THE LIFE SCIENCES LAW REVIEW

EIGHTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

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This article was first published in April 2020
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Published in the United Kingdom
by Law Business Research Ltd, London
Meridian House, 34-35 Farringdon Street, London, EC4A 4HL, UK

www.TheLawReviews.co.uk

ISBN 978-1-83862-476-7

Printed in Great Britain by
Encompass Print Solutions, Derbyshire
Tel: 0844 2480 112

ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following for their assistance throughout the preparation of this book:

ANAND AND ANAND

ANTHIAZAMMIT LEGAL

BIRD & BIRD

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VIEIRA DE ALMEIDA

WALDER WYSS LTD

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PREFACE

The eighth edition of *The Life Sciences Law Review* covers a total of 33 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 has seen a number of significant developments. Shortly after the publication date for this edition, the European Union will begin enforcing significant changes in the regulatory regime for medical devices. The United States is considering measures to improve the transparency of pricing for prescription drugs. The United Kingdom is addressing changes to drug regulatory systems that must accompany the country's withdrawal from the EU, and drug and device manufacturers are actively planning for the effects of Brexit on their supply chains. The governments in India and China continue to consider changes in their regulatory systems for drugs and medical devices.

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, which 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 annual publication will be 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 2020

Chapter 24

SINGAPORE

Melanie Ho and Chang Man Phing[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), the Poisons Act (Chapter 234) and the Sale of Drugs Act (Chapter 282), with subsidiary legislation and guidelines as promulgated by the HSA, the MOH and the Singapore Medical Council (SMC), which regulates registered medical practitioners.[3] In particular, 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)[4] 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).

Competition issues arising out of the pharmaceutical and medical sector are regulated under the Competition Act (Chapter 50B). Privacy issues arising out of clinical trials are regulated under the Personal Data Protection Act[5] and the relevant subsidiary legislation of the MA and HPA.[6]

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1 Melanie Ho and Chang Man Phing are partners at WongPartnership LLP.

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

4 Act No. 29 of 2015.

5 Act No. 26 of 2012.

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

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,[7] including traditional medicines, homeopathic medicines and quasi-medicinal products). The Poisons Act regulates specific substances (excluding use in medicines supplied by medical practitioners),[8] 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.[9] To ensure consistency across the regulation of all healthcare professionals, the MOH announced that a single Secretariat of Healthcare Professional Boards (SPB) will be established to oversee the secretariat and operational functions of 11 professional boards with effect from 1 January 2020.[10] 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'.[11]

In January 2019, the SMC, in consultation with the MOH and the Ministry of Law, has appointed a committee comprising members from the medical and legal fraternities to review sentencing sanctions and principles in disciplinary proceedings involving medical professionals.[12] In March 2019, another committee was set up by the MOH comprising medical and legal professionals to look into and provide appropriate recommendations on the taking of informed consent and the SMC's disciplinary process.[13] The outcomes of these reviews were published on 28 November 2019.[14]

7 See https://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Clinical_Trials/Overview/Regulatory_Framework.html.

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

9 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).

10 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.

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

12 SMC Press Release 'SMC Appoints Sentencing Guidelines Committee' dated 17 January 2019.

13 MOH Press Release 'MOH appoints members of Workgroup to review the taking of informed consent and SMC Disciplinary Process' dated 14 March 2019.

14 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.

i Classification

As mentioned above, 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.;[15] medical devices used for the diagnosis, prevention, monitoring, treatment or alleviation of disease not through pharmacological, immunological or metabolic means;[16] cosmetic products used on the external parts of the human body to clean, perfume, change appearance, etc.;[17] therapeutic products used for a therapeutic, preventive, palliative or diagnostic purpose that is constituted by certain specified chemical and biological active ingredients, etc.;[18] complementary health products, including Chinese proprietary medicines and traditional medicines.[19]

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.[20]

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),[21] which doctors have to abide by to carry out any of the procedures listed therein. The list of invasive treatments that non-specialists can perform has been reduced under Table 1 of the APOC Guidelines, compared to its predecessors in 2008. Additionally, the list of invasive surgeries, previously under List A, is now reflected in Table 2, with a clear list of specialists who can perform the procedure. List B procedures under the 2008 Guidelines are now disallowed unless performed in the context of a formal and approved clinical trial.[22] Doctors intending to perform procedures or use devices outside Table 1 or 2 have to apply to the APOC to include the procedure or device under Table 1 or 2 before doing so.[23]

15 Medicines Act, Section 3.

16 Paragraph 1 of the First Schedule to the HPA.

17 Paragraph 2 of the First Schedule to the HPA.

18 Paragraph 3 of the First Schedule to the HPA.

19 See https://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Clinical_Trials/Overview/Regulatory_Framework.html.

20 See https://www.hsa.gov.sg/content/dam/HSA/HPRG/Complementary_Health_Products/Overview_Framework_Policies/Food-Health_Product_Classification/ClassificationTree_Sep18.pdf.

21 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.

22 The MOH's letter to all licensees and managers of medical and dental clinics entitled 'Revised Regime of Non-List A Aesthetic Procedures' dated 1 March 2015.

23 Aesthetic Practices Oversight Committee, Guidelines on Aesthetic Practices for Doctors (updated October 2016) at [25].

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.[24] In the third phase, which commenced on 1 November 2017, provisions on the regulation of human biomedical research took effect.[25] These include the taking of consent, and the constitution of institutional review boards (IRBs)[26] 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.[27] 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,[28] to maintain a record containing a detailed description of the condition of each tissue under the tissue bank's supervision and control,[29] to establish a system to ensure the quality and safety of any tissue under the tissue bank's supervision and control,[30] and restrictions on disclosure of information on tissue donors.[31]

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[32] or are contrary to public interest.[33]

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

24 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.

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

26 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.

27 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.

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

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

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

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

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

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

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.[34] 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.[35]

The BAC (appointed by the Singapore Cabinet) released its Ethics Guidelines for Human Biomedical Research in June 2015. These Ethics Guidelines do not have statutory force, but operate alongside the more recent HBRA subsidiary legislation to provide guidance and emphasise the fundamental principles of solidarity, respect for persons, justice, proportionality, sustainability, beneficence and research integrity.[36]

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.[37]

Written approval from the Director of Medical Services must be obtained[38] for all research involving human embryos, human oocytes[39] and human-animal combination gametes or embryos.[40]

Animal models

Any research facility that uses animals for scientific purposes must obtain a licence from the Animal & 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.[41]

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

34 Fourth Schedule to the HBRA.

35 Third Schedule to the HBRA.

36 BAC's Ethics Guidelines (June 2015) at Paragraphs 2.3–2.17.

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

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

39 Human oocytes include those obtained from excised ovarian tissue.

40 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.

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

iii Clinical trials

Therapeutic and medicinal products

The Health Products (Clinical Trials) Regulations 2016 introduced a new 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),[42] 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.[43]

Under the CTC and CTA/CTN regimes for medicinal products and therapeutic products respectively, a sponsor is mandatory.[44] Insurance must be maintained to provide for compensation in the event of injury or loss.[45]

Medical devices

A CTC or a CTA/CTN is not necessary for studies assessing the safety, performance or effectiveness of a medical device.[46] Prior approval by each institution's IRB is, however, still required.[47] The Health Products (Medical Device) Regulations (HP(MD)R) also regulate the use of medical devices in clinical trials.[48]

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.[49] The term 'remedy' encompasses a broad range of treatments, including the use of

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 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.

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

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

46 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.

47 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.

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

49 ECEG 2016 at Guideline B6.

medical devices.[50] Under the ECEG 2016, doctors may offer innovative therapy[51] to patients in desperate or dire situations, and where conventional therapy is unhelpful.[52] Patients' informed consent must be obtained; failing to do so can result in the doctor being struck off the Register of Medical Practitioners.[53] 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.[54]

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.[55]

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,[56] 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 relevant licences or a qualified practitioner.[57] However, prior approval from the HSA must be sought.[58] 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.[59]

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.[60]

The Human Biomedical Research (Requirements for Appropriate Consent – Exemption) Regulations 2019 has reduced the elements of 'appropriate consent' required

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

51 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.

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

53 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.

54 ECEG 2016 at Guideline B8.

55 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.

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

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

58 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.

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

60 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.

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.[61]

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,[62] 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 be granted if the drug is intended for treatment of a serious life-threatening condition and can potentially address local unmet medical needs;[63] 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.[64]

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.[65] An abridged evaluation process for registration has been provided for the other three classes, to allow faster market access.[66] New categories of exceptions for the manufacture of medical devices without a licence have been introduced, namely for clinical labs already licensed under the PHMCA,[67]

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

62 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 (January 2019).

63 '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 (January 2019) at Paragraph 14.2.1.

64 Third Schedule to the Health Products (Medical Devices) Regulations 2010; Medical Device Guidance – Guidance on Medical Device Product Registration (June 2018) at Paragraph 2.

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

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

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

and where the supply of medical devices is intended for charitable purposes.[68] The category of implantable medical devices has been expanded to include orthopaedic, neurological, breast, intraocular and cardiovascular implants.[69] In another amendment, wellness devices have been expressly excluded from the HP(MD)R.[70]

All medical devices must adhere to the Essential Principles for Safety and Performance for Medical Devices in the First Schedule to the HP(MD)R[71] prior to their placement on the Singapore market. Requirements under all applicable legislation[72] 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.[73]

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.[74] The standardisation of regulation allows for the efficient trading of medical devices among ASEAN states, though it should be noted that 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.[75] Instead, the HSA must be notified before the supply or sale of the cosmetic product.[76] 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.[77] 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.[78]

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

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

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

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

72 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.

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

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

75 Guidelines on the Control of Cosmetic Products (Revised December 2018) at Paragraph 1.

76 Guidelines on the Control of Cosmetic Products (Revised December 2018) at Paragraph 5.

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

78 Guidelines on the Control of Cosmetic Products (Revised December 2018) at Paragraphs 5 and 10.

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.[79]

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.[80]

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.[81] Typically, a biosimilar product is eligible for registration through an abridged evaluation route.

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.[82]

The HP(TP)R[83] and MA[84] 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.

Under the Inland Revenue Authority of Singapore's Productivity and Innovation Credit Scheme (the PIC Scheme), businesses may receive a tax deduction of up to 400 per cent or allowances of up to S$400,000 (the cap) of their expenditure per year in research and development (R&D) from the years of assessment 2011 to 2018.[85] R&D expenditure[86] exceeding the cap will enjoy a tax deduction of 150 per cent if the R&D is done in Singapore. Any other R&D expenditure, including expenditure of R&D carried out overseas, will enjoy a tax deduction of 100 per cent. Accordingly, businesses engaged in R&D of new drugs may enjoy substantial tax benefits under the PIC Scheme.[87]

79 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Complementary_Health_Products/TM.html.

80 Section 5 of Medicines Act.

81 Guidance on Registration of Biosimilar Products (November 2016).

82 Section 36A of the Patents Act.

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

84 Section 19A of the Medicines Act.

85 See https://www.iras.gov.sg/irashome/Schemes/Businesses/Productivity-and-Innovation-Credit-Scheme/.

86 R&D expenditure also encompasses staff costs and consumables. See Part 4 of IRAS Research and Development (R&D) Claim Form.

87 See https://www.iras.gov.sg/irashome/Schemes/Businesses/Productivity-and-Innovation-Credit-Scheme/Six-Qualifying-Activities-under-PIC/ under 'Research and Development (R&D) Activities'.

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.[88]

Under the HPA[89] and MA,[90] 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.[91] 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.[92]

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.[93]

As with other health products, the HSA has the power to suspend, cancel or reclassify the registration of cosmetic products, as set out above.[94]

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.[95] 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

88 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.

89 Section 27 of the Health Product Act.

90 Section 16 of the Medicines Act.

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

92 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices (August 2018) at Paragraph 8.

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

94 Section 27 of the Health Products Act.

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

or Cooperation Scheme Guide to Good Manufacturing Practice for Medicinal Products.[96] 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 the First Schedule to the Health Products (Medical Devices) Regulations 2010.[97]

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.[98]

Unlike medicinal products, prior approval from the HSA is not required for advertisements relating to therapeutic products.[99] 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 Second Schedule to the HP(ATP)R respectively.[100]

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.[101]

With regard to cosmetic products, advertisements cannot include claims that they have therapeutic benefits or can be used for therapeutic purposes,[102] nor can they create an erroneous impression regarding the formulation, composition, quality or safety of the product.[103]

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

96 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.

97 Regulation 33 of the Health Products (Medical Devices) Regulations 2010.

98 Section 50 of the Medicines Act.

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

100 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.

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

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

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

the public into believing that any of the services are medically endorsed'.[104] 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.[105]

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[106] or wholesale dealer's licence for medicinal products.[107] A licensee for a therapeutic product must appoint a responsible person to ensure compliance with the HSA's good distribution practice (GDP).[108] 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.[109] 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.

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.[110]

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.[111]

104 ECEG 2016 at Guideline I2(4).

105 ECEG 2016 at Guideline I2(5).

106 See https://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Audit_and_Licensing_Of_Importers_Wholesale_Dealers_and_Exporters.html.

107 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Audit_and_Licensing_Of_Importers_Wholesale_Dealers_and_Exporters/Chinese_Proprietary_Medicines.html.

108 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.

109 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices (August 2018) at Paragraph 5.2.

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

111 Regulation 11 of the Health Products (Therapeutic Products) Regulations 2018.

xii Imports and exports

Under the HPA, a person must now obtain an importer's licence to import therapeutic products or medical devices,[112] and a wholesaler's licence to export them.[113] Importers and exporters of therapeutic products must also appoint a person to be responsible for ensuring compliance with the HSA's GDP standards.[114] 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.[115] Companies applying for an importer's or wholesaler's licence for therapeutic products for patients' use or restricted activities between 1 November 2016 and 31 October 2019 are eligible for a fee waiver to facilitate the adoption of this new regulatory regime.[116]

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.[117]

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.[118] 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.

112 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.

113 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.

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

115 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices (August 2018) at Paragraph 5.2.

116 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Audit_and_Licensing_Of_Importers_Wholesale_Dealers_and_Exporters/Medicinal_Products.html.

117 Part II of the Medicines Act.

118 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[119] and psychotropic substances or medicinal products with psychotropic substances,[120] 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.[121]

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.[122]

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.[123]

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),[124] 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).[125] Subsidised drugs cover up to 90 per cent of the total volume of public medication prescriptions and are reviewed and

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

120 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.

121 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.

122 Section 49 of the Health Products Act.

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

124 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/content/moh_web/medishield-life/about-medishield-life/what-is-medishield-life.html.

125 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.[126] Subsidies are also provided for medical devices, such as implants.[127] 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.[128] 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.[129]

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.[130]

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.[131]

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 PAYORS

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.[132]

The ECEG 2016 also provides guidance to doctors in relation to issues of financial conflicts of interest.[133] 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

126 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.

127 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.

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

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

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

131 Section 28 of the Health Products Act.

132 SAPI Code of Marketing Practices (2016).

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

the ECEG 2016.[134] 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).[135]

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.[136] The rationale is to ensure that the patient's interests would take priority over the doctor's personal financial interests.[137] 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.[138] In addition, the Academy of Medicine, the College of Family Physicians and the Singapore Medical Association have also jointly issued recommendations[139] that doctors can consider a cap for

134 Guideline H3(5) of the ECEG 2016.

135 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.

136 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.

137 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.

138 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.

139 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'.[140] 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.[141]

The ECEG 2016 further provides more detailed guidelines on the relationships between doctors and the medical industry.[142] 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.[143] Although rare, class actions are possible.[144]

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

The Competition Commission of Singapore is the primary regulator in this space. In October 2013, the Commission indicated that it would be actively considering the issue of patent disputes and 'pay-for-delay' agreements.[145]

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.

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

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

142 ECEG 2016 Guideline I1.

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

144 Under Order 15, Rule 12 of the Rules of Court of Singapore.

145 See https://www.cccs.gov.sg/media-and-publications/speeches/welcome-address-by-mr-toh-han-li-chief-executive-of-ccs-at-the-intellectual-property-management-community-of-practice-seminar-competition-law-and-payfordelay-patent-cases.

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.[146]

VIII CURRENT DEVELOPMENTS

As Singapore continues to experience low fertility rates, the adoption of new methods of fertility assistance has come under active consideration. Thus, the BAC has formed a review group to look into the ethical, legal and social issues arising from mitochondrial genome replacement technology.[147] The MOH is currently reviewing the use of pre-implantation genetic screening (PGS) and its ethical implications, having commenced a three-year pilot programme to assess its clinical effectiveness at improving in vitro fertilisation (IVF) cycle outcomes by screening for chromosomal abnormalities in embryos created through IVF.[148] The pilot programme is scheduled to end in December 2019, when the MOH will evaluate the clinical outcomes to evaluate whether PGS should become a routine clinical service.[149]

A recent High Court judgment[150] has prompted governmental reviews of the status of surrogacy in Singapore.[151] While surrogacy is not available in Singapore, the authorities have been faced with issues in relation to the legal status of children birthed through gestational surrogacy overseas (e.g., parentage, citizenship, residential status of the child). The case raised interesting questions about allowing the adoption of such a child by the child's biological father, who intended to raise the child within the context of a homosexual relationship. Governmental reviews may result in legislative changes to the terms of assisted reproduction services, currently governed by the PHMCA.[152]

To control rising healthcare costs, the MOH has published the Fee Benchmarks for Private Sector Surgeon Fees (as of 13 November 2018) covering 222 surgical procedures.[153]

146 See https://www.nrf.gov.sg/rie2020.

147 See www.bioethics-singapore.org/index/activities/current-projects.html. Mitochondrial gene replacement allows the replacement of mutant mitochondrial genes in unfertilised oocytes or zygotes with normal donor mitochondria, preventing the passing of the condition from mother to child. See also www.straitstimes.com/singapore/three-parent-baby-to-avoid-diseases.

148 See www.moh.gov.sg/content/moh_web/home/pressRoom/Parliamentary_QA/2016/pre-implantation-genetic-screening--pgs-.html and https://www.nuh.com.sg/wbn/slot/u3007/Patients%20and%20Visitors/Newsroom/Media%20Articles/2016/Nov_2016/TODAY_Pg18_ThreeHospitalsOfferEmbryoScreeningTechniquePilotStudy%20_15Nov16.pdf.

149 *Singapore Parliamentary Debates, Official Report* (5 November 2019) Vol 94 at Col 18 (Gan Kim Yong, Minister for Health).

150 *UKM v. Attorney-General* [2018] SGHCF 18.

151 See https://www.straitstimes.com/singapore/parliament-authorities-looking-at-adoption-laws-and-surrogacy-does-not-support-gay.

152 Regulation 18(1) read with Second Schedule to the Private Hospitals and Medical Clinics Regulations.

153 MOH, Fee Benchmarks for Private Sector Surgeon Fees (As of 13 November 2018).

While the benchmarks are not intended to be a fee cap,[154] doctors who charge above the benchmarks are expected to explain to patients and other stakeholders why their charges exceed the benchmarks.[155]

The current PHMCA is to be replaced with a new Healthcare Services Act (HCSA),[156] 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' 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.[157]

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 the end of 2022. 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.

When the HCSA was first proposed in 2017, it was intended to make it mandatory for licensed hospitals and medical clinics under the HCSA to contribute critical patient health information to the National Electronic Health Records (NEHR). The NEHR is a database owned by the MOH to collect summary patient health records across different healthcare providers. At present, contribution is voluntary with primarily public institutions contributing patient data. Patients who do not wish for their records to be accessed via the NEHR may opt out, but by default their specified health data would be contributed to the NEHR.[158] However, mandatory contribution to the NEHR has been deferred due to various events.

Before the HCSA could be enacted in 2019 as originally intended, Singapore witnessed its worst cyberattack, which occurred within the database of Singapore's largest group of healthcare institutions, consisting of four hospitals and other healthcare centres.[159] The personal particulars of 1.5 million patients, and outpatient particulars of around 159,000 people, were stolen. A Committee of Inquiry was convened[160] and it issued a report on its

154 MOH, Fee Benchmarks for Private Sector Surgeon Fees (As of 13 November 2018) at Paragraph 7(a)(ii).

155 Fee Benchmarks Advisory Committee Report (9 November 2018).

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

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

158 The draft Healthcare Services Bill was made available to the public at https://www.moh.gov.sg/docs/librariesprovider8/default-document-library/healthcare_services_(draft)_bill_2017122241b0a3bc9c8c4d65b2ac0bbfa0aa81bf.pdf.

159 See https://www.straitstimes.com/singapore/personal-info-of-15m-singhealth-patients-including-pm-lee-stolen-in-singapores-most.

160 WongPartnership LLP represented MOH Holdings Private Limited in the inquiry.

findings in December 2018.[161] In January 2019, the Personal Data Protection Commission imposed fines on both the company responsible for administering the electronic medical record system and the healthcare institution (fined S$750,000 and S$250,000 respectively).[162] The latter is the same institution that manages the NEHR.

Soon after the above inquiry was concluded, the MOH disclosed in January 2019 that another major data breach of healthcare information had been detected. This time, involving the data of more than 14,000 people diagnosed with HIV.[163] 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.[164]

As a result, plans for the mandatory contribution of patient medical data to the NEHR have been deferred. The NEHR is still undergoing a series of cybersecurity assessments to ensure that the system is sufficiently robust.[165]

The recent data breaches have given rise to concerns about the adoption of telemedicine. Singapore has seen a growth in the telemedicine sector with reports that funding into Asian telemedicine start-ups have grown since 2010.[166] To ensure that telemedicine and other similar new and innovative services can be developed in a safe and controlled environment, the MOH launched a new Licensing Experimentation and Adaptation Programme (LEAP) on 18 April 2018, with telemedicine as the first service to come under LEAP.[167] Under LEAP, the MOH is working alongside telemedicine providers to develop more timely, fit-for-purpose and effective regulations, with an intended focus on 'tele-consultation and mobile medicine (house call) services that provide direct clinical care, such as triage, history taking, diagnosis and treatment under the HCSA'.[168] With the experience gathered through the LEAP framework, the MOH will be revising the National Telemedicine Guidelines issued in 2015, with the revised edition expected to be published in 2020.[169]

The Workgroup to Review the Taking of Informed Consent and SMC Disciplinary Process convened by the SMC in consultation with the MOH and the Ministry of Law issued its recommendations on 28 November 2019. Key recommendations include: first, a new test for informed consent in response to the Singapore Court of Appeal's recent adoption

161 Public Report of the Committee of Inquiry Into The Cyber Attack On Singapore Health Services Private Limited's Patient Database On Or Around 27 June 2018 (10 January 2019).

162 Decision of the Commissioner for Personal Data Protection in the matter of an investigation under Section 50(1) of the Personal Data Protection Act 2012 [2019] SGPDPC 3 at [136] – [137]; see also https://www.pdpc.gov.sg/-/media/Files/PDPC/PDF-Files/Press-Room/2019/Media-Release---SingHealth-and-IHIS_15-Jan-2019.pdf.

163 https://www.bbc.com/news/world-asia-47027867.

164 *Singapore Parliamentary Debates, Official Report* (12 February 2019) Vol 94 (Gan Kim Yong, Minister for Health).

165 *Singapore Parliamentary Debates, Official Report* (15 January 2019) Vol 94 (Gan Kim Yong, Minister for Health); Edwin Tong, Senior Minister of State, Ministry of Health, 'Closing Speech for Second Reading of the Healthcare Services Bill', 6 January 2020 at [53].

166 https://www.businesstimes.com.sg/brunch/the-doctor-is-online-why-telemedicine-apps-need-to-tread-with-caution.

167 https://www.moh.gov.sg/news-highlights/details/moh-launches-first-regulatory-sandbox-to-support-development-of-telemedicine.

168 https://www.moh.gov.sg/our-healthcare-system/licensing-experimentation-and-adaptation-programme-(leap)---a-moh-regulatory-sandbox.

169 *Singapore Parliamentary Debates, Official Report* (7 October 2019) Vol 94 (Gan Kim Yong, Minister for Health).

of the Modified-Montgomery test in 2017,[170] 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]'.[171] 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,[172] establishing an Inquiry Committee to filter out 'frivolous, vexatious, misconceived' or unsubstantiated complaints at an earlier stage,[173] granting the Complaints Committee wider-ranging powers,[174] and encouraging mediation in the disciplinary process.[175] It remains to be seen if and how the Workgroup's recommendations will translate into legislation.

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

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

172 Workgroup to Review the Taking of Informed Consent and SMC Disciplinary Process, 'Report of Recommendations' dated 28 November 2019, Recommendation 4.3.

173 Workgroup to Review the Taking of Informed Consent and SMC Disciplinary Process, 'Report of Recommendations' dated 28 November 2019, Recommendation 4.1.

174 Workgroup to Review the Taking of Informed Consent and SMC Disciplinary Process, 'Report of Recommendations' dated 28 November 2019, Recommendation 5.4.

175 Workgroup to Review the Taking of Informed Consent and SMC Disciplinary Process, 'Report of Recommendations' dated 28 November 2019, Recommendations 6.1–6.3.

Appendix 1

ABOUT THE AUTHORS

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Melanie Ho is a 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, and representing plaintiffs against medical practitioners and hospitals.

In 2017, she succeeded in an appeal against insurer AIA for claims involving at least S$1.2 million and acted for the Singapore Medical Council in highly publicised disciplinary proceedings against a Singaporean oncologist for professional misconduct. Melanie has been actively involved in setting up internal standard operating protocols and reviewing numerous directives issued by regulatory bodies. Melanie 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 the lead partner in the review and drafting of the statutory framework governing Dubai Healthcare City's healthcare professionals. 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 recommended disputes resolution lawyer in *The Legal 500 Asia Pacific* 2015, and a highly regarded legal practitioner in the area of life sciences, having been selected by her peers in *Best Lawyers* 2017 and 2018 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.

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Chang Man Phing's main areas of practice encompass civil and commercial litigation, including disputes relating to companies, shareholders and directors, insurance, contracts and employment contracts. She regularly advises companies on potentially litigious matters involving breach of fiduciary duties, breach of confidentiality obligations and breach of non-compete and non-solicitation clauses. She specialises in medical law and healthcare matters and regularly acts for patients seeking redress against hospitals and medical practitioners through medical negligence claims. She has acted for US pharmaceutical company Merck Sharp & Dohme in proceedings in Singapore involving worldwide litigation. She has also acted for Cordlife Group Limited, a major player in Singapore's cord blood banking services industry, in both litigation and licensing advisory matters.

Man Phing is also a prosecuting counsel for the Singapore Medical Council, Singapore Dental Council, Allied Health Professions Council and Council of Estate Agencies in disciplinary proceedings against errant members. With her extensive experience, she undertakes advisory works for healthcare institutions, statutory boards and multinational corporations. She has advised the Singapore Medical Council in the review of amendments to the legislative framework and was also part of the team of lawyers in the review and drafting of the statutory framework governing Dubai Healthcare City's healthcare professionals and operators. Separately, she provides legal advice to various institutions, including the Health Promotion Board, the National University of Singapore and the National Council of Social Services.

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ISBN 978-1-83862-476-7