of NPCB, 'Malaysian Guidelines for the Reporting & Monitoring', http://portal.bpfk.gov.my/index.cfm?menuid=27&parentid=16, 3 July 2008 (accessed 5 January 2015).

Medical devices

The manufacturer or authorised representative has the following post-registration obligations:

a monitoring the safety and performance of the medical device by putting in place a post-market surveillance system and maintaining proper records of any vigilance reporting of adverse incidents;[39]

b maintaining a distribution record in respect of the registered medical device;[40]

c establishing and implementing documented procedures for reported problems or complaints related to the medical device;[41]

d reporting to the MDA about any reportable incident occurring inside or outside Malaysia wherein the timelines for report vary according to the nature of the incident; and[42]

e reporting to the MDA as soon as possible after completion of a recall of a medical device.[43]

Health-care professionals, patients, manufacturers and local authorised importers or distributors may report through the adverse incident reporting scheme any problem about medical devices to the Postmarket Evaluation Branch of the MDA.

viii Manufacturing control

Medicinal products and cosmetics

A manufacturer of a medicinal product must not manufacture its products unless it holds a manufacturer's licence.[44] A cosmetic manufacturer is prohibited from manufacturing unless it is authorised in accordance with the cosmetic notification note or it is responsible for placing the notified cosmetic in the market.[45] There shall be a sanitation programme for the maintenance of the manufacturer's premises and records of the programme shall be kept.[46] The manufacturer is required to conduct regular inspection of its manufacturing and quality control activities.[47] It must also establish a quality control department under the supervision of a suitably qualified person.[48] Proper records of the distribution of every batch of finished registered products or notified cosmetics must be maintained to enable complete and rapid recall if necessary.[49]

39 Section 38, MD.

40 Ibid., Section 37.

41 Ibid., Section 39.

42 Ibid., Section 40.

43 Ibid., Section 42.

44 Regulation 7(1), CDC.

45 Ibid., Regulation 18A(1)(a) and (b).

46 Ibid., Regulation 21.

47 Ibid., Regulation 24.

48 Ibid., Regulation 23.

49 Ibid., Regulation 25.

Medical devices

A manufacturer is obliged to ensure the medical device:[50]

a conforms to the prescribed essential principles of safety and performance;

b is manufactured in accordance with good manufacturing practice and any written directive issued by the MDA; and

c is labelled, packaged and marked in accordance with the prescribed manner.

ix Advertising and promotion

Medicinal products

No person shall take part in the publication of any advertisement referring to any article that is calculated to lead to the use of that article as a medicine, an appliance or a remedy for the purpose of treatment or prevention of disease or conditions of human beings other than diseases specified in the Schedule to the Medicines (Advertisement and Sale) Act 1956 (MAS), unless such an advertisement has been approved by the Medicine Advertisement Board.[51] Advertisements should not refer to any article in a way calculated to lead to the use of that article for the purpose of:

a prevention, diagnosis or treatment of the disease and condition of human beings as specified in the Schedule;

b practising contraception among human beings;

c improving the condition or functioning of the human kidney or heart, or improving the sexual function or sexual performance of human beings;[52] and

d procuring the miscarriage of women.[53]

Among other restrictions, the Advertisement Guidelines on Medical Products and Appliances[54] provides that advertisements of medicines should not contain impressions of professional advice or endorsement, misleading statements and unsubstantiated tests, trials and research.

Medical devices

No person shall make any misleading or fraudulent claims in respect of a medical device in any advertisement.[55] Advertising is prohibited for medical devices that have not been registered.[56] The MDA is currently finalising an advertising code for medical devices.

50 Section 4, MD.

51 Section 4B, MAS.

52 Ibid., Section 3.

53 Ibid., Section 4.

54 Pharmaceutical Services Divisions, Ministry of Health Malaysia, 'Advertisement Guidelines on Medical Products and Appliances', 18 September 2014.

55 Section 44(2), MD.

56 Section 44(1), MD.

x Distributors and wholesalers

Medicinal products

Along with a registration for a product, a wholesaler must also apply for a wholesaler's licence prior to selling or supplying the product.[57] The wholesaler's licence is valid for one year. Wholesalers are required to comply with good distribution practice (GDP),[58] the measures that need to be considered regarding the storage, transportation and distribution of any registered product and its related materials such that the nature and quality intended is preserved when it reaches the consumer.[59] The NPCB's Guidelines on Good Distribution Practice 2013 provide a standard to justify the status and inspection of a wholesaler's facilities. It covers areas such as quality management, personnel, premises and facilities, stock handling, disposal of products, documentation, transportation, product complaints and product recall.

Medical devices

The manufacturer and authorised representative shall maintain a distribution record in respect of each medical device manufactured, imported, exported and placed in the market. The requirement of compliance with good distribution practice for medical devices (GDPMD) is a prerequisite for satisfying the requirement of having a quality management system in place.[60] The GDPMD requirements stipulate specific areas of organisation under the GDPMD regulatory compliance system, including the responsibilities of the manufacturer and authorised representative, resource management, supply chain and device-specific matters, as well as surveillance and vigilance.[61]

xi Classification of products

Medicinal products and cosmetics

The classification of products is guided by the NPCB's Guidance on Classification, which provides the definitions of the various subgroups of products under said products. Cosmetics, on the other hand, can be identified by ascertaining the composition, method of use (external use or ingestion), intended main function, product presentation (product claims, labelling, promotional literature and advertisements) and physiological effect.[62] The subgroups of the six classified medicinal products are appended as below:

57 Regulation 7(1), CDC.

58 DRGD, p. 79.

59 NPCB, Ministry of Health Malaysia, 'Guidelines on Good Distribution Practice (GDP)', Introduction, 2013.

60 MDA, Ministry of Health Malaysia, 'Good Distribution Practice for Medical Devices', MDA/RR No. 1: July 2013, Part 1: Preliminary, Scope and application, p. 5.

61 Ibid., p. 2.

62 NPCB, Ministry of Health, 'ASEAN Cosmetic Claim Guideline', Annex 1, Part 8, accessed on 5 January 2015.

Medicinal product	*Subgroup*
New drug product Any pharmaceutical product that has not been previously registered.	New chemical entity/radiopharmaceutical substance New combination product Supplemental product
Biologics Refers to biotechnology products, biological products, biopharmaceutical and biological substances.	Vaccines Blood products Monoclonal antibodies (therapeutics) Recombinant proteins
Generic A product that is essentially similar to a currently registered product in Malaysia. This term is inapplicable to biologics.	Scheduled poison (known as controlled medicine or controlled poison listed in the First Schedule of the Poisons Act) Non-scheduled poison (known as non-poison or 'over-the-counter' and contains active ingredients that are not listed in the First Schedule of the Poisons Act and excludes active ingredients categorised under health supplements or natural products or cosmetics)
Health supplements Any product that supplements a diet and serves to maintain, enhance and improve the health function of the human body.	*a* Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, and other bioactive substances *b* Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolite *c* Synthetic sources of ingredients mentioned in (a) and (b), and which may only be used where the safety of these has been proven
Natural products	Traditional medicine Finished herbal product Herbal remedy Homeopathic medicine
Veterinary products	No subgroup

Medical devices[63]

All medical devices shall be classified into four classes, namely Classes A, B, C and D depending on the level of risk to the patients, users and other persons at the point of usage. The risk presented by a particular device depends on its intended purpose, intended users, mode of operation and effectiveness of the risk management techniques applied during design, manufacture and use. The classification rules are provided in Appendixes 1 and 2 of the First Schedule to the MDR. Other factors that may influence the classification include the degree of invasiveness into the body, duration of contact of the device with the body and whether the device is intended to have a biological effect on the body.

63 Regulation 3 and First Schedule, MDR.

xii Imports and exports

Medicinal products

An import licence shall be obtained before one can import any medicinal product.[64] The processing fee for such an application is 500 ringgit.[65] A prerequisite for obtaining an import licence is compliance with the principles of GDP. The NPCB also requires the submission of a Certificate of Analysis for each batch of imported registered products for verification of compliance with GDP.[66]

Medical devices

An 'establishment'[67] must obtain a licence to import or export medical devices that are to be placed in the market[68] for a processing fee of 250 ringgit.[69] An establishment that intends to export a registered medical device has to apply to the MDA for an export permit by paying the prescribed fee of 100 ringgit.[70] For a medical device that is intended for transit, only a notification is required. Export permits will not be issued for medical devices that will be exported to countries without diplomatic ties with Malaysia, such as Israel.[71]

xiii Controlled substances

The Dangerous Drugs Act criminalises the importation and exportation of raw opium, coca leaves, poppy straw and cannabis except with the authorisation of the Minister of Health. It is also an offence to import into and export from Malaysia any specified dangerous drug.[72] No dangerous drug shall be imported into[73] and exported from[74] Malaysia unless the consignor is in possession of an authorisation. Every dangerous drug imported into Malaysia from a signatory to the Single Convention on Narcotic Drugs shall be accompanied by an export authorisation or diversion certificate.[75] Manufacture of dangerous drugs is permitted for anyone licensed or authorised to do so. Only certain

64 Regulation 7, CDC.

65 Ibid., Regulation 13(1).

66 NPCB, Ministry of Health Malaysia, 'Certificate of Analysis (COA) for each Batch of Imported Registered Products', Circular, 99 dlm. BPFK/PPP/01/03 Jld.2, 11 January 2013.

67 Manufacturers, importers, distributors and local authorised representatives but does not include retailers.

68 Section 15(1), MD.

69 Fifth Schedule, MDR.

70 Ibid and Section 45, MD.

71 MDA, Ministry of Health Malaysia, 'Medical Device for the Purpose of Export and Transit and Medical Device for Import/Export from/to Countries without Diplomatic Ties with Malaysia', Circular Letter of the Medical Device Authority No. 4 Year 2014, (1) dlm. MDA. 100-1/8/5, 22 May 2014.

72 Section 12(1), Dangerous Drugs Act 1952 (DD).

73 Section 20(3), DD.

74 Section 19(2), DD.

75 Section 20(4), DD.

classes of persons are authorised to supply drugs.[76] A person shall not advertise for sale by way of wholesale dealing or supply, procure or offer to supply or procure by way of wholesale dealing, to or for any person unless he or she is licensed to do so.[77]

xiv Enforcement

Medicinal products and cosmetics

The officers and inspectors may:

a enter into and inspect any place and drug;[78]

b mark, seal, secure, weigh, count or measure any drug;[79] and

c demand, select and take samples of drugs for the purpose of analysis.[80]

In addition to the appointed officers and inspectors, the Pharmacy Enforcement Division of the Ministry of Health has the core responsibility for the enforcement of the Sale of Drugs Act. It consists of five different units, each of which has distinctive roles. Its main functions are, among others:[81]

a conducting raids on premises selling illegal products;

b conducting audits on controlled medicinal products and cosmetics;

c coordinating and monitoring screening, inspection and authorisation of medicinal products and cosmetics;

d conducting prosecutions in the courts for commission of offences;

e monitoring advertisement advertised; and

f conducting analysis on sample products available in the market that are suspected of infringing the law.

Medical devices

The Minister of Health may appoint any officer from the Ministry to exercise any enforcement action.[82] Each authorised officer has an authority card issued by the Ministry and is required to produce it on demand when carrying out enforcement duties.[83] The officer has all the powers of a police officer of whatever rank. The officer may at any time without a warrant enter into premises and search and seize anything deemed necessary if there is reasonable cause to believe that a delay in obtaining

76 Regulation 8, Dangerous Drugs Regulations 1952 (DDR).

77 Ibid., Regulation 18.

78 Section 4(1)(a), Sale of Drugs Act 1952 (SD).

79 Ibid., Section 4(1)(b).

80 Ibid., Section 5(1).

81 Pharmaceutical Services Divisions, Ministry of Health Malaysia, Official Portal of Pharmaceuticals Services Divisions, 'Pharmacy Enforcement Division', www.pharmacy.gov.my/v2/en/content/pharmacy-enforcement-division.html, 22 November 2013 (accessed 5 January 2015).

82 Section 48, MD.

83 Ibid., Section 49.

a search warrant would adversely affect the investigation.[84] The officer has the power to examine orally[85] and require attendance of anyone acquainted with the case[86] and to gain access to computerised data.[87] No costs or damages arising from the enforcement action can be recovered unless the enforcement was made without reasonable cause.[88]

III PRICING AND REIMBURSEMENT

The prices of drugs are determined by market forces. Health care in Malaysia consists of the private and public sectors wherein drugs obtained from the latter are almost free of charge. The Pharmacy Practice and Development Division conducts price monitoring activity and provides annual voluntary reporting to ensure the transparency of medicine pricing information. It also develops policies, guidelines and standard operating procedures related to monitoring and control of medicine pricing and drug tariff development.[89]

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Medicinal products and cosmetics

Any person aggrieved by a decision of the NPCB or DCA may make a written appeal to the Minister of Health within 14 days from the date the decision is made known to that person. Although the Minister's decision shall be final,[90] the Malaysian courts have the power to conduct judicial review on administrative decisions.

Medical devices

Any person aggrieved by a decision of the MDA may appeal by sending a duplicate notice of appeal to the Minister by registered post within 30 days from the date of the decision of the MDA.[91] The Minister may set up an appeal committee to advise him or her in determining the appeal. The Minister's decision is final[92] but also subject to judicial review.

84 Ibid., Section 52.

85 Ibid., Section 61.

86 Ibid., Section 60.

87 Ibid., Section 53.

88 Ibid., Section 57.

89 Pharmaceutical Services Divisions, Ministry of Health Malaysia, 'Drug Price', www.pharmacy.gov.my/v2/en/apps/drug-price, December 2013 (accessed 5 January 2015).

90 Regulation 18, CDC.

91 Regulation 17, MDR.

92 Section 47(3), MD.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

If the Code of Professional Conduct of the MMC is breached, a registered practitioner under the Medical Act 1971 will be subject to the disciplinary authority of the MMC.[93] The Code stipulates, among others, that:[94]

a a practitioner may not prescribe or dispense drugs or an appliance purely for financial benefit or if the practitioner has accepted an improper inducement;

b a practitioner shall not be associated with any commercial enterprise in the manufacture or sale of any substance that is claimed to be of value in the prevention or treatment of disease but is unproven or of an undisclosed nature or composition;

c if a practitioner has a financial interest in any facility to which he or she refers patients for diagnostics tests for procedures or for inpatient care, the practitioner must disclose that interest to the patient; and

d a practitioner shall declare his or her interest before participating in discussion that could lead to the purchase by a public authority of goods or services, in which the practitioner or one of his or her immediate family members has a direct or indirect pecuniary interest.

The non-binding MMC Guideline for Relationship between Doctors and the Pharmaceutical Industry complements the aforementioned Code and also applies to other organisations supplying therapeutic or diagnostic materials and devices, or other health products and services. It addresses matters such as sponsorship by companies and institutions, remuneration for services, ethics committee approval for remuneration arrangements, gifts and entertainment.[95] Health-care practitioners in the government sector are also required to maintain a standard of living proportionate to their emolument[96] and are prohibited from giving or accepting any form of entertainment[97] and presents[98] by virtue of the Public Officers (Conduct and Discipline) Regulations 1993 (POCD).

Under the Malaysian Anti-Corruption Commission Act 2009 (MACCA), if it is proved that both manufacturers or institutions and health-care professionals have given, promised or offered, as well as solicited, received or agreed to receive, any form of 'gratification', both parties are presumed to have done so with a corrupt intent.[99]

93 Section 29(b), Medical Act 1971 (MA).

94 Malaysian Medical Council, Ministry of Health, 'Code of Professional Conduct', http://mmc.gov.my/v1/docs/Code_of_Professional_Conduct.pdf, 9 December 1986 (accessed 5 January 2015).

95 MMC, Ministry of Health Malaysia, 'Guideline of the Malaysian Medical Council: MMC Guideline 007/2006 – Relationship between Doctors and the Pharmaceutical Industry', http://mmc.gov.my/v1/docs/Relationship%20Between%20Doctors%20&%20The%20Pharmaceutical%20Industry.pdf, p.10, 14 November 2006.

96 Regulation 11, POCD.

97 Regulation 9, POCD.

98 Regulation 8, POCD.

99 Section 50, MACC.

The MACCA gives a broad interpretation of 'gratification' and does not define the level of corporate hospitality and gifts that is acceptable. Therefore, the MACCA further curtails the common practice of pharmaceutical companies offering sponsorships and gifts to health-care practitioners for the purposes of marketing any medicinal material, device or service.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

The current regulatory regime does not provide any publicly funded compensation scheme for persons injured by medicines or medical devices. Victims may file civil suits against the offenders under the Sale of Goods Act 1957 and Consumer Protection Act 1999 and for the tort of negligence.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

A 'pay for delay' agreement between patent proprietors and generic manufacturers is a horizontal agreement and may be construed as an anti-competitive practice under the Competition Act 2010.[100] The Malaysian Competition Commission, which is the regulatory body for competition law, is considerably proactive in its enforcement action against infringers.

ii Transactional issues

Where an invention is the product of combined efforts of two or more persons, the Patents Act 1983 states that the right to obtain a patent is owned jointly by those persons.[101] The joint owners have the freedom to agree on the extent of their share to the ownership. A patent licence contract must be concluded by all the joint owners. Where a patent licence contract is concluded between the parties, the contracting parties are required to inform the Registrar of Patents and the Registrar will record the transaction in the Register.[102] The patent regime in Malaysia permits compulsory licences in circumstances such as interdependence between an earlier patent and later technological advancement, non-production of the patented product, unreasonably high prices of the patented product, insufficiency of the production of the patented product, national emergency or public interest, and where the manner of exploitation of the patent is anti-competitive.[103]

100 Section 4(2)(c), Competition Act 2010.

101 Section 18(3), Patents Act 1983 (PA).

102 Section 42(3), PA.

103 Sections 49 and 49A, PA.

VIII CURRENT DEVELOPMENTS

i Human biological tissues

Although not having the force of law, the Guideline on the Use of Human Biological Tissues for Research provides a simple yet standardised practice among the IRB and IEC in the collection, storage and use of patients' biological tissues for research.[104] The requirement for informed consent from patients with regards to their biological matters under the Guideline, however, appears to be inconsistent with the Personal Data Protection Act 2010, which exempts a health-care professional (in the capacity of a data user) from obtaining consent for processing a patient's sensitive personal data (mental or physical health records) for medical purposes.[105] At the moment, the Personal Data Protection Commissioner has not issued any guidelines on the use of medical records for research purposes.

ii The Traditional and Complementary Medicine Act 2013 (TCM)

The TCM will come into force in mid-2015 after the Ministry of Health has finalised the regulations supporting the Act.[106] The TCM is expected to change the landscape of the traditional medicine practice, which is still prevalent in modern Malaysian society. Currently, the traditional and complementary medicines that are recognised under the TCM are traditional Malay, Chinese and Indian medicines as well as homeopathy and complementary therapies.[107] When the TCM is enforced, the traditional practitioners will be required to register with the Traditional and Complementary Medicine Council (TCMC). An applicant for registration shall be provisionally registered as a practitioner and will be required to undergo a period of residency of not less than one year with any hospital or institution in Malaysia that is approved by the TCMC.[108] A provisionally registered practitioner may apply for a certificate of registration with the TCMC after completing his or her residency, with the registration criteria and eligibility requirements depending on the particular practice area.[109]

104 National Committee for Clinical Research, Ministry of Health Malaysia, 'Guideline on the Use of Human Biological Tissues for Research', 31 October 2006.

105 Section 40(1)(b)(iv)(A), Personal Data Protection Act 2010.

106 The Star Online, Nation, 'TCM Act to be enforced next year', www.thestar.com.my/News/Nation/2014/10/31/TCM-Act-to-be-enforced-next-year-Law-passed-in-2012-provides-for-setting-up-of-traditional-medicine/, 31 October 2014 (accessed 5 January 2015).

107 Section 3, TCM.

108 Section 22, TCM.

109 Section 23, TCM.

Appendix 1

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Lin Li is a partner at the firm and the head of the IP and technology department. She handles contentious matters involving life science-related products; patent, trademark, copyright and industrial design infringement; passing off including seizure and anti-counterfeiting actions; and notably provides strategic advice on settlement negotiations. She also advises on domain name issues and disputes. Lin Li is regularly engaged by clients to advise on product regulatory matters and cross-border transactions involving licensing, technology transfer, assignment and franchising. A major part of her practice consists of advising and working closely with local and international clients on the management and protection of their IP portfolio in various sectors. She regularly speaks at seminars and workshops on franchising law and personal data protection. Lin Li read law at the University of Leeds, United Kingdom (second upper) and is admitted as an advocate and solicitor of the High Court of Malaya.

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