THE LIFE SCIENCES LAW REVIEW

SIXTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

THE LIFE SCIENCES LAW REVIEW

SIXTH EDITION

Reproduced with permission from Law Business Research Ltd
This article was first published in April 2018
For further information please contact Nick.Barette@thelawreviews.co.uk

Editor
Richard Kingham

THE LAWREVIEWS

PUBLISHER
Tom Barnes

SENIOR BUSINESS DEVELOPMENT MANAGER
Nick Barette

BUSINESS DEVELOPMENT MANAGERS
Thomas Lee, Joel Woods

ACCOUNT MANAGERS
Pere Aspinall, Sophie Emberson,
Laura Lynas, Jack Bagnall

PRODUCT MARKETING EXECUTIVE
Rebecca Mogridge

RESEARCHER
Arthur Hunter

EDITORIAL COORDINATOR
Gavin Jordan

HEAD OF PRODUCTION
Adam Myers

PRODUCTION EDITOR
Caroline Fewkes

SUBEDITORS
Simon Tyrie and Gina Mete

CHIEF EXECUTIVE OFFICER
Paul Howarth

Published in the United Kingdom
by Law Business Research Ltd, London
87 Lancaster Road, London, W11 1QQ, UK

www.TheLawReviews.co.uk

ISBN 978-1-912228-19-5

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

© 2018 Law Business Research Ltd

THE LAW REVIEWS

THE ACQUISITION AND LEVERAGED FINANCE REVIEW

THE ANTI-BRIBERY AND ANTI-CORRUPTION REVIEW

THE ASSET MANAGEMENT REVIEW

THE ASSET TRACING AND RECOVERY REVIEW

THE AVIATION LAW REVIEW

THE BANKING LITIGATION LAW REVIEW

THE BANKING REGULATION REVIEW

THE CARTELS AND LENIENCY REVIEW

THE CLASS ACTIONS LAW REVIEW

THE CONSUMER FINANCE LAW REVIEW

THE CORPORATE GOVERNANCE REVIEW

THE CORPORATE IMMIGRATION REVIEW

THE DISPUTE RESOLUTION REVIEW

THE DOMINANCE AND MONOPOLIES REVIEW

THE EMPLOYMENT LAW REVIEW

THE ENERGY REGULATION AND MARKETS REVIEW

THE ENVIRONMENT AND CLIMATE CHANGE LAW REVIEW

THE EXECUTIVE REMUNERATION REVIEW

THE FOREIGN INVESTMENT REGULATION REVIEW

THE FRANCHISE LAW REVIEW

THE GAMBLING LAW REVIEW

THE GOVERNMENT PROCUREMENT REVIEW

THE HEALTHCARE LAW REVIEW

THE INITIAL PUBLIC OFFERINGS REVIEW

THE INSOLVENCY REVIEW

THE INSURANCE AND REINSURANCE LAW REVIEW

THE INTELLECTUAL PROPERTY AND ANTITRUST REVIEW

THE INTELLECTUAL PROPERTY REVIEW

THE INTERNATIONAL ARBITRATION REVIEW

THE INTERNATIONAL CAPITAL MARKETS REVIEW

THE INTERNATIONAL INVESTIGATIONS REVIEW

THE INTERNATIONAL TRADE LAW REVIEW

THE INVESTMENT TREATY ARBITRATION REVIEW

THE INWARD INVESTMENT AND INTERNATIONAL TAXATION REVIEW

THE ISLAMIC FINANCE AND MARKETS LAW REVIEW

THE LENDING AND SECURED FINANCE REVIEW

THE LIFE SCIENCES LAW REVIEW

THE MERGER CONTROL REVIEW

THE MERGERS AND ACQUISITIONS REVIEW

THE MINING LAW REVIEW

THE OIL AND GAS LAW REVIEW

THE PATENT LITIGATION LAW REVIEW

THE PRIVACY, DATA PROTECTION AND CYBERSECURITY LAW REVIEW

THE PRIVATE COMPETITION ENFORCEMENT REVIEW

THE PRIVATE EQUITY REVIEW

THE PRIVATE WEALTH AND PRIVATE CLIENT REVIEW

THE PRODUCT REGULATION AND LIABILITY REVIEW

THE PROJECTS AND CONSTRUCTION REVIEW

THE PUBLIC COMPETITION ENFORCEMENT REVIEW

THE PUBLIC–PRIVATE PARTNERSHIP LAW REVIEW

THE REAL ESTATE LAW REVIEW

THE REAL ESTATE M&A AND PRIVATE EQUITY REVIEW

THE RESTRUCTURING REVIEW

THE SECURITIES LITIGATION REVIEW

THE SHAREHOLDER RIGHTS AND ACTIVISM REVIEW

THE SHIPPING LAW REVIEW

THE SPORTS LAW REVIEW

THE TAX DISPUTES AND LITIGATION REVIEW

THE TECHNOLOGY, MEDIA AND TELECOMMUNICATIONS REVIEW

THE THIRD PARTY LITIGATION FUNDING LAW REVIEW

THE TRADEMARKS LAW REVIEW

THE TRANSFER PRICING LAW REVIEW

THE TRANSPORT FINANCE LAW REVIEW

www.TheLawReviews.co.uk

ACKNOWLEDGEMENTS

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

ANAND AND ANAND

ARTHUR COX

BAE, KIM & LEE LLC

BAKER MCKENZIE

BECH-BRUUN LAW FIRM P/S

BIRD & BIRD

BULL & CO ADVOKATFIRMA AS

CALISSENDORFF SWARTING ADVOKATBYRÅ

CASTRÉN & SNELLMAN ATTORNEYS LTD

COVINGTON & BURLING LLP

D+B RECHTSANWÄLTE PARTNERSCHAFT MBB

DECHERT LLP

ESTUDIO BECCAR VARELA

FIALDINI EINSFELD ADVOGADOS

FIEBINGER POLAK & PARTNER RECHTSANWÄLTE GMBH

GORODISSKY & PARTNERS LAW FIRM

HOET PELÁEZ CASTILLO & DUQUE – ABOGADOS

JONES DAY

LATIN LEX INTERNATIONAL

LEE AND LI, ATTORNEYS-AT-LAW

PORTOLANO CAVALLO

RODRIGO, ELÍAS & MEDRANO ABOGADOS

RUTA PUMPUTIENE LAW FIRM

S HOROWITZ & CO

SHUSAKU YAMAMOTO

SOŁTYSIŃSKI KAWECKI & SZLĘZAK

TOMPKINS WAKE

VIEIRA DE ALMEIDA

WONGPARTNERSHIP LLP

CONTENTS

PREFACE

The sixth edition of *The Life Sciences Law Review* covers a total of 34 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.

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 current 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.

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

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2018

Chapter 28

SINGAPORE

Melanie Ho and Jacqueline Chua[1]

I INTRODUCTION

The life sciences industry in Singapore is regulated by the Health Sciences Authority (HSA), a body established under the Health Sciences Authority Act (Chapter 122C) and operating under the oversight of the Singapore Ministry of Health (MOH). Pharmaceuticals, complementary medicines, cosmetics, medical devices and other health products (collectively, health products) 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.[2] In particular, the Ethical Code and Ethical Guidelines (ECEG) set ethical benchmarks for medical practitioners, and a departure from the same may result in disciplinary action. The ECEG was revised in 2016 and came into force on 1 January 2017 (ECEG 2016).

Partially in force as of 1 November 2017, human biomedical research is regulated by the Human Biomedical Research Act (HBRA) (Act No. 29 of 2015) and recent sub-legislation, namely the Human Biomedical Research Regulations 2017 and the Human Biomedical Research (Restricted Research) Regulations 2017. The legislation is supplemented by the Ethics Guidelines for Human Biomedical Research (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 (Act No. 26 of 2012) and the relevant subsidiary legislation of the MA and HPA.[3]

1 Melanie Ho and Jacqueline Chua are partners at WongPartnership LLP.

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

3 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. Recently, the HPA was amended to transfer to the HPA the regulation of chemical and biological drugs, now defined as therapeutic products, as part of the HSA's continuing effort to consolidate the regulation of health products into one Act. Medical devices and cosmetic products are still regulated by the HPA. The MA regulates other medicinal products (such as cell, tissue and gene therapy products, and complementary health products,[4] including traditional medicines, homeopathic medicines and quasi-medicinal products). The Poisons Act regulates specific substances found in drugs and medicinal products[5] except for therapeutic products,[6] and the Sale of Drugs Act regulates any substance or mixture of substances used as medicine sold for medicinal purposes.

i Classification

The definitions of therapeutic products, medicinal products, medical devices and cosmetic products are set out in the respective Acts, as set out in Section I. Generally, chemical and biological drugs are now defined as therapeutic products and governed by the HPA, while cell, tissue and gene therapy products and complementary health products remain as medicinal products under the MA.[7] Therapeutic products are only for use in human beings, must fall within any of the intended purposes listed in the First Schedule of the HPA, and must contain any of the active ingredients listed therein, while medicinal products are not exclusive to human use and need not contain the active ingredients aforementioned.

Food and supplements of a food nature (including food-based complementary health products) are under the purview of the Agri-Food and Veterinary Authority (AVA) 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 AVA, depending on whether the product appears to be part of a daily diet, taken as supplement to a diet, or taken for medicinal purposes.[8]

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 (APOC Guidelines),[9] 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 with 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

4 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Clinical_Trials/Overview/Regulatory_Framework.html.

5 The Schedule (Poisons List) to the Poisons Act.

6 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/therapeutic-productsportover/Key_Features-Changes.html#HP_TP.

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

8 See www.hsa.gov.sg/content/dam/HSA/HPRG/Complementary_Health_Products/Overview_Framework_Policies/Food-Health_Product_Classification/ClassificationTreeFeb07pdf.pdf.

9 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.

procedures under the 2008 Guidelines are now disallowed unless performed in the context of a formal and approved clinical trial.[10] 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.[11]

ii Non-clinical studies

In vitro human biomedical research

The HBRA is an Act that regulates the conduct of human biomedical research, which first came into force on 1 July 2016 and will continue to be enforced in stages. On 1 January 2017, the provisions prohibiting commercial trading of and the advertising of commercial trading of human tissue came into force. More recently, on 1 November 2017, the provisions on consent, institutional review boards (IRBs),[12] savings and transition of research conduct, regulation of human biomedical research, prohibited and restricted human biomedical research, and waiver of requirements for appropriate consent came into force.[13] The regulations pertaining to human tissue activities and tissue banks,[14] enforcement powers to stop human biomedical research or tissue banking activities that contravene the HBRA or any relevant codes of practice or ethics, activities not properly reviewed by an IRB,[15] or are contrary to public interest, have not yet come into force.

In tandem with the above, new subsidiary legislation, namely the Human Biomedical Research Regulations 2017 and the Human Biomedical Research (Restricted Research) Regulations 2017, came into force on 1 November 2017. Read with the HBRA, the 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.[16] 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.[17]

Notably, commercial trading of human tissue was outlawed on 1 January 2017 and offenders may be fined up to S$100,000 or imprisoned for up to 10 years, or both.[18]

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

10 The MOH's letter to all Licensees, Managers of Medical and Dental Clinics entitled 'Revised Regime of Non-List A Aesthetic Procedures' dated 1 March 2015.

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

12 Institutional Review Boards are made 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.

13 Sections 6 to 31, 65 and 68, and the Third, Fourth and Fifth Schedules of HBRA.

14 Sections 34 to 39 of HBRA.

15 Sections 42 to 53 of HBRA.

16 Fourth Schedule of HBRA.

17 Third Schedule of HBRA.

18 Section 32 of HBRA. See also Human Organ Transplant Act (Chapter 131A) and *Public Prosecutor v. Tang Wee Sung* [2008] SGDC 262.

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.[19]

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 by fertilisation of a human egg by human sperm, for a period of more than 14 days, is prohibited.[20]

Written approval from the Director of Medical Services must be obtained[21] for all research involving human embryos, human oocytes[22] and human-animal combination gametes or embryos.[23]

Animal models

Any research facility that uses animals for scientific purposes must obtain a licence from the AVA. 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 establish an Institutional Animal Care and Use Committee to oversee and evaluate the animal care and use programmes of an institution.[24]

Singapore adheres to the Organisation for Economic Cooperation and Development (OECD) Mutual Acceptance of Data scheme. Acceptance to this harmonising scheme amounts to an endorsement that Singapore's generated research data complies with OECD's Principles of Good Laboratory Practice. Such data can be accepted automatically by other OECD countries, and facilitates the sharing of research.

iii Clinical trials

Therapeutic and medicinal products

Formerly under the Medicines (Clinical Trial) Regulations, the clinical trials for therapeutic products are now governed under the HPA and its subsidiary legislation, the Health Products (Clinical Trials) Regulations.

Previously, all clinical trials required a clinical trial certificate (CTC) issued by the HSA.[25] However, for therapeutic products, the CTC regime has been replaced with the new risk-based Clinical Trial Authorisation-Clinical Trial Notification under the Health Products (Clinical Trials) Regulations.[26] A clinical trial of a therapeutic product may either require a clinical trial authorisation (CTA) or a clinical trial notification (CTN), 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

19 BAC's Ethics Guidelines at Paragraphs 2.3 to 2.17.

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

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

22 Human oocytes include those obtained from excised ovarian tissue.

23 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.

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

25 Regulation 5 of the Medicines (Clinical Trial) Regulations.

26 Clinical Trials Guidance – Determination of whether a clinical trial requires CTA, CTN or CTC at Paragraph 1.2.1.

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 CTC is still necessary.[27]

Under the CTC and CTA-CTN regimes for medicinal products and therapeutic products respectively, a sponsor is mandatory.[28] Insurance must be maintained to provide for compensation in the event of injury or loss.[29]

Medical devices

A CTC or a CTA-CTN is not necessary for studies assessing the safety, performance or effectiveness of a medical device.[30] Prior approval by each institution's IRB is, however, still required.[31] The Health Products (Medical Device) Regulations (HP(MD)R) also regulate the use of medical devices in clinical trials.[32]

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.[33] 'Remedy' encompasses a broad range of treatments, including the use of medical devices.[34] Under the ECEG 2016, doctors may offer innovative therapy[35] to patients in desperate or dire situations, and where conventional therapy is unhelpful.[36] Patients' informed consent must be obtained; failing to do so can result in the doctor being struck off the Singapore Register of Medical Practitioners.[37] 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.[38]

27 Clinical Trials Guidance – Determination of whether a clinical trial requires CTA, CTN or CTC at Paragraph 1.2.2.

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

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

30 Clinical Trials Guidance – Determination of whether a clinical trial requires CTA, CTN or CTC at Paragraph 1.3.2.

31 Clinical Trials Guidance – Determination of whether a clinical trial requires CTA, CTN or CTC at Paragraph 1.2.1.

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

33 ECEG 2016 at Guideline B6.

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

35 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.

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

37 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.

38 ECEG 2016 at Guideline B8.

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.[39]

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,[40] 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.[41] However, prior approval from the HSA must be sought.[42] 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.[43]

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.[44]

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 have to be subjected 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,[45] the screening and evaluation fees may be abridged.

39 Clinical Trials Guidance – Alternative measures for investigational product management for clinical trials of locally registered therapeutic products or medicinal products at Paragraph 1.2.

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

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

42 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 at Paragraph 2.2.

43 Therapeutic Products Guidance – Import and Supply of an Unregistered Therapeutic Product for Patients' Use at Paragraph 2.2.

44 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 at Paragraph 1.2.

45 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, November 2016.

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:

a the drug is intended for treatment of a serious life-threatening condition and can potentially address local unmet medical needs;[46] or

b 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 such devices being placed on the Singapore market. There are four risk classes for the classification of general medical devices.[47] All medical devices must adhere to the Essential Principles for Safety and Performance for Medical Devices in the First Schedule of HP(MD)R[48] prior to their placement on the Singapore market. Requirements under all applicable legislation[49] for the supply and use of any medical devices must also be met. Additionally, the APOC Guidelines set out the minimum level of competence the doctor must have to operate the medical devices.[50]

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.[51] 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.

46 '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 2016 at Paragraph 14.2.1.

47 Medical Device Guidance – Guidance on Medical Device Product Registration in Singapore 2014 at Paragraph 2.

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

49 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.

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

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

Cosmetic products

With the implementation of the ASEAN Cosmetic Directive, product, manufacturer and import licences are no longer required.[52] Instead, the HSA must be notified before the supply or sale of the cosmetic product.[53] 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.[54] 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.[55]

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.[56]

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.[57]

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.[58] 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.[59] The extension is, however, only available for pharmaceutical products, and not medical devices.

The HP(TP)R[60] and MA[61] 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 (PIC Scheme), businesses may receive up to 400 per cent tax deduction or allowances of up to S$400,000 (the cap) of their expenditure per year in research and development

52 Guidelines on the Control of Cosmetic Products (2017) at Paragraph 1.
53 Guidelines on the Control of Cosmetic Products (2017) at Paragraph 5.
54 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Cosmetic_Products/Overview.html.
55 Guidelines on the Control of Cosmetic Products (2017) at Paragraphs 5 and 10.
56 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Complementary_Health_Products/TM.html.
57 Section 5 of Medicines Act.
58 Guidance on Registration of Biosimilar Products 2016.
59 Section 36A of the Patents Act.
60 Regulation 26(1) of the Health Product (Therapeutic Products) Regulations.
61 Section 19A of the Medicines Act.

(R&D).[62] R&D expenditure[63] exceeding the cap will enjoy 150 per cent tax deduction if the R&D is done in Singapore. Any other R&D expenditure, including expenditure of R&D carried out overseas, will enjoy 100 per cent tax deduction. Accordingly, businesses engaged in R&D of new drugs may enjoy substantial tax benefits under the PIC Scheme.[64]

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.[65]

Under the HPA[66] and MA,[67] 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.[68] 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.[69]

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.[70]

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

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

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

64 See www.iras.gov.sg/irashome/picredit.aspx.

65 If the defect leads to a serious threat of 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.

66 Section 27 of the Health Product Act.

67 Section 16 of the Medicines Act.

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

69 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices at Paragraph 7.

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

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.[71] 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.[72] 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 of the Health Products (Medical Devices) Regulations 2010.[73]

As regards cosmetic products manufactured in Singapore, such products 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.[74]

Unlike medicinal products, prior approval from the HSA is no longer required for advertisements relating to therapeutic products.[75] Instead, advertisements of therapeutic products are 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 of the MA and the Second Schedule of the HP(ATP)R respectively.[76]

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.[77]

As regards cosmetic products, advertisements cannot include claims that they have therapeutic benefits or can be used for therapeutic purposes,[78] nor can they create an erroneous impression regarding the formulation, composition, quality or safety of the product.[79]

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

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

72 Regulation 4 of the Health Product (Therapeutic Product) Regulations 2016. Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices at Paragraph 4.5.

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

74 Section 50 of the Medicines Act.

75 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/therapeutic-productsportover/Key_Features-Changes.html#HP_TP_ADV.

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

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

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

79 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'.[80] 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.[81]

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[82] or wholesale dealer's licence for medicinal products.[83] A licensee for a therapeutic product must appoint a responsible person to ensure compliance with the HSA's good distribution practice (GDP).[84] The licence for medicinal products will only be granted if the company has been audited and found to comply with the HSA's GDP.

As regards medical devices, a wholesaler must possess either a GDP for medical devices certificate or ISO 13485 certificate with the scope for storage and distribution.[85] 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. Such reclassification may be effected by an application by the party who registered the therapeutic product or through legislative mechanisms.[86]

80 ECEG 2016 at Guideline I2(4).

81 ECEG 2016 at Guideline I2(5).

82 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.

83 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.

84 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.

85 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices at Paragraph 4.5.

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

xii Imports and exports

Under the HPA, a person must now obtain an importer's licence to import therapeutic products or medical devices,[87] and a wholesaler's licence to export them.[88] Importers and exporters of therapeutic products must also appoint a person to be responsible for ensuring compliance with the HSA's GDP standards.[89] 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.[90] 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 is eligible for a fee waiver to facilitate the adoption of this new regulatory regime.[91]

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.

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.[92] 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.

To import or export controlled drugs[93] and psychotropic substances or medicinal products with psychotropic substances,[94] 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.[95]

---

87 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.

88 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.

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

90 Medical Device Guidance – Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices at Paragraph 4.5.

91 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.

92 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.

93 As defined in the First Schedule of the Misuse of Drugs Act.

94 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.

95 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Audit_and_Licensing_Of_Importers_Wholesale_Dealers_and_Exporters/

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.[96]

As regards 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 such establishments, including clinical laboratories.[97]

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),[98] 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).[99] Subsidised drugs cover up to 90 per cent of the total volume of public medication prescriptions, and are reviewed and updated regularly by the MOH.[100] Subsidies are also provided for medical devices, such as implants.[101] 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.[102]

Controlled_Drugs_Psychotropic_and_Restricted_Substances.html.

96 Section 49 of the Health Products Act.

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

98 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.

99 See www.moh.gov.sg/content/moh_web/home/costs_and_financing/schemes_subsidies/drug_subsidies.html. 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.

100 See https://www.moh.gov.sg/content/moh_web/home/costs_and_financing/schemes_subsidies/drug_subsidies.html and https://www.moh.gov.sg/content/moh_web/home/pressRoom/Media_Forums/2015/list-of-subsidised-drugs-updated-regularly--moh-.html.

101 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.

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

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.[103]

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.

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.[104]

The ECEG 2016 also provides guidance to doctors in relation to issues of financial conflicts of interest.[105] 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 the ECEG 2016.[106] 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).[107]

Presently, 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.[108] The rationale is to ensure that the patient's interests would take priority over

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

104 SAPI Code of Marketing Practices (2016).

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

106 Guideline H3(5) of the ECEG 2016.

107 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.

108 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 to

the doctor's personal financial interests.[109] 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.

If done on a large scale, the termination of contracts with TPAs may result in wider implications for the healthcare sector. For doctors, there may be a substantial loss of patient referrals from the TPAs. Patients who rely on the subsidised rates when visiting doctors on the TPA panel may now need to change healthcare providers or pay their existing doctor's new non-subsidised rates. In turn, this may increase the patient load of the public healthcare sector as private-paying patients may now have to switch to government-run polyclinics for subsidised rates to reduce their medical expenses.

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.[110] In addition, the Academy of Medicine, the College of Family Physicians and the Singapore Medical Association have also jointly issued recommendations[111] that doctors can consider a cap for 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.

The ECEG 2016 further provides more detailed guidelines on the relationships between doctors and the medical industry.[112] 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

give doctors an additional six months to comply with the same. 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.

109 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.

110 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.

111 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 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.

112 ECEG 2016 Guideline I1.

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.[113] Although rare, class actions are possible.[114]

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.[115]

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.[116]

VIII CURRENT DEVELOPMENTS

With the advent of technology, the pace of research is accelerated and the potential dangers of carrying out unorthodox and unethical research programmes are heightened. While there is immense potential for the use of technology to improve healthcare services to benefit the public, it is equally important to ensure that any risk of abuse or harm caused to the public is minimised, or eliminated, through timely regulation. This explains the recent enactment of the Human Biomedical Research Act and its subsidiary legislation in 2016 and 2017.

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

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

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

115 See https://www.ccs.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.

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

genome replacement technology with the aim of publishing a public consultation report.[117] The MOH is currently reviewing the use of pre-implantation genetic screening (PGS) and its ethical implications, having commenced a three-year pilot programme in the first half of 2017 to assess its clinical effectiveness at improving *in vitro* fertilisation (IVF) cycle outcomes by screening for chromosomal abnormalities in embryos created through IVF.[118]

To deal with rising healthcare costs in Singapore, the MOH has recently indicated that it will be implementing fee benchmarks for doctors. Moving forward, the MOH is working with stakeholders such as healthcare providers and insurers[119] to manage the costs of healthcare in Singapore, and to review and implement recommendations made by the Health Insurance Task Force.[120] Notably, the implementation of fee benchmarks is a voluntary exercise and the MOH will not compel doctors to follow them. It remains to be seen whether doctors will use these fee benchmarks as a meaningful reference for their own pricing, or whether they will continue to practise as before, given that compliance with these benchmarks is not compulsory. From a regulatory perspective, the question arises as to how far a doctor can deviate from the recommendations and when this may cross the line into the realm of overcharging.

In a bid to improve the quality of healthcare and patient safety, and to lower costs, the government is looking at introducing new legislation in 2018 to ensure that all medical records will be shared electronically across both private and public healthcare establishments and clinics. The aim is for healthcare providers to have quick and accurate access to each patient's medical history, to enable customised and better care to cater for each patient's unique needs. Previously, medical records were only shared by public hospitals and polyclinics in Singapore. The government recognises that this may lead to increased transitional costs in the short term for private healthcare establishments and clinics, and the government has indicated that it will set aside S$20 million in funding to ease this advancement towards the One Patient, One Health Record system.[121]

117 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.

118 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.

119 See https://www.moh.gov.sg/content/moh_web/home/pressRoom/Parliamentary_QA/2017/health-insurance-task-force--hitf--report.html.

120 Health Insurance Task Force (HITF), *Managing the Cost of Health Insurance in Singapore* (13 October 2016). The HITF found that rising surgery fees was a key factor in rising healthcare costs, and proposed certain recommendations to lower health insurance costs, including educating consumers, introducing medical fee benchmarks, enhancing insurance procedures, and more.

121 'Full steam ahead for national medical e-database not easy, but necessary', *The Straits Times* (9 November 2017) and Speech by Mr Gan Kim Yong, Minister for Health, at the FutureHealth 2017 conference on 8 November 2017.

Appendix 1

ABOUT THE AUTHORS

MELANIE HO

WongPartnership LLP

Melanie Ho is the 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 has been a lead partner in the review and drafting of the statutory framework governing Dubai Healthcare City's healthcare professionals since 2013. She was lauded as one of the key players for investigations work by *Global Investigations Review 100* – 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 recognised as a leading lawyer in *Who's Who Legal: Life Sciences* 2017 and in *Best Lawyers* since 2014. Melanie participated in a roundtable discussion to distil the changes in the regulation of medical practices and innovation, which was featured in *Who's Who Legal: Life Sciences* 2013.

JACQUELINE CHUA

WongPartnership LLP

Jacqueline's areas of practice encompass a range of matters with a special interest in medical law and professional negligence. She has acted as defence counsel for and prosecutor against medical practitioners across a range of specialist disciplines in numerous disciplinary proceedings before the Singapore Medical Council. She has also been involved in various high-profile medical negligence lawsuits before the Singapore High Court, including successfully defending two doctors from a S$1 million claim commenced by their former patient, and successfully striking out an unmeritorious claim made by a patient's mother against two hospitals and the paediatricians involved in the minor's care. Jacqueline also regularly undertakes non-contentious advisory work for healthcare institutions, statutory boards and multinational corporations. Recently, she has advised a healthcare conglomerate in the review and drafting of their existing regulations and standard operating procedures.

She was also part of the team of lawyers who were specially selected to conduct the Medical Protection Society and Singapore Medical Association training course for medical experts.

WONGPARTNERSHIP LLP

12 Marina Boulevard
Level 28
Marina Bay Financial Centre
Tower 3
Singapore 018982
Tel: +65 6416 8000
Fax: +65 6532 5722
melanie.ho@wongpartnership.com
jacqueline.chua@wongpartnership.com
www.wongpartnership.com

ISBN 978-1-912228-19-5