THE LIFE SCIENCES LAW REVIEW

TENTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

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PREFACE

The tenth edition of *The Life Sciences Law Review* covers a total of 30 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as 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.

The past year, like its predecessor, was dominated by the covid-19 pandemic. Manufacturers of healthcare products continued to expedite the development and testing of drugs, biologics, diagnostics and personal protective equipment. Vaccines, many making use of novel technologies, have moved from the laboratory to the clinic and then to patients in record times; a matter of months rather than years or decades. Regulatory agencies have reviewed marketing applications with unprecedented speed and efficiency. Manufacturers and international organisations have worked closely together in an effort to ensure equitable access to vaccines and other important healthcare products in low- and middle-income countries, but much work remains to be done. In the wake of the pandemic, it is to be hoped that governments learn from the lessons of covid-19, placing systems and structures in place for the next pandemic or other health emergency and expediting the development and approval of new healthcare products to deal with endemic health issues such as cancer, coronary heart disease and genetic disorders.

In times like these, it is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems that govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this year's publication will be especially helpful in this respect.

All of the chapters have 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 publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
February 2022

Chapter 20

SINGAPORE

Melanie Ho and Alvin Lim[1]

I INTRODUCTION

The life sciences industry in Singapore is regulated by the Health Sciences Authority (HSA),[2] operating under the oversight of the Singapore Ministry of Health (MOH). Regulation of health products such as pharmaceuticals, cosmetics, medical devices fall under the purview of the HSA.

The regulatory framework for medicinal and other health-related products consists of the Health Products Act (Chapter 122D) (HPA), the Medicines Act (Chapter 176) (MA), the Medicines (Advertisement and Sale) Act (Chapter 177),[3] the Poisons Act (Chapter 234) and the Sale of Drugs Act (Chapter 282).[4] The Singapore Medical Council (SMC) regulates registered medical practitioners.[5] The SMC Ethical Code and Ethical Guidelines (ECEG 2016) set ethical benchmarks for medical practitioners.

Human biomedical research is regulated by the Human Biomedical Research Act (HBRA)[6] and subsidiary legislation, namely, the Human Biomedical Research Regulations 2017, the Human Biomedical Research (Restricted Research) Regulations 2017, the Human Biomedical Research (Exemption) Regulations 2018, the Human Biomedical Research (Tissue Banking) Regulations 2019, the Human Biomedical Research (Requirements for Appropriate Consent – Exemptions) Regulations 2019, and the Human Biomedical Research (Tissue Banking and Notification – Exemption) Regulations 2019. The legislation is supplemented by the Ethics Guidelines for Human Biomedical Research (the Ethics Guidelines) of the Bioethics Advisory Committee (BAC).

II THE REGULATORY REGIME

Control of all medicinal products, devices and substances falls under the purview of the HSA. The HPA governs the regulation of therapeutic products, medical devices and cosmetic products as part of the HSA's continuing efforts to consolidate the regulation of health products into one Act. The MA regulates medicinal products (such as cell, tissue and gene therapy products and complementary health products, including traditional medicines,

1 Melanie Ho and Alvin Lim are partners at WongPartnership LLP.

2 A body established under the Health Sciences Authority Act (Chapter 122C).

3 To be repealed on the coming into operation of Section 76(1) of the Medicines Act (Chapter 176).

4 ibid.

5 Registered medical practitioners refer to doctors registered under the Medical Registration Act (Chapter 174).

6 Act No. 29 of 2015.

homeopathic medicines and quasi-medicinal products). The Poisons Act regulates specific substances (excluding use in medicines supplied by medical practitioners),[7] whereas the Sale of Drugs Act regulates the sale of any substance or mixture of substances used as a medicine.

Separately, healthcare professionals are governed by their respective professional boards which fall under the auspices of the MOH. Each profession is self-regulated and the respective professional boards have issued their own guidelines and practice circulars to supplement the statutory framework.[8] To ensure consistency across the regulation of all healthcare professionals, a single Secretariat of Healthcare Professional Boards (SPB) has been established to oversee the secretariat and operational functions of 11 professional boards with effect from 1 January 2020.[9] The SPB is intended to streamline the regulatory framework for all healthcare professionals to bring about 'better efficiency and productivity across all the professional boards'.[10]

i Classification

The regulatory regime classifies relevant products into the following categories: medicinal products used to treat or prevent disease, to diagnose disease, for contraception, to induce anaesthesia, etc.;[11] medical devices used for the diagnosis, prevention, monitoring, treatment or alleviation of disease not through pharmacological, immunological or metabolic means;[12] cosmetic products used on the external parts of the human body to clean, perfume, change appearance, etc.;[13] therapeutic products used for a therapeutic, preventive, palliative or diagnostic purpose that is constituted by certain specified chemical and biological active ingredients, etc.;[14] complementary health products, including Chinese proprietary medicines and traditional medicines.[15]

Food and supplements of a food nature (including food-based complementary health products) fall under the purview of the Singapore Food Agency (SFA) and regulated under the Sale of Food Act (Chapter 283). If there is ambiguity in classifying a product as a food or health product, clarification should be sought from either the HSA or the SFA, depending on whether the product appears to be part of a daily diet, taken as supplement to a diet, or taken for medicinal purposes.[16]

7 The Schedule (Poisons List) to and Section 7 of the Poisons Act.

8 Examples of Professional Boards are the Singapore Medical Council (SMC), Singapore Dental Council (SDC), Singapore Nursing Board (SNB), Singapore Pharmacy Council (SPC), Traditional Chinese Medicine Practitioners Board (TCMPB), Optometrists and Opticians Board (OOB), Family Physicians Accreditation Board (FPAB), Specialists Accreditation Board (SAB), Dental Specialists Accreditation Board (DSAB), and Pharmacy Specialists Accreditation Board (PSAB).

9 Ministry of Health Circular titled 'Provision of Shared Services by The Secretariat Of Healthcare Professional Boards (SPB) To All Healthcare Professional Board' dated 15 November 2019.

10 Ministry of Health Circular titled 'Frequently Asked Questions on the New Amalgamated Secretariat of Healthcare Professional Boards (SPB)' dated 15 November 2019, FAQ 3.

11 Medicines Act, Section 3.

12 Paragraph 1 of the First Schedule to the HPA.

13 Paragraph 2 of the First Schedule to the HPA.

14 Paragraph 3 of the First Schedule to the HPA.

15 Paragraph 3(2) of the First Schedule to the HPA.

16 https://www.hsa.gov.sg/health-supplements/overview.

For devices used primarily for aesthetic purposes (e.g., lasers for skin tightening and dermabrasion), the Aesthetics Practice Oversight Committee (APOC) has revised its Guidelines of Aesthetic Practices (the APOC Guidelines),[17] which doctors have to abide by to carry out any of the procedures listed therein.

ii Non-clinical studies

In vitro human biomedical research

The HBRA, which regulates the conduct of human biomedical research, first came into force on 1 July 2016 (the first phase) and was enforced in stages. On 1 January 2017, provisions prohibiting the commercial trading of, and the advertising of commercial trading of, human tissue came into force (the second phase). Notably, commercial trading of human tissue was outlawed and offenders may be fined up to S$100,000 or imprisoned for up to 10 years, or both.[18] In the third phase, which commenced on 1 November 2017, provisions on the regulation of human biomedical research took effect.[19] These include the taking of consent, and the constitution of institutional review boards (IRBs)[20] in relevant research institutions as part of the system of 'self-accountability' for reviewing research proposals.

The next phase (the fourth phase) came into force in 2019. Under this phase, provisions on the regulation of human tissue research are now effective.[21] Subsidiary legislation regulating tissue banking includes the Human Biomedical Research (Tissue Banking) Regulations 2019 and the Human Biomedical Research (Tissue Banking and Notification – Exemption) Regulations 2019. The legislative framework serves to regulate, among other things, the duties of tissue banks, such as to notify the Director of Medical Services of its activities,[22] to maintain a record containing a detailed description of the condition of each tissue under the tissue bank's supervision and control,[23] to establish a system to ensure the quality and safety of any tissue under the tissue bank's supervision and control,[24] and restrictions on disclosure of information on tissue donors.[25]

17 Aesthetic Practice Oversight Committee, Guidelines on Aesthetic Practices for Doctors (updated October 2016). The new Guidelines do not have retrospective effect. Incidents that occurred before 1 August 2016 will have to be referred to the 2008 Guidelines on Aesthetic Practices.

18 Section 32 of HBRA. Section 32 of the HBRA does not apply to the trading of human organs and blood, which is separately prohibited under Section 14 of the Human Organ Transplant Act (Chapter 131A). See also *Public Prosecutor v. Tang Wee Sung* [2008] SGDC 262.

19 Sections 6–31, 65 and 68, and the Third, Fourth and Fifth Schedules to the HBRA.

20 Institutional review boards (IRBs) are made up of no fewer than five individuals meeting the qualifications under Regulations 11 and 12 of the Human Biomedical Research Regulations 2017. The appointed IRB is to review the researchers and research proposals to ensure they comply with the HBRA 2015 and its subsidiary legislation. See also https://www.moh.gov.sg/docs/librariesprovider5/legislation/hbra-faqs-17-apr-2018.pdf.

21 Human Biomedical Research Act 2015 (Commencement) Notification 2019 provides that Sections 34–36, 37–39 and 64 of the HBRA came into operation on 1 November 2019.

22 Sections 34, 35(1) and 36 of the HBRA; Regulations 4–14 of the Human Biomedical Research (Tissue Banking) Regulations 2019.

23 Section 35(2) of the HBRA; Regulation 22 of the Human Biomedical Research (Tissue Banking) Regulations 2019.

24 Section 35(2) of the HBRA; Regulation 26 of the Human Biomedical Research (Tissue Banking) Regulations 2019.

25 Section 39 of the HBRA; Regulation 16 of the Human Biomedical Research (Tissue Banking) Regulations 2019.

Other provisions of the HBRA relate to codes of practice and ethics, and enforcement powers with respect to activities that contravene the HBRA or any relevant codes of practice or ethics[26] or are contrary to public interest.[27]

Subsidiary legislation regulating human biomedical research includes the Human Biomedical Research Regulations 2017, the Human Biomedical Research (Restricted Research) Regulations 2017 and the Human Biomedical Research (Requirements for Appropriate Consent – Exemption) Regulations 2019. Read with the HBRA, this legislation cumulatively regulates the conduct of human biomedical research, and subjects certain types of research to stricter controls, such as research involving human eggs or embryos, human-animal combination embryos, and the introduction of human stem cells (pluripotent or not) into animals.[28] Ethically unacceptable human biomedical research, such as the implantation of human-animal embryos into both human beings and animals, is also prohibited under the legislation.[29]

The BAC revised its Ethics Guidelines for Human Biomedical Research in in October 2021.[30] These Ethics Guidelines do not have statutory force but operate alongside the HBRA subsidiary legislation to provide guidance and emphasise the fundamental principles of solidarity, respect for persons, justice, proportionality, sustainability, beneficence and research integrity.[31]

For the creation of human embryos under the Human Cloning and Other Prohibited Practices Act (Chapter 131B), the development of a human embryo created other than via fertilisation of a human egg by human sperm, for a period of more than 14 days, is prohibited.[32]

Written approval from the Director of Medical Services must be obtained[33] for all research involving human embryos, human oocytes[34] and human-animal combination gametes or embryos.[35]

Animal models

Any research facility that uses animals for scientific purposes must obtain a licence from the Animal and Veterinary Services (AVS). Further, the research facility must comply with the National Advisory Committee for Laboratory Animal Research Guidelines on the Care and Use of Animals for Scientific Purposes and allow AVS to carry out inspection of the research facilities. The facility must also establish an Institutional Animal Care and Use Committee to oversee and evaluate its animal care and use programmes.[36]

Singapore adheres to the Organisation for Economic Co-operation and Development (OECD) Mutual Acceptance of Data scheme. Acceptance of this harmonising scheme

26 Section 42(1)(b) of HBRA.

27 Section 42(1)(d) of HBRA.

28 Fourth Schedule to the HBRA.

29 Third Schedule to the HBRA.

30 See https://www.bioethics-singapore.gov.sg/publications/publications/bacethicsguidelines2021.

31 BAC's Ethics Guidelines (October 2021) at Paragraphs 2.3–2.17.

32 Section 7 of Human Cloning and Other Prohibited Practices Act.

33 Section 31 read with the Fourth Schedule to the HBRA and Regulations 3 and 4 of the Human Biomedical Research (Restricted Research) Regulations 2017.

34 Human oocytes include those obtained from excised ovarian tissue.

35 Human-animal combination gametes or embryos are those containing both human and animal genetic or non-genetic material and includes embryos created by the fertilisation of human and animal gametes.

36 Rule 7(1) of Animal & Birds (Care and Use of Animals for Scientific Purposes) Rules.

amounts to an endorsement that Singapore-generated research data complies with the OECD's Principles of Good Laboratory Practice. Such data can be accepted automatically by other OECD countries, facilitating the sharing of research.

iii Clinical trials

Therapeutic and medicinal products

The Health Products (Clinical Trials) Regulations 2016 sets out the assessment regime for clinical trials. A clinical trial of a therapeutic product may either require a clinical trial authorisation (CTA) or a clinical trial notification (CTN),[37] depending on the risk classification of the therapeutic product. A high-risk therapeutic product is a product that is locally unregistered or its use is unapproved, and therefore requires a CTA. Low-risk therapeutic products only require a CTN, as the products have already been reviewed by the HSA for product registration. A CTN can be obtained in a shorter time than a CTA because low-risk therapeutic products undergo a simplified regulatory screening and verification process. For the clinical trial of medicinal products, a Clinical Trial Certificate (CTC) in accordance with the Medicines Act is still necessary.[38]

Under the CTC and CTA/CTN regimes for medicinal products and therapeutic products respectively, a sponsor is mandatory.[39] Insurance must be maintained to provide for compensation in the event of injury or loss.[40]

Medical devices

A CTC or a CTA/CTN is not necessary for studies assessing the safety, performance or effectiveness of a medical device.[41] Prior approval by each institution's IRB is, however, still required.[42] The Health Products (Medical Device) Regulations (HP(MD)R) also regulate the use of medical devices in clinical trials.[43]

37 Clinical Trials Guidance: Determination of Whether a Clinical Trial Requires Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC) (May 2017) – Determination of whether a clinical trial requires a CTA, CTN or CTC at Paragraph 1.2.1.

38 Clinical Trials Guidance: Determination of Whether a Clinical Trial Requires Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC) (May 2017) – Determination of whether a clinical trial requires a CTA, CTN or CTC at Paragraph 1.2.2.; See also Section 18 of the MA, and the Medicines (Clinical Trials) Regulations 2016.

39 Regulation 4(1) of Medicines (Clinical Trials) Regulations 2016 and Regulation 4(1) of Health Products (Clinical Trials) Regulations 2016.

40 Regulation 9(2) of Medicines (Clinical Trials) Regulations 2016.

41 Clinical Trials Guidance: Determination of Whether a Clinical Trial Requires Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC) (May 2017) – Determination of whether a clinical trial requires a CTA, CTN or CTC at Paragraph 1.3.2.

42 Clinical Trials Guidance: Determination of Whether a Clinical Trial Requires Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC) (May 2017) – Determination of whether a clinical trial requires a CTA, CTN or CTC at Paragraph 1.2.1.

43 Regulations 3A, 4C, 5B, 10A, 13A, 39A and 39B of Health Products (Medical Device) Regulations 2010.

Ethical considerations

The ECEG 2016 stipulates that a doctor must not offer patients remedies that are not generally accepted by the profession, except in the context of a formal and approved clinical trial.[44] The term 'remedy' encompasses a broad range of treatments, including the use of medical devices.[45] Under the ECEG 2016, doctors may offer innovative therapy[46] to patients in desperate or dire situations, and where conventional therapy is unhelpful.[47] Patients' informed consent must be obtained; failing to do so can result in the doctor being struck off the Register of Medical Practitioners.[48] The ECEG 2016 further mandates that any medical research must be approved by an ethics committee and conform to the Singapore Guidelines for Good Clinical Practice.[49]

Additionally, the HSA's Guideline on Alternative Measures for Investigational Product Management for Investigator-Initiated Clinical Trials helps to overcome difficulties faced in managing investigational products without contravening the principles of the aforementioned Guidelines for Good Clinical Practice.[50]

Privacy issues

Privacy issues arising out of clinical trials are regulated under the Personal Data Protection Act[51] and the relevant subsidiary legislation of the MA and HPA.[52]

iv Named-patient and compassionate-use procedures

The Health Products (Therapeutic Products) Regulations (HP(TP)R) allow imports of therapeutic products for use on a named-patient exemption basis. Under this exemption,[53] the importer's and wholesaler's licences are not required for the import of an unregistered therapeutic product that is required by a healthcare institution or a pharmacy holding the

44 ECEG 2016 at Guideline B6.

45 *Pang Ah San v. Singapore Medical Council* [2014] 1 SLR 1094 (SGHC) at [26].

46 Innovative therapy is defined as a completely novel or significantly modified standard therapy with little or nothing in the way of studies or evidence of efficacy, effects or side effects. See also SMC Handbook on Medical Ethics 2016 at B6.1.

47 SMC Handbook on Medical Ethics 2016 at B6.1.

48 See *Shorvon Simon v. Singapore Medical Council* [2006] 1 SLR(R) 182 (SGCA) at [9] to [11] for a summary of the findings of the disciplinary committee.

49 ECEG 2016 at Guideline B8.

50 Clinical Trials Guidance: Alternative Measures for Investigational Product Management for Clinical Trials of Locally Registered Therapeutic Products or Medicinal Products (May 2017) – Paragraph 1.2.

51 Act No. 26 of 2012.

52 Health Products (Clinical Trials) Regulations 2016 and Medicines (Clinical Trials) Regulations 2016.

53 Regulation 51 of the Health Products (Therapeutic Products) Regulations 2016.

relevant licences or a qualified practitioner.[54] However, prior approval from the HSA must be sought.[55] For a company acting on behalf of a hospital or clinic to import therapeutic products on this exemption basis, the importer's and wholesaler's licences must still be obtained.[56]

The HSA's Guidance on the Requirements for Exemption from Product Registration for Import of an Unregistered Medical Device for Supply on a Named-Patient Basis further allows licensed qualified practitioners to seek approval for the supply of unregistered medical devices in an emergency, or in circumstances in which conventional therapies have failed. These applications are made to the HSA and the HSA's approval is conditional upon, inter alia, the requirement to report adverse events arising from the use of such medical devices.[57]

The Human Biomedical Research (Requirements for Appropriate Consent – Exemption) Regulations 2019 has reduced the elements of 'appropriate consent' required when the tissue donor's tissue is being removed primarily for a therapeutic or diagnostic purpose (i.e., consent taking in the presence of a prescribed witness under Section 6(d) of the HBRA), but this exemption does not extend to tissue use for restricted biomedical research.[58]

v Pre-market clearance

Therapeutic products

Therapeutic products are divided into two broad categories for registration in Singapore: a new drug application (NDA) and a generic drug application (GDA). Pursuant to the Guidance on Therapeutic Product Registration in Singapore, companies are subject to screening and regulatory evaluation before obtaining a licence for a therapeutic product.

Depending on whether the NDA or GDA has been previously evaluated and approved, as well as the subcategory of the NDA or GDA,[59] the screening and evaluation fees may be abridged.

Applicants seeking approval for an NDA that has been approved by at least one drug regulatory agency at the time of submission may also apply for priority review, which will

54 A registered medical practitioner under the Medical Registration Act (Chapter 174) and a registered dentist under the Dental Registration Act (Chapter 76).

55 Regulation 51(3) of the Health Product (Therapeutic Products) Regulations 2016; Therapeutic Products Guidance – Import and Supply of an Unregistered Therapeutic Product for Patients' Use (November 2016) at Paragraph 2.2.

56 Therapeutic Products Guidance – Import and Supply of an Unregistered Therapeutic Product for Patients' Use (November 2016) at Paragraph 2.2.

57 Medical Device Guidance – Guidance on the Requirements for Exemption from Product Registration for Import of an Unregistered Medical Device for Supply on a Named-Patient Basis (June 2010) at Paragraph 1.2.

58 Regulations 2 and 3 of the Human Biomedical Research (Requirements for Appropriate Consent – Exemption) Regulations 2019.

59 Whether it is (1) the first strength of a 'new' chemical or biological entity; (2) the first strength of a new drug product containing a new combination or proportion of a registered chemical in a new dosage form, presentation or format for use by a new route of administration or for new indications, dosage recommendations or patient populations; or (3) subsequent strengths of a new drug product. See Paragraph 5.2 of Guidance on Therapeutic Product Registration in Singapore (August 2021).

be granted if the drug is intended for treatment of a serious life-threatening condition and can potentially address local unmet medical needs;[60] or there is currently a local public health concern.

Medical devices

The HPA and HP(MD)R require medical devices, other than those exempted in the aforesaid regulations, to be registered with the HSA prior to being placed on the Singapore market. There are four risk classes for the classification of general medical devices.[61]

Several notable amendments to the HP(MD)R came into force in 2018. Product registration is no longer required for Class A medical devices (low-risk) that are manufactured, imported or obtained from a validly licensed manufacturer, importer or supplier.[62] An abridged evaluation process for registration has been provided for the other three classes, to allow faster market access.[63] New categories of exceptions for the manufacture of medical devices without a licence have been introduced, namely for clinical labs already licensed under the Private Hospitals and Medical Clinics Act (PHMCA),[64] and where the supply of medical devices is intended for charitable purposes.[65] The category of implantable medical devices has been expanded to include orthopaedic, neurological, breast, intraocular and cardiovascular implants.[66] In another amendment, wellness devices have been expressly excluded from the HP(MD)R.[67]

All medical devices must be evaluated by the HSA. The HSA must be satisfied of two criteria before registering a medical device: (1) that the overall intended benefits of the medical device outweigh the overall risks; and (2) based on the conformity of the medical device with the safety and performance requirements set out on the HSA's website, that the medical device is suitable for its intended purpose and that any risk associated with its use is minimised.[68] Requirements under all applicable legislation[69] for the supply and use of any medical devices must also be met. Additionally, for medical practitioners, the APOC Guidelines set out the minimum level of competence required for the operation of certain medical devices in aesthetic procedures.[70]

60 'Local unmet needs' is defined by the absence of a treatment option, or the lack of safe and effective alternative treatment, such that the drug would be a significant improvement compared to available marketed products, as demonstrated by (1) evidence of increased effectiveness in treatment, prevention or diagnosis; or (2) elimination or a substantial reduction of a treatment-limiting drug reaction. See Therapeutic Products Guidance – Guidance on Therapeutic Product Registration in Singapore (August 2021) at Paragraph 14.2.1.

61 Third Schedule to the Health Products (Medical Devices) Regulations 2010; Medical Device Guidance – Guidance on Medical Device Product Registration (August 2021) at Paragraph 2.

62 Regulation 10b of the Health Products (Medical Devices) Regulations 2010.

63 Regulation 26 of the Health Products (Medical Devices) Regulations 2010.

64 Regulation 3B of the Health Products (Medical Devices) Regulations 2010.

65 Regulation 3C of the Health Products (Medical Devices) Regulations 2010.

66 Fifth Schedule to the Health Products (Medical Devices) Regulations 2010.

67 Order 5 of the Health Products (Exemptions) (Amendment) Order 2018.

68 Regulation 25 of the Health Products (Medical Devices) Regulations 2010.

69 For example, the Private Hospitals and Medical Clinics Act (Chapter 248), Medical Registration Act (Chapter 174), Dental Registration Act (Chapter 76), Radiation Protection Act (Chapter 262), etc. See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview.html.

70 Aesthetic Practices Oversight Committee, Guidelines on Aesthetic Practices for Doctors 2016.

The Association of Southeast Asian Nations (ASEAN) has developed a standardised framework for regulating medical devices – the ASEAN Agreement on Medical Device Directive (AMDD). Under the AMDD, only registered medical devices that conform to its standards are allowed in the Member States' markets.[71] The standardisation of regulation allows for the efficient trading of medical devices among ASEAN states, though the AMDD has yet to be fully implemented as Member States are still aligning the AMDD with their local legislation. Additionally, the ASEAN Product Working Group for Traditional Medicines and Health Supplements was established in 2004 with the aim of harmonising technical requirements, exploring possible mutual recognition arrangements and eliminating technical barriers to trade for traditional medicine and health supplements without compromising the health and safety of the users. Once these harmonisation efforts come to fruition, life sciences companies will enjoy easier access to the entire ASEAN market.

Cosmetic products

With the implementation of the ASEAN Cosmetic Directive, manufacturer and import licences are no longer required.[72] Instead, the HSA must be notified before the supply or sale of the cosmetic product.[73] Acknowledgement of a product notification does not constitute an agreement that the product has met all regulatory requirements. The onus is on the company responsible for placing the product on the market to ensure that it meets the requirements of the ASEAN Cosmetic Directive.[74] Only a Singapore-registered company can file a product notification, subject to payment of varying fees based on the risk level of the cosmetic products.[75]

Traditional medicines, homeopathic medicines and health supplements

Traditional medicines (e.g., traditional Malay and Indian medicines), homeopathic medicines and health supplements are not subject to pre-marketing approval or licensing for their import, manufacture or sale in Singapore. Dealers and sellers of this category of medicines are responsible for ensuring their safety and quality.[76]

Chinese proprietary medicine

Under the Medicines Act, Chinese proprietary medicine dealers must obtain approval from the HSA prior to the import, export, sale or supply of Chinese proprietary medicine.[77]

Biosimilar medicinal products

To be registered as a biosimilar medicinal product, the product must fall under the definition of a 'biosimilar product' in the HSA's Guidance on Registration of Biosimilar Products in Singapore.[78] Typically, a biosimilar product is eligible for registration through an abridged evaluation route.

71 Article 1(1) of the ASEAN Agreement on Medical Device Directive.

72 Guidelines on the Control of Cosmetic Products (Revised April 2019) at Paragraph 1.

73 Guidelines on the Control of Cosmetic Products (Revised April 2019) at Paragraph 5.

74 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Cosmetic_Products/Overview.html.

75 Guidelines on the Control of Cosmetic Products (Revised April 2019) at Paragraphs 5 and 10.

76 See www.hsa.gov.sg/traditional-medicines/regulatory-overview-of-traditional-medicines.

77 Section 5 of Medicines Act.

78 Guidance on Registration of Biosimilar Products (November 2016) at Paragraph 1.3.

vi Regulatory incentives

The Patents Act (Chapter 221) allows for a one-off patent extension of up to five years for pharmaceutical products in a limited exception.[79]

The HP(TP)R[80] and MA[81] provide for a data exclusivity regime over a five-year period. The data provided by the company to the HSA is protected by the HSA, which is obliged to take reasonable steps to ensure that the data submitted remains confidential and is not used when evaluating the grant of any other application.

vii Post-approval controls

Therapeutic products

The product licence holder must put in place a system to ensure responsibility and liability for its products on the market and be able to take appropriate action, if necessary. For therapeutic products, the duty to maintain records and report defects and adverse effects is now required by legislation. Every manufacturer, importer, supplier or registrant of a therapeutic product must report the defect to the HSA as soon as it is identified.[82]

Under the HPA[83] and MA,[84] the HSA has the power to suspend, revoke or vary licences. A licence may be revoked at the request of the licence holder, or if the HSA is satisfied that there is an infringement of a patent, or if there was fraud or misrepresentation in the application process.

Medical devices

Registrants of medical devices are required to notify the HSA of any changes to particulars provided in relation to the registration of the medical devices, or changes that may affect the safety, quality or efficacy of a registered medical device.[85] In addition, registrants must report any defects or adverse effects that occur in connection with the medical device.

The HSA may also suspend or cancel the registration of a health product (including medical devices) if there is suspicion of fraud or misrepresentation in the first instance or safety concerns in the use of the health product.[86]

79 Section 36A of the Patents Act.

80 Regulation 26(1) of the Health Product (Therapeutic Products) Regulations 2016.

81 Section 19A of the Medicines Act.

82 If the defect leads to a serious threat to personal or public health, it must be reported within 48 hours. All other product defects must be reported within 15 days. See Regulation 34 of the Health Product (Therapeutic Products) Regulations 2016.

83 Section 27 of the Health Product Act.

84 Section 16 of the Medicines Act.

85 Regulation 49 of the Health Products (Medical Devices) Regulations 2010.

86 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices (August 2021) at Paragraph 8.

Cosmetic products

The manufacturer, importer, supplier or registrant of a health product or any cosmetic product has a duty to inform the HSA in the event of any defect or adverse effect arising from the use of the health product. Further, persons or companies supplying a product to the market must retain a product information file, which includes key information about the product's composition and safety assessments.[87]

As with other health products, the HSA has the power to suspend, cancel or reclassify the registration of cosmetic products, as set out above.[88]

viii Manufacturing controls

A valid licence from the HSA is required for the manufacturing of health products and medicinal products under the HPA and MA, respectively.[89] For therapeutic products, under the HP(TP)R, a manufacturer's licence will only be granted when the manufacturing facilities have been audited and found to comply with the Pharmaceutical Inspection Convention or Cooperation Scheme Guide to Good Manufacturing Practice for Medicinal Products.[90] For medical devices, an ISO 13485 certificate for finished medical device manufacturing is required to obtain a manufacturer's licence. Additionally, a manufacturer of medical devices must comply with the requirements set out in HSA website.[91]

Cosmetic products manufactured in Singapore must comply with Appendix VI of the ASEAN Cosmetic Documents entitled 'ASEAN Guidelines for Cosmetic Good Manufacturing Practice'.

ix Advertising and promotion

It is an offence under the HPA and MA to issue false or misleading advertisements relating to therapeutic products or medicinal products.[92]

Unlike medicinal products, prior approval from the HSA is not required for advertisements relating to therapeutic products.[93] Advertisement of therapeutic products is governed by the HPA and the Health Products (Advertisement of Therapeutic Products) Regulations (HP(ATP)R). The onus is on the advertiser to ensure compliance with rules under the HP(ATP)R, with the HSA undertaking a monitoring role to ensure due compliance. Advertisements for both medicinal products and therapeutic products must not claim to prevent, alleviate or cure certain diseases or conditions specified in the First Schedule to the MA and the Third Schedule to the HP(ATP)R, respectively.[94]

87 ASEAN Cosmetic Directive – Guidelines for Product Information File 2007.

88 Section 27 of the Health Products Act.

89 Section 12 of the Health Products Act and Section 6(2) of the Medicines Act.

90 Regulation 4 of the Health Product (Therapeutic Product) Regulations 2016. Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices (August 2018) at Paragraph 5.2.

91 Regulation 33 of the Health Products (Medical Devices) Regulations 2010. See also https://www.hsa.gov.sg/medical-devices/regulatory-overview.

92 Section 50 of the Medicines Act.

93 Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations 2016 (November 2016) at Paragraph 2.2.

94 Section 51 read with the First Schedule to the Medicines Act for medicinal products, Regulation 6 read with the Second Schedule to the Health Products (Advertisement of Therapeutic Products) Regulations 2016. The list of diseases and conditions in both Schedules are the same.

Advertisements and promotions of medical devices also do not require prior approval from the HSA, but such advertisements must not be false or misleading, and must be capable of verification by objective evidence, pursuant to the HP(MD)R.[95]

With regard to cosmetic products, advertisements cannot include claims that they have therapeutic benefits or can be used for therapeutic purposes,[96] nor can they create an erroneous impression regarding the formulation, composition, quality or safety of the product.[97]

The ECEG 2016 also prohibits doctors from associating themselves with 'parties that do not provide legitimate medical or medical support services in a way which could mislead the public into believing that any of the services are medically endorsed'.[98] Doctors are only allowed to promote food, vitamins, tonics and health and nutrition supplements if there is sufficient scientific basis or if they are generally accepted by the medical profession.[99]

x Distributors and wholesalers

Any person (except for licensed manufacturers) must apply for the relevant wholesaler's licence for the resale of registered therapeutic products or medical devices[100] or wholesale dealer's licence for medicinal products.[101] A licensee for a therapeutic product must appoint a responsible person to ensure compliance with the HSA's good distribution practice (GDP).[102] The licence for medicinal products will only be granted if the company has been audited and found to comply with the HSA's GDP.

With regard to medical devices, a wholesaler must possess either a GDP for medical devices certificate or ISO 13485 certificate with the scope for storage and distribution.[103] A licensed local manufacturer does not require a wholesaler's licence to supply, by wholesale, any medical devices it manufactures.

In respect of cosmetic devices, the company responsible for supplying the cosmetic product in the market must notify the HSA before doing so.

xi Classification of products

The classification of therapeutic products is carried out by the Therapeutic Products Branch, a department of the HSA. Therapeutic products are classified under three forensic classes: prescription-only medicines, pharmacy-only medicines and general sales list medicines.

95 Regulation 19 of the Health Products (Medical Device) Regulations 2010.

96 Regulation 9(a) of the Health Products (Cosmetic Products – ASEAN Cosmetics Directive) Regulations 2007.

97 Regulation 9(b) of the Health Products (Cosmetic Products – ASEAN Cosmetics Directive) Regulations 2007.

98 ECEG 2016 at Guideline I2(4).

99 ECEG 2016 at Guideline I2(5).

100 See https://www.hsa.gov.sg/about-us/health-products-regulation.

101 ibid.

102 Guidance notes on duties of responsible persons named in the importer's licence and wholesaler's licence 2016 at Paragraph 4. For duties and responsibilities of responsible persons, see Regulation 39 of the Health Products (Therapeutic Products) Regulations 2016.

103 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices (August 2021) at Paragraph 5.2.

Therapeutic products may be reclassified if the product has been deemed sufficiently safe for use with reduced, or without, medical supervision. The reclassification may be effected by an application by the party who registered the therapeutic product or through legislative mechanisms.[104]

Introduced in 2018, the collaborative prescribing service will allow collaborative prescribing practitioners (e.g., accredited pharmacists and nurses) to prescribe and dispense pharmacy-only and prescription-only medicines without having a medical practitioner sign them off. This will save both time and costs for patients and also ease the patient load on the already stretched healthcare system.[105]

xii Imports and exports

Under the HPA, a person must now obtain an importer's licence to import therapeutic products or medical devices,[106] and a wholesaler's licence to export them.[107] Importers and exporters of therapeutic products must also appoint a person to be responsible for ensuring compliance with the HSA's GDP standards.[108] This requirement of a responsible person does not extend to importers and exporters of medical devices, although they must possess either a GDP for medical devices certificate or ISO 13485 certificate with the scope for storage and distribution.[109]

Imports and exports of medicinal products remain under the purview of the MA, and importers of such products require either a product licence or an import licence, while exporters require a product licence.[110]

xiii Controlled substances

As a party to both the 1961 United Nations Single Convention on Narcotic Drugs and 1971 United Nations Convention on Psychotropic Drugs, Singapore conforms to the international control measures provided in both conventions.[111] The Misuse of Drugs Act makes it an offence to import, export or traffic controlled drugs, or to import, export or supply controlled equipment, materials or substances if one knows or has reason to believe that they are to be used in or for the manufacture of a controlled drug.

104 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Western_Medicines/Reclassified_Medicines.html.

105 Regulation 11 of the Health Products (Therapeutic Products) Regulations 2016.

106 Section 13 of the Health Products Act. However, a holder of a manufacturer's licence for therapeutic products may import health products without an importer's licence if the health product is required for the purpose of carrying out the manufacture of a therapeutic product. See Regulation 54 of the Health Products (Therapeutic Products) Regulations 2016.

107 Section 14 read with Section 2 of the Health Products Act. However, a holder of an importer's licence may export therapeutic products without a wholesaler's licence if the imported therapeutic products were imported solely for the purpose of export. See Regulation 53 of the Health Products (Therapeutic Products) Regulations 2016.

108 Regulation 39 of the Health Products (Therapeutic Products) Regulations 2016.

109 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices (August 2021) at Paragraph 5.2.

110 Part II of the Medicines Act.

111 These control measures are implemented via, inter alia, the Misuse of Drugs Act (Chapter 185), the Health Products (Therapeutic Products) Regulations 2016 and the Medicines (Export Licence for Psychotropic Substances) Regulations.

To import or export controlled drugs[112] and psychotropic substances or medicinal products with psychotropic substances,[113] an applicant must obtain an import or export licence from the HSA, and the purpose of the import or export will be assessed before the licence is processed and issued.[114]

xiv Enforcement

The HSA has the right of entry into premises for the purpose of ascertaining whether there is, or has been, any contravention of the MA. Any duly authorised person has the power to inspect, take samples and seize goods and documents to ascertain whether any contravention of the MA has taken place.

Under the HPA, an enforcement officer may, at any time and without warrant, enter, inspect and search a premise if there is reason to suspect a contravention of the HPA. The enforcement officer may also seize items, require a person to furnish information or documents in his or her knowledge, or arrest, without warrant, a person who is believed to have committed an offence under the HPA.[115]

With regard to private hospitals and medical clinics, the MOH's Director of Medical Services or any authorised enforcement officer may, at any time and without warrant, enter, inspect and search any premises if there is reasonable cause to suspect a contravention of the Private Hospitals and Medical Clinics Act (Chapter 248), or to assess the quality and appropriateness of the services provided, and the practices carried out in those establishments, including clinical laboratories.[116]

III PRICING AND REIMBURSEMENT

Apart from a national medical savings scheme (Medisave) and a health insurance scheme for Singapore citizens and permanent residents (Medishield Life),[117] patients receive drug subsidies based on their paying status and the scheme under which the drug is covered (e.g., the Standard Drug List and Medication Assistance Fund).[118] Subsidised drugs cover up to 90 per cent of the total volume of public medication prescriptions and are reviewed and

112 As defined in the First Schedule to the Misuse of Drugs Act.

113 Regulation 3 of the Medicines (Export Licence for Psychotropic Substances) Regulations. Note that the Regulations were amended in 2016 to include medicinal products containing psychotropic substances.

114 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Audit_and_Licensing_Of_Importers_Wholesale_Dealers_and_Exporters/Controlled_Drugs_Psychotropic_and_Restricted_Substances.html.

115 Section 49 of the Health Products Act.

116 Section 12 of the Private Hospitals and Medical Clinics Act (Chapter 248).

117 Medisave allows Singaporean Citizens or Permanent Residents to set aside part of their income for future medical expenses. See https://www.moh.gov.sg/content/moh_web/home/costs_and_financing/schemes_subsidies/medisave.html#1. MediShield Life is a basic health insurance plan, administrated by the Central Provident Fund Board, which helps to pay for hospital bills and selected costly outpatient treatments such as dialysis and chemotherapy for cancer. See https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies/medishield-life.

118 See https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies/drug-subsidies-schemes. However, note that some drugs are only subsidised for specific, appropriate clinical indications for which the drugs are assessed to be clinically effective and cost-effective.

updated regularly by the MOH.[119] Subsidies are also provided for medical devices, such as implants.[120] In 2014, the government launched the Pioneer Generation Package, which provides senior citizens who were born before 1950 and obtained citizenship before 1987 with additional discounts on subsidised medications, as well as subsidies on their Medishield Life premiums.[121] In August 2018, the government launched the Merdeka Generation Package for Singaporeans born in the 1950s, to help them cope with healthcare and other expenses, covering areas such as outpatient subsidies, Medisave account top-ups, MediShield Life premium subsidies and payouts for long-term care.[122]

Health technology assessments are carried out by the Healthcare Technology Assessment (HTA) Unit under the auspices of the MOH. As part of its health technology assessments, the HTA Unit carries out reviews and cost-effectiveness analyses, and develops clinical practice guidelines in Singapore.[123]

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Any person aggrieved by the HSA's decision in relation to granting, renewing or revoking a licence, or the registration of a health product, may appeal to the Minister of Health, whose decision is final.[124]

Notwithstanding the finality of the Minister's decision, applicants may apply for a judicial review of the Minister's decision in accordance with common law administrative law principles; for example, where the Minister's decision has exceeded its jurisdiction or where the Minister reached his or her decision in breach of the rules of natural justice.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

The Singapore Association of Pharmaceutical Industries' Code of Marketing Practices guides the conduct of marketing and promotion of medicinal and therapeutic products in Singapore and serves as the basis for regulation within the industry.[125]

The ECEG 2016 also provides guidance to doctors in relation to issues of financial conflicts of interest.[126] While the requirements on disclosure of interests and prohibitions on exerting undue influence on patients still apply, the ECEG 2016 has expanded the scope of conflicts of interest to include the material interests of individuals close to doctors. Further, the practice of asking for fee kickbacks or other compensation in exchange for referring patients to other medical service professionals or healthcare facilities is prohibited under

119 See https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies/drug-subsidies-schemes and https://www.straitstimes.com/forum/letters-on-the-web/list-of-subsidised-drugs-reviewed-regularly.

120 See https://www.moh.gov.sg/content/moh_web/home/pressRoom/pressRoomItemRelease/2004/medical_service_package_to_ensure_good_healthcare_at_affordable_prices_for_all_Singaporeans.html.

121 See www.pioneers.sg/en-sg/Pages/Overview.aspx.

122 See https://www.todayonline.com/singapore/new-merdeka-generation-package-help-spo reans-born-1950s-healthcare-needs.

123 Khoo Ai Leng, *Formulary Management – A Practical Guide* (1st edition, NHG Pharmacy & Therapeutics Office 2014).

124 Section 28 of the Health Products Act.

125 SAPI Code of Marketing Practices (2016).

126 Guideline H3(1)-(5) of the ECEG 2016.

the ECEG 2016.[127] Additionally, if the factual circumstances reveal a corrupt intent and the breach is egregious, this may potentially be an offence of corruption under the Prevention of Corruption Act (Chapter 241).[128]

At present, doctors can only charge patients for fees paid to third-party administrators (TPAs) and managed care companies if the sums paid reflect the actual work they do and are not contingent on the services provided by the doctor or the amount of fees collected from patients.[129] The rationale is to ensure that the patient's interests would take priority over the doctor's personal financial interests.[130] Examples of TPA services include intermediary processing and managing of insurance claims and employer medical benefits. Historically, a large number of healthcare institutions would charge a fixed percentage of the total amount of the fees billed to patients for TPA services. The sharing or splitting of fees with a TPA or managed care company, merely for the privilege of being referred a patient with no commensurate work being done to justify the fees, is now considered unethical. In practice, whether the fees paid to a TPA would constitute an infringement of the ECEG 2016 would very much depend on the basis for the fees and the specific circumstances in each case. As a breach of the ECEG 2016 may lead to disciplinary sanctions against a doctor, some doctors have chosen to terminate their contracts with TPAs to avoid the risk of being sanctioned.

To give more clarity on the implementation of the new rules, the SMC has in various advisories stated that TPAs can still be paid a fee but the quantum must be commensurate to and fairly reflect the complexity of the actual work executed by the said third party. There also needs to be transparency to the patients about the fees payable to the TPA.[131] In addition, the Academy of Medicine, the College of Family Physicians and the Singapore Medical Association have also jointly issued recommendations[132] that doctors can consider a cap for

127 Guideline H3(5) of the ECEG 2016.

128 See *Public Prosecutor v. Khoo Yong Hak* [1995] 1 SLR(R) 769 (SGHC) at [23] to [26]. Section 5 of the Prevention of Corruption Act (Chapter 241) makes it an offence to corruptly solicit, receive, give, promise or offer any gratification as an inducement to any person (or public servant) doing or forbearing to do anything in respect of any matter.

129 Guideline H3(7) of the ECEG 2016 states that doctors may only pay managed care companies, third-party administrators, insurance entities or patient referral services fees that reflect their actual work in handling and processing the patients and cautions that such fees must not be so high as to constitute 'fee splitting' or 'fee sharing'. Further, doctors are required to disclose any such fees to their patients. Although the ECEG 2016 came into force on 1 January 2017, Guideline H3(7) only came into force on 1 July 2017, giving doctors an additional six months to comply; see Paragraphs 9 and 10 of the Advisory on the Payment of Fees to Managed Care Companies, Third Party Administrators, Insurance Entities or Patient Referral Services by the Singapore Medical Council on 13 December 2016. This was reiterated in the Second Advisory on the Payment of Fees to Managed Care Companies, Third Party Administrators, Insurance Entities or Patient Referral Services by the Singapore Medical Council on 23 June 2017, Paragraph 4.

130 See Paragraph 11 of the Advisory on the Payment of Fees to Managed Care Companies, Third Party Administrators, Insurance Entities or Patient Referral Services ('Third Parties') by the Singapore Medical Council on 13 December 2016.

131 Advisory on the Payment of Fees to Managed Care Companies, Third Party Administrators, Insurance Entities or Patient Referral Services by the Singapore Medical Council on 13 December 2016, and the Second Advisory on the payment of fees to managed care companies, third-party administrators, insurance entities or patient referral services by the Singapore Medical Council on 23 June 2017.

132 Joint opinion on Transactions with Managed Care/Third Party Administrators (TPAs) on 14 December 2016, Joint Advisory on Fees paid to Managed Care and Third-Party Administrator

TPA fees, a fixed methodology that allows TPAs to achieve a reasonable and appropriate profit margin, or a fee schedule for different scenarios to cater for the different types and complexities of work done by TPAs.

In late 2018, the local media reported that public hospitals retained the practice of engaging foreign agents who received payment from the public hospitals for 'administrative services' (i.e., to facilitate and assist foreign patients seeking medical treatment in Singapore for a certain percentage of the patient's hospital bill). The MOH requested that public hospitals terminate all contracts with such foreign agents. The MOH's position was that the 'priority of public healthcare institutions is to serve Singaporeans' healthcare needs', and they are 'not allowed to actively market themselves to foreign patients'.[133] In light of the MOH announcement, there have been reports that foreign agents are turning to private practitioners and private hospitals for such referral arrangements.[134]

The ECEG 2016 further provides more detailed guidelines on the relationships between doctors and the medical industry.[135] In particular, financial reimbursements for doctors appearing at educational events must be fair, reasonable and commensurate with the time and expertise they have provided, and doctors must personally pay for any unrelated activities, additional stay or the costs of any accompanying persons. They also cannot accept extravagant gifts, hospitality or other inducements from companies that could be seen to potentially affect their decisions about patient care.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

The regulatory regime does not provide special liability or compensation schemes in relation to medical products. Accordingly, compensation for injuries arising from medicinal products and medical devices derive from common law or statute.[136] Although rare, class actions are possible.[137]

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

Competition issues arising out of the pharmaceutical and medical sector are regulated under the Competition Act (Chapter 50B). The Competition and Consumer Commission of Singapore is the primary regulator in this space. It has the added function of administering the Consumer Protection (Fair Trading) Act (Chapter 52A).[138]

companies on 11 April 2017, and Joint Advisory on Fees Paid to Managed Care and Third-Party Administrator (TPA) Companies on 23 June 2017 by Academy of Medicine, Singapore, College of Family Physicians, Singapore, and Singapore Medical Association.

133 See https://www.straitstimes.com/singapore/health/moh-puts-a-stop-to-foreign-patient-referral-contracts.

134 See https://www.straitstimes.com/singapore/medical-industrys-rogue-agents.

135 ECEG 2016 Guideline I1.

136 For example, Section 14 of the Sale of Goods Act (Chapter 393) or Section 6 of the Consumer Protection (Fair Trading) Act (Chapter 52A).

137 Under Order 4, Rule 6 of the Rules of Court Singapore 2021.

138 See https://www.cccs.gov.sg/about-cccs.

ii Transactional issues

In terms of strategic collaborations, Singapore provides diverse partnership opportunities with its public sector research institutes, leading pharmaceutical and biotechnology companies based in Singapore, clinical research units in hospitals, and international research organisations. Companies can also collaborate with scientists in Singapore's public sector institutes to work on developing new medical technology innovations and applications. In addition, the government provides funding in the life sciences industry: for example, S$4 billion was pledged to further health and biomedical sciences research under the Research, Innovation and Enterprise 2020 plan.[139] In the Research, Innovation and Enterprise 2025 plan, the government will build on this existing health and biomedical science capabilities through the human health and potential domain, incorporating a new emphasis on furthering human potential.[140]

VIII CURRENT DEVELOPMENTS

The covid-19 pandemic and technological developments have been key drivers in developments in the healthcare sector and the concomitant regulatory regimes.

Singapore introduced a Pandemic Special Access Route (PSAR) to expedite access to critical vaccines, medicines and medicinal devices. Applications under the PSAR would be considered for interim authorisation if there is reasonable quality, safety and efficacy (QSE) data suggesting that the potential benefits outweigh the known risks when used during the covid-19 pandemic, and there is continuing QSE data generated from ongoing studies to support the eventual transition of the interim authorisation to full registration.[141]

Telehealth has seen a prolific acceleration in the number of service providers and market penetration. From operating under a regulatory sandbox in 2018, the delivery of remote healthcare has evolved into a core aspect of the healthcare landscape and is provisioned for continuing care during the pandemic. Telehealth providers are coming on board to provide care not just for the common ailments such as a cough and cold, but also chronic diseases such as hypertension and diabetes, post-surgery care advice, cardiac rehabilitative care, physiotherapy and speech therapy, just to name a few. We anticipate an increasing transition of the delivery of non-critical care onto remote platforms.

Direct telemedicine providers (doctors and dentists offering teleconsultations and organisations that provide such services) will be licensed under the upcoming Healthcare Services Act (HCSA).[142] Regulatory guidance has been issued on the supply of registered therapeutic products through e-pharmacy, which prescribe requirements for the handling, storing and packing of medication and IT security, among others.[143] The regulatory landscape will continue to evolve in tandem with an increased emphasis on the remote assessment of health, diagnosis, treatment and intervention.

139 See https://www.mti.gov.sg/Resources/publications/Research-Innovation-and-Enterprise-RIE-2020.

140 https://www.nrf.gov.sg/rie2025-plan.

141 See: https://www.hsa.gov.sg/hsa-psar.

142 The HCSA is yet to come into force. Based on present information, the HCSA will be implemented in three phases across 2022 and 2023. The licensing regime for telemedicine providers is currently anticipated to be implemented in end 2023.

143 https://www.hsa.gov.sg/docs/default-source/hprg-ald/guide-mqa-032.pdf.

The turn towards remote provision of healthcare services and goods extends beyond medical practitioners and clinicians. Manufacturers, suppliers and retailers of medical devices and pharmaceutical products are looking to leverage on e-commerce platforms to connect directly with the end consumer. Relevant considerations should include whether prescriptions are required, whether such products and devices are for professional use, and the relevant advertising regulations.

The integration of healthcare and technology is not without risk. Since Singapore's worst cyberattack in 2018, which occurred within the database of Singapore's largest group of healthcare institutions and resulted in the theft of personal particulars of 1.5 million patients, the targeting of patient data remains a live threat. In August 2021, a ransomware attack on a private eye clinic affected the personal data and clinical information of more than 70,000 patients.[144] In October 2021, a data breach in a private healthcare group resulted in the theft of personal data including insurance policy details, which were put up for sale on hacking forums and could be purchased with Bitcoin.[145] These incidents have heightened public scrutiny on the frameworks in place to safeguard confidential data, especially with the increased prevalence of data use across the healthcare sector. The National Electronic Health Records (NEHR), a database owned by the MOH to collect summary patient health records across different healthcare providers, is still undergoing a series of cybersecurity assessments to ensure that the security infrastructure is sufficiently robust. In the meantime, the MOH has issued the Healthcare Cybersecurity Essentials to strengthen cybersecurity awareness and signal the importance of cybersecurity as a critical part of clinical operations.[146]

Developments in artificial intelligence (AI) and 3D printing represent the next frontier in healthcare technology. The regulatory regime is playing catch-up to these developments. In July 2021, the HSA Medical Devices Branch Issued Regulatory Guidelines for 3D-Printed Medical Devices.[147] In October 2021, the MOH, HSA and the Integrated Health Information Systems co-developed the Artificial Intelligence Health Guidelines, to guide the safe and ethical development and implementation of AI in the healthcare sector.[148] Ethical issues on the deployment of AI and usage of 3D printing in healthcare will continue to trend.

The current PHMCA is to be replaced with a the upcoming HCSA,[149] which will broaden the scope of regulatory coverage from the present hospitals, medical clinics and other healthcare institutions, to include allied health and non-physician healthcare, traditional medicine and complementary and alternative medicine. A new risk-based regulatory approach is expected be adopted whereby licences, which were previously premise-based, are now to be issued based on the types of services provided, such as hospital services and long-term residential care services, among others. Better safeguards for patient safety and welfare will also be implemented. The MOH will be empowered to directly 'step-in' or appoint a 'step-in'

144 https://www.straitstimes.com/tech/tech-news/nearly-73500-patients-data-affected-in-ransomware-attack-on-eye-clinic-in-spore.

145 https://www.straitstimes.com/singapore/courts-crime/fullerton-health-vendor-hacked-personal-details-of-customers-sold-online.

146 https://www.moh.gov.sg/docs/librariesprovider5/hrg-cybersecurity/healthcare-cybersecurity-essentials.pdf.

147 https://www.hsa.gov.sg/docs/default-source/hprg-mdb/gudiance-documents-for-medical-devices/regulatory-guideline-for-3d-printed-medical-devices.pdf.

148 https://www.moh.gov.sg/docs/librariesprovider5/eguides/1-0-artificial-in-healthcare-guidelines-(aihgle)_publishedoct21.pdf.

149 See https://www.moh.gov.sg/hcsa/about-hcsa.

operator to take over a residential healthcare entity licensee that is in serious financial trouble, not complying with the provisions of the HCSA, or is otherwise carrying on its operations in a manner that is detrimental to the interests of patients or customers.[150]

The Bill for the HCSA was passed in Parliament on 6 January 2020, with implementation to be carried out in three phases from early 2021 to end 2022. Due to the pandemic, the phased implementation has been delayed and is anticipated to take place from early 2022 to end 2023. The first phase will bring PHMCA laboratory licensees under the Bill's regulatory regime, while the second phase will involve medical clinics and other ambulatory care services, as well as ambulance services. In the third phase, hospital and long-term care services, as well as other new licensable services will be regulated by the Bill.

Contemporary issues in Singapore have arisen relating to the taking of informed consent by a medical practitioner from a patient and the SMC disciplinary process. A Workgroup appointed by the MOH undertook a comprehensive review of these areas and, on 28 November 2019,[151] published its report on these areas. Key recommendations include:

a First, a new test for informed consent in response to the Singapore Court of Appeal's recent adoption of the Modified-Montgomery test in 2017,[152] which introduced a patient-centric assessment of 'material information'. The new formulation of the test proposed by the Workgroup wishes to 'make it clear that [materiality of information to be given to patients] should be assessed by a [responsible body of doctors]'.[153]

b Second, substantive reforms to the SMC's disciplinary process have been mooted, including establishing a new Disciplinary Commission to separate the SMC's investigation and adjudication functions,[154] establishing an Inquiry Committee to filter out 'frivolous, vexatious, misconceived' or unsubstantiated complaints at an earlier stage,[155] granting the Complaints Committee wider-ranging powers,[156] and encouraging mediation in the disciplinary process.[157]

It remains to be seen if and how the Workgroup's recommendations will translate into legislation.

150 Edwin Tong, Senior Minister of State, Ministry of Health, 'Opening Speech for Second Reading of the Healthcare Services Bill', 6 January 2020.

151 Workgroup to Review the Taking of Informed Consent and SMC Disciplinary Process, 'Report of Recommendations' dated 28 November 2019. See https://www.moh.gov.sg/docs/librariesprovider5/default-document-library/wg-report.pdf.

152 *Hii Chii Kok v Ooi Peng Jin London Lucien and another* [2017] SGCA 38.

153 Workgroup to Review the Taking of Informed Consent and SMC Disciplinary Process, 'Report of Recommendations' dated 28 November 2019, at [56].

154 id., Recommendation 4.3.

155 id., Recommendation 4.1.

156 id., Recommendation 5.4.

157 id., Recommendations 6.1–6.3.

Appendix 1

ABOUT THE AUTHORS

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Melanie Ho is a partner in the health sciences and biotechnology practice and leading lawyer in medical law in Singapore. Her depth of experience includes advising and acting for the Singapore Medical Council and Singapore Dental Council in disciplinary actions taken against doctors, representing plaintiffs against medical practitioners and hospitals, and major players in the healthcare and pharmaceutical industries.

Some of the clients that Melanie has acted for include the plaintiff patient in a lawsuit against Changi Hospital and the Braun group of companies, and MSD, in a multijurisdictional dispute between two global pharmaceutical giants involving the use of the 'Merck' name. She succeeded in an action against insurer AIA who rejected a claim on the basis of suicide, changing the landscape of personal accident insurance. For two decades, Melanie has been counsel to the Singapore Medical Council in various highly publicised disciplinary proceedings and successful in appeals to the Court of Three Judges.

Melanie has been actively involved in setting up internal standard operating protocols and reviewing numerous directives issued by regulatory bodies. She was the lead partner in the review and drafting of the statutory framework governing Dubai Healthcare City's healthcare professionals. She is the first and only Singaporean lawyer invited by the Dubai Healthcare City Authority to sit on its Appeals Board, which hears appeals relating to professional misconduct cases.

She was lauded as one of the three pillars in the firm's investigations team by Global Investigations Review 100 2019 – a guide to the world's top 100 leading firms for corporate investigations. Melanie is a highly regarded legal practitioner in the area of life sciences, having been selected by her peers in *Best Lawyers 2022* for her work in litigation and medical malpractice litigation. She is also recognised as a leading lawyer in *Who's Who Legal: Life Sciences 2017* for product liability.

ALVIN LIM

WongPartnership LLP

Alvin LIM is a partner in the specialist and private client disputes practice.

Alvin has a breadth of experience in healthcare and medical law. Alvin has acted for the Singapore Medical Council in disciplinary proceedings against a prominent oncologist relating to cutting-edge cancer treatment and the viability of the surgical resection of a tumour,

and against a general surgeon for carrying out treatment that was not generally accepted by the profession and outside the context of a clinical trial. He has acted in proceedings against a medical practitioner for sending derogatory emails attacking the authority and integrity of the medical regulatory body. These cases involved complex and novel medical issues, and constitutional issues in relation to a medical practitioner's freedom of speech.

He has also acted for a global pharmaceutical giant, in claims for infringement of intellectual property rights and breach of contract in Singapore proceedings, as part of multi-jurisdictional litigation in the involving the use of the 'Merck' name.

In addition to the healthcare sphere, Alvin has an active practice in civil and commercial litigation. He has acted in a wide range of disputes relating to cross-border investments, shareholding and directorships, company law, and financial instruments involving loan facilities, bonds, options and forex trading. Alvin also advises on regulatory matters, including data protection law. He has advised on investigations by the Personal Data Protection Commission of a data breach and the forensic analysis of the company's IT infrastructure.

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