The Life Sciences Law Review

Fifth Edition

Editor
Richard Kingham

Law Business Research

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CONTENTS

EDITOR'S PREFACE

The fifth edition of *The Life Sciences Law Review* covers a total of 37 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

Now, more than ever, it is important for leaders in the pharmaceutical and medical device industries and their advisers to be knowledgeable about the laws and regulations in major jurisdictions around the world. In the past year, there have been significant developments in the regulation of drugs and medical devices, especially in the United States, where a new law – the 21st Century Cures Act – was passed at the end of 2016. There are prospects for further developments in the coming year. The new president and the Republican-controlled Congress will consider legislative measures affecting the pharmaceutical and medical device sectors, including proposed repeal of the Affordable Care Act, continuing inquiries into pricing of medical products and reauthorisation of user fee laws that fund a substantial part of the drug and device approval processes. The United Kingdom will initiate formal proceedings to begin the process of withdrawing from the European Union, with potential consequences for the medical products sectors. Other jurisdictions, including China and India, are considering reforms to their regulatory systems for medicinal products.

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 2017

Chapter 29

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 Health Sciences Authority Act (Chapter 122C), 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 Medicine (Advertisement and Sale) Act (Chapter 177), the Poisons Act (Chapter 234) and the Sale of Drugs Act (Chapter 282), together with subsidiary legislation and guidelines 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) sets ethical benchmarks for medical practitioners, and a departure from the same may result in disciplinary action. The ECEG has recently been revised and came into force on 1 January 2017 (the ECEG 2016).

Partially in force as of 1 July 2016, human biomedical research is regulated by the Human Biomedical Research Act (HBRA) (Act No. 29 of 2015), and supplemented by the Ethics Guidelines for Human Biomedical Research (Ethics Guidelines) of the Bioethics Advisory Committee (BAC).

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).

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]

II THE REGULATORY REGIME

Control of all medicinal products, devices and substances fall under the purview of the HSA. Recently, the HPA was amended to transfer the regulation of chemical and biological drugs,[4] now defined as therapeutic products, to the HPA as part of the HSA's ongoing effort to consolidate the regulation of health products to one Act. Medical devices and cosmetic products are still regulated by the HPA.[5] The MA regulates other medicinal products (such as cell, tissue and gene therapy products, and complementary health products,[6] including traditional medicines, homeopathic medicines and quasi-medicinal products).[7] The Poisons Act regulates specific substances found in drugs and medicinal products[8] except for therapeutic products,[9] and the Sale of Drugs Act regulates any substance or mixture of substances used as medicine sold for medicinal purposes.[10]

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, *supra*. 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.[11] Therapeutic products are only for use in humans, 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 mentioned above.

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

3 Health Product (Clinical Trials) Regulations 2016; Medicines (Clinical Trials) Regulations 2016.

4 First Schedule to the Health Products Act.

5 First Schedule to the Health Products Act.

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

7 Section 3 of the Medicines Act.

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

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

10 Section 2 of the Sale of Drugs Act.

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

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, or taken as supplement to a diet.[12]

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),[13] which doctors have to abide by to carry out any such procedures listed therein. The list of invasive treatment 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 surgery, 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.[14] 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.[15]

ii Non-clinical studies

In vitro human biomedical research

The new HBRA, which regulates the conduct of human biomedical research, came into force on 1 July 2016. The key amendments to the HBRA that have not come into force include:

a obtaining and withdrawing consent, and when consent may be waived by an institutional review board (IRB);[16]

b the composition of an IRB and their functions and duties;[17]

c regulation of human biomedical research;[18]

d regulation of human tissue activities and tissue banks;[19] and

e 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, or is contrary to public interest.[20]

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

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

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

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

16 Sections 6 to 14 of HBRA.

17 Sections 15 to 21 of HBRA.

18 Sections 22 to 31 of HBRA; for prohibited human biomedical research see Third Schedule; for restricted human biomedical research see Fourth Schedule.

19 Sections 32 to 39 of HBRA.

20 Sections 42 to 53 of HBRA.

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.[21]

The BAC (appointed by the Singapore Cabinet) released its Ethics Guidelines for Human Biomedical Research in June 2015. These Ethics Guidelines emphasise the fundamental principles of solidarity, respect for persons, justice, proportionality, sustainability, beneficence and research integrity,[22] and cover the following main areas:

a consent;
b personal information in research;
c biobanking and research involving human biological materials;
d human genetic research; and
e human stem cell research.

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.[23] Such research can also only be justified where there is strong scientific merit and potential medical benefit.

Written approval from the director of medical services must be obtained for all research involving human embryos, human oocytes[24] and human-animal combination gametes or embryos.[25]

Animal models

Any research facility that uses animals for scientific purposes must obtain a licence from the AVA.[26] 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,[27] and establish an Institutional Animal Care and Use Committee to oversee and evaluate the animal care and use programmes of an institution.[28]

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

21 Section 32 of HBRA. See also *Public Prosecutor v. Tang Wee Sung* [2008] SGDC 262.

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

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

24 Human oocytes include those obtained from excised ovarian tissue.

25 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.

26 Section 3 of Animal & Birds (Care and Use of Animals for Scientific Purposes) Rules.

27 Section 4(4) of Animal & Birds (Care and Use of Animals for Scientific Purposes) Rules.

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

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.[29] 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.[30] 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,[31] 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.[32]

For the clinical trial of medicinal products, a CTC is still necessary.[33]

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

Medical devices

A CTC or a CTA-CTN is not necessary for studies assessing the safety, performance or effectiveness of a medical device.[34] Prior approval by each institution's IRB is, however, still required.[35] The Health Products (Medical Device) Regulations (HP(MD)R) also regulate the controls on the use of medical devices in clinical trials.[36]

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

30 Clinical Trials Guidance – Determination of whether a clinical trial requires clinical trial authorisation (CTA), clinical trial notification (CTN) or clinical trial certificate (CTC), at Paragraph 1.2.1.

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

32 Clinical Trials Guidance – Determination of whether a clinical trial requires clinical trial authorisation (CTA), clinical trial notification (CTN) or clinical trial certificate (CTC) at Paragraph 1.2.1.

33 Clinical Trials Guidance – Determination of whether a clinical trial requires clinical trial authorisation (CTA), clinical trial notification (CTN) or clinical trial certificate (CTC) at Paragraph 1.2.3.

34 Clinical Trials Guidance – Determination of whether a clinical trial requires clinical trial authorisation (CTA), clinical trial notification (CTN) or clinical trial certificate (CTC) at Paragraph 1.3.2.

35 MOH Governance Framework for Human Biomedical Research, December 2007.

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

Ethical considerations

The ECEG 2016 stipulates that a doctor must not offer remedies to patients that are not generally accepted by the profession, except in the context of a formal and approved clinical trial.[37] Remedy encompasses a broad range of treatments, including the use of medical devices.[38] Under the ECEG 2016, doctors may offer innovative therapy[39] to patients in desperate or dire situations and where conventional therapy is unhelpful.[40] Patients' informed consent must be obtained, and failing to do so can result in the doctor being struck off the Singapore register of medical practitioners.[41] The ECEG 2016 also further mandates that any medical research must be approved by an ethics committee, and conform to the Singapore Guidelines for Good Clinical Practice.[42]

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.[43]

iv Named-patient and compassionate use procedures

The Health Products (Therapeutic Products) Regulations (HP(TP)R) allows imports of therapeutic products for use on a named-patient exemption basis. Under this exemption,[44] 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.[45] However, prior approval from the HSA must be sought.[46] 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.[47]

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

37 Guideline B6 of the ECEG 2016.

38 *Pang Ah San v. Singapore Medical Council* [2013] SGHC 266 at [26].

39 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 B6.1 of Ethical Code and Ethical Guidance Handbook for Doctors 2016.

40 B6.1 of the Ethical Code and Ethical Guidance Handbook for Doctors 2016.

41 See *Shorvon Simon v. Singapore Medical Council* [2006] 1 SLR(R) 182 for a summary of the findings of the disciplinary committee.

42 Guideline B8 of the ECEG 2016.

43 See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Clinical_Trials/Overview/Regulatory_Guidelines/Guideline_on_Alternative_Measures_for_Investigational_Product_Management.html.

44 Regulation 51 of the Health Products (Therapeutic Products) Regulations 2015.

45 A person registered under the Medical Registration Act (Chapter 174) and a person registered under the Dentists Act (Chapter 76).

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

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

allows licensed qualified practitioners[48] to seek approval for the supply of unregistered medical devices in an emergency or in circumstances in which conventional therapies have failed.[49] Such an application is 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.

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 submit 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,[50] 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:

a the drug is intended for treatment of a serious life-threatening condition and can potentially address local unmet medical needs;[51] 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.[52] There are four risk classes for the classification of medical devices. All medical devices must adhere to the Essential Principles for Safety and Performance for Medical

48 A person registered under the Medical Registration Act (Chapter 174) and a person registered under the Dentists Act (Chapter 76).

49 Paragraph 1.2 of 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.

50 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.

51 '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 Paragraph 14.2.1 of Guidance on Therapeutic Product Registration in Singapore, November 2016.

52 Paragraph 1 of the Medical Device Guidance, Guidance on Medical Device Product Registration in Singapore.

Devices in the First Schedule of HP(MD)R[53] prior to their placement on the Singapore market. Requirements under all applicable legislation[54] for the supply and use of any medical devices must also be met. Additionally, the APOC Guidelines sets out the minimum level of competence the doctor must have to operate the medical devices.[55]

The Association of Southeast Asian Nations (ASEAN) has developed a standardised framework for regulating medical devices – the ASEAN Medical Device Directive (AMDD). Under the AMDD, only registered medical devices that conform to its standards are allowed in the Member States' markets. With the standardisation of regulation, this allows for the efficient trade 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, product, manufacturer and import licences are no longer required.[56] Instead, the HSA must be notified before the supply or sale of the cosmetic product. 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 Cosmetics Directive. Only a Singapore-registered company can file a product notification with the fees varying based on the risk level of the cosmetic products.

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.

Chinese proprietary medicine

Under the Medicines (Prohibition of Sale and Supply) (Amendment) Order 2012, Chinese proprietary medicine dealers must obtain approval from the HSA's Chinese Proprietary Medicines Unit prior to importing or manufacturing Chinese proprietary medicine.

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53 First Schedule of the Health Products (Medical Devices) Regulations.

54 For example, the Private Hospitals and Medical Clinics Act, Medical Registration Act, Dental Registration Act and Radiation Protection Act etc. See www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/ Medical_Devices/Overview.html for more details.

55 Aesthetic Practices Oversight Committee, Guidelines on Aesthetic Practice for Doctors (updated August 2016).

56 Paragraph 20 of the HSA's Guidelines on the Control of Cosmetic Products.

Biosimilar medicinal products

In order to be registered as a biosimilar medicinal product, the product must fall under the definition in the HSA's Guidance on Registration of Biosimilar Products[57] in Singapore. 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.[58] Such extension is, however, only available for pharmaceutical products, and not medical devices.

The HP(TP)R[59] and MA[60] 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 (R&D). R&D expenditure[61] 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.[62]

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.[63] Every manufacturer, importer, supplier or registrant of a therapeutic product must report the defect to the HSA upon knowledge of the defect.[64]

Under the HPA[65] and MA,[66] the HSA has the power to suspend, revoke or vary licences. The revocation of a licence may be done on 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.

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57 Guidance on Registration of Biosimilar Products 2016.

58 Section 36A of the Patents Act.

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

60 Section 19A of the Medicines Act.

61 R&D expenditure also encompasses staff costs and consumables.

62 www.iras.gov.sg/irashome/picredit.aspx.

63 Regulation 33 of Health Product (Therapeutic Products) Regulations.

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

65 Section 27 of the Health Product Act.

66 Section 16 of the Medicines Act.

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.[67] In addition, registrants must report any defects or adverse effects that occur in connection with the medical device.[68]

The HSA may also suspend or cancel the registration of a health product (including medical device) if there is the 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 of 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 on 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.

viii Manufacturing controls

Under the HPA, a valid licence is required for the manufacture of health products and medicinal products under the HSA 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 ISO13485 certificate for finished medical device manufacturing is required to obtain a manufacturer's licence.[73] 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.[74]

As regards cosmetics products manufactured in Singapore, such products must comply with Appendix VI of the ASEAN Cosmetic Documents titled ASEAN Guidelines for Cosmetic Good Manufacturing Practice.

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

68 Regulation 42 of the Health Products (Medical Devices) Regulations.

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

70 ASEAN Cosmetic Directive, Guidelines for Product Information File.

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

72 Regulation 4 of the Health Product (Therapeutic Product) Regulations 2016.

73 Paragraph 4.5 of the Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices.

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

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.[75]

Unlike medicinal products,[76] prior approval from the HSA is no longer required for the advertisements of therapeutic products.[77] 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. Both advertisements of medicinal products and therapeutic products must not claim to prevent, alleviate or cure certain diseases or conditions specified in the first and second schedule of the MA and HP(ATP)R respectively.[78]

Advertisements and promotions of medical devices also do not require prior approval from the HSA,[79] but such advertisements must not be false or misleading, and must be capable of verification by objective evidence, pursuant to the HP(MD)R. [80]

As regards cosmetic products, advertisements cannot include claims that they have therapeutic benefits or can be used for therapeutic purposes,[81] nor can they create an erroneous impression regarding the formulation, composition, quality or safety of the product.[82]

The ECEG 2016 also prohibits doctors from associating themselves with parties that do not provide legitimate medical or medical support services in a way that could mislead the public into believing that such services are medically endorsed,[83] and only allows doctors 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.[84]

75 Section 50 of the Medicines Act.

76 Advertisements for medicinal products still require prior approval from the HSA. See Sections 49(4) and 52 of the Medicines Act, and Section 3 of the Medicines (Medical Advertisements) Regulations.

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

78 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. The list of diseases and conditions in both schedules are the same.

79 Paragraph 1 of the Guidance on Medical Device Advertisements and Sales Promotion.

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

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

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

83 Guideline I2(4) of the ECEG 2016.

84 Guideline I2(5) of the ECEG 2016.

x Distributors and wholesalers

Any person (except for licensed manufacturers) must apply for the relevant wholesaler's licence for the resale purposes of registered therapeutic products or medical devices[85] or wholesale dealer's licence for medicinal products.[86] A licensee for a therapeutic product[87] must appoint a responsible person to ensure compliance with the HSA's good distribution practice (GDP). The granting of such licence for medicinal products will also only be carried out if the company has been audited and found to comply with the HSA's good distribution practice.[88]

As regards medical devices, a wholesaler must possess either a GDP for medical devices certificate or ISO13485 certificate with the scope for storage and distribution.[89] A licensed local manufacturer does not require a wholesaler's licence to supply, by wholesale, any medical devices it manufactures.[90]

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:[91] prescription-only medicines, pharmacy-only medicines and general sales list medicines.

Therapeutic products may be reclassified if it 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.[92]

85 www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Over view/Audit_and_Licensing_Of_Importers_Wholesale_Dealers_and_Exporters/Medicinal_Products.html.

86 www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Over view/Audit_and_Licensing_Of_Importers_Wholesale_Dealers_and_Exporters/Chinese_Proprietary_Medicines.html.

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

88 Guidance Notes on Good Distribution Practice (August 2015).

89 Paragraph 4.5 of the Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices.

90 Paragraph 2 of the Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices.

91 www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Western_Medicines/Overview.html; see also Division II of the Health Products (Therapeutic Products) Regulations 2016.

92 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,[93] and a wholesaler's licence to export them.[94] Importers and exporters of therapeutic products must also appoint a person to be responsible for ensuring compliance with the HSA's GDP standards.[95] 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 ISO13485 certificate with the scope for storage and distribution.[96] Companies applying for an importer's or wholesaler's licence for therapeutic products for patients' use or restricted activities will be given a fee waiver from 1 November 2016 to 31 October 2019 to facilitate the adoption of this new regulatory regime.[97]

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,[98] while exporters require a product licence.[99]

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.[100] The Misuse of Drugs Act makes it an offence to import, export or traffic controlled drugs,[101] 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.[102]

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93 Section 13 of the HPA. 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 (Regulation 54 of the Health Products (Therapeutic Products) Regulations 2016).

94 Section 14 of the HPA, read with section 2 of the HPA. 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 (Regulation 53 of the Health Products (Therapeutic Products) Regulations 2016).

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

96 Paragraph 4.5 of the Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices.

97 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.

98 Section 5(2) of the Medicines Act.

99 Section 5(1)(a) of the Medicines Act.

100 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.

101 Sections 5 and 7 of the Misuse of Drugs Act.

102 Section 10A of the Misuse of Drugs Act.

In order to import or export controlled drugs[103] and psychotropic substances or medicinal products with psychotropic substances,[104] 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.[105]

xiv Enforcement

The HSA has rights of entry into premises for the purposes of ascertaining if there is, or has been, any contravention of the MA,[106] and any such 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.[107]

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.[108] 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 he or she believes has committed an offence under the HPA.[109]

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 assess the quality and appropriateness of the services provided, and the practices carried out in such establishments, including clinical laboratories.[110]

III PRICING AND REIMBURSEMENT

Apart from a national medical savings scheme (Medisave)[111] and health insurance scheme for Singapore citizens and permanent residents (Medishield Life), patients receive drug subsidies based on their paying status and the scheme under which the drug is covered (e.g., Standard Drug List, Medication Assistance Fund and in-patient drug subsidy).[112] Subsidised drugs

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

104 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.

105 www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overvi ew/Audit_and_Licensing_Of_Importers_Wholesale_Dealers_and_Exporters/Controlled_Drugs_Psychotropic_and_Restricted_Substances.html.

106 Section 56 of the Medicines Act.

107 Section 57 of the Medicines Act.

108 Section 49 of the Health Products Act.

109 Section 49 of the Health Products Act.

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

111 Medisave allows Singaporean Citizens or Permanent Residents to set aside part of their income for future medical expenses.

112 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 clinical indications.

cover up to 90 per cent of the total volume of medication prescriptions, and are reviewed and updated on a regular basis by the MOH.[113] Subsidies are also provided for medical devices, such as implants.[114] In 2014, the government also 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.[115]

Health technology assessments are carried out by the Healthcare Technology Assessment Branch (HTAB) under the auspices of the MOH. As part of its health technology assessments, the HTAB carries out reviews, cost-effectiveness analyses, and develops clinical practice guidelines in Singapore.[116]

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Any person aggrieved by the HSA's decision in relation to granting, renewing or revoking a licence,[117] or the registration of a health product,[118] may appeal to the Minister of Health, whose decision is final.

Notwithstanding the finality of the Minister's decision, applicants may apply for 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 Practice guides the conduct of marketing and promotion of medicinal products and therapeutic products in Singapore and serves as the basis for self-discipline within the industry.

The ECEG 2016 also provides guidance to doctors in relation to issues of financial conflicts of interests.[119] While the requirements on disclosure of interests and prohibitions on exerting undue influence on patients still apply,[120] the ECEG 2016 has expanded the scope of conflicts of interests to include the material interests of individuals close to doctors. Further,

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

114 www.moh.gov.sg/content/moh_web/home/pressRoom/pressRoomItemRelease/2004/medical_service_packag e_to_ensure_good_healthcare_at_affordable_prices_for_all_Singaporeans.html.

115 www.pioneers.sg/en-sg/Pages/Overview.aspx.

116 www.gai.nus.edu.sg/niha/wp-content/uploads/2013/04/workshop/NIHA-Workshop-PPT5-DrPwee.pdf.

117 Section 4 of the Medicines Act for medicinal products, section 28 of the Health Products Act for therapeutic products, medical devices or cosmetics.

118 Section 38 of the Health Products Act.

119 Guidelines H3(1)-(5) of the ECEG 2016.

120 Guidelines 4.6.1-4.6.3 of the ECEG 2002.

the practice of fee kickbacks or other compensation for referring patients to other medical service professionals or healthcare facilities is prohibited under the ECEG 2016,[121] and is also an offence under the Prevention of Corruption Act.[122]

Doctors can pay fees to third-party administrators and managed care companies only if the sums paid reflect the actual work that they do, and are not contingent on the services provided by the doctor or the amount of fees collected from patients.[123] This is a new guideline that comes into force on 1 July 2017[124] and would render all fee-splitting arrangements illegal even if they were entered into prior to this date. The SMC would deem unethical the sharing or splitting of fees with a third-party administrator or managed care companies or a referring doctor, merely for the privilege of being referred a patient, with no commensurate work done justifying such fees.

Finally, the ECEG 2016 now provides more detailed guidelines on the relationships between doctors and the medical industry.[125] In particular, financial reimbursements for doctors appearing at educational events must be fair, reasonable and commensurate with their time and expertise provided,[126] and doctors must personally pay for any unrelated activities, additional stay or the costs of any accompanying persons.[127] They also cannot accept extravagant gifts, hospitality or other inducements from companies that could be seen to potentially affect their decisions on patient care.[128]

121 Guideline H3(5) of the ECEG 2016.

122 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.

123 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 so high as to constitute 'fee splitting' or 'fee sharing'. Further, doctors are required to disclose any such fees to their patients.

124 Although the ECEG 2016 will come into force on 1 January 2017, Guideline H3(7) will only come into force on 1 July 2017 so as to give the doctors an additional six months to comply with the new Guideline. See Paragraph 10 of the 'Advisory on the Payment of Fees to Managed Care Companies, Third Party Administrators, Insurance Entities or Patient Referral Services', Professor Tan Ser Kiat, President of the Singapore Medical Council, 13 December 2016.

125 Guideline I1 of the ECEG 2016.

126 Guideline I1(2) of the ECEG 2016.

127 Guideline I1(7) of the ECEG 2016.

128 Guideline I1(8) of the ECEG 2016.

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.[129] Although rare, class actions are possible.[130]

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.[131]

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.[132] 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. Examples include the Biomedical Sciences Accelerator Programme, launched by SPRING Singapore,[133] to identify, invest in and assist new medical technology companies to help bring their innovative ideas to market, as well as Bio*One Capital, a dedicated fund manager for biomedical sciences under the Singapore Economic Development Board, which invests in innovative healthcare IT, services, devices and companies.[134]

VIII CURRENT DEVELOPMENTS

The 2016 amendments expanding the scope of the HPA to include therapeutic products are in line with the government's plan to consolidate and streamline the regulation of health products under one Act.[135] The amendments are a welcome change as they promote efficiency

129 For example, Section 14 of the Sale of Goods Act or Section 6 of the Consumer Protection (Fair Trading) Act.

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

131 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.

132 www.edb.gov.sg/content/edb/en/industries/industries/pharma-biotech.html.

133 See, for example, https://www.spring.gov.sg/NewsEvents/PR/Pages/Three-Medtech-Start-ups-Get-3Million-in-SPRING-Investment-20130313.aspx.

134 http://pharmaboardroom.com/pharmadirectory/bio-one-capital/.

135 Singapore Parliamentary Debates, Official Report (13 April 2016) vol 94 at 3.15pm (Mr Gan Kim Yong, Minister for Health).

and compliance, and address previous concerns by stakeholders that the fragmented regulatory controls gave rise to uncertainty and made legal compliance with the overlapping regulatory controls unnecessarily complicated.[136]

The ECEG 2016 also provides a timely update to the practice of medicine locally, and aligns Singapore's standards of medical ethics with other developed jurisdictions, while accommodating modern medical practice.[137] With regards to the life sciences, the new guidelines on the use of innovative therapy,[138] telemedicine,[139] and industry sponsorship of educational or research events,[140] provide greater clarity on the ethical standards doctors must abide by in their engagements with the life sciences industry. It also remains to be seen whether any steps beyond the prohibition of fee sharing arrangements with third-party administrators[141] will be implemented following MOH's approval of the Health Insurance Task Force's report on health insurance costs in Singapore,[142] especially given the Task Force's finding that rising surgery fees was a key factor in raising healthcare costs in Singapore.[143]

The SMC has also issued the SMC Handbook on Medical Ethics, expounding on the guidelines in the ECEG 2016 while providing advice on a variety of best practices. The Handbook is to be read with the ECEG 2016, but the ECEG 2016 will take precedence in the event of any discrepancy.[144]

Against this backdrop, two recent developments in medical litigation are worth noting. First, the courts appear to be taking a harsher stance against professional medical misconduct, noting a need to recalibrate sentences upwards for such cases.[145] Secondly, as courts increasingly appoint medical assessors,[146] attention has been paid to their roles and responsibilities. In her speech at the 2016 Annual Medicolegal Seminar, the Honourable Justice Judith Prakash noted that medical assessors could play a more active role in trials,[147] and the courts are likely to expand their roles in the future.[148]

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136 Public Consultation on Proposed Health Products Act (Amendment of First Schedule) Order, (HSA, 9 Jan 2012) at [2].

137 2016 Edition of the SMC Ethical Code and Ethical Guidelines and Handbook on Medical Ethics, Explanatory Notes – Principles of Revised ECEG, (Working Committee for the review of ECEG, 13 September 2016), ('Explanatory Notes – Principles Of Revised ECEG') at [3(a)] and [5(a)].

138 Guideline B6(4) of the ECEG 2016.

139 Guideline A6 of the ECEG 2016.

140 Guideline I1 of the ECEG 2016.

141 See Guideline H3(7) of the ECEG 2016.

142 www.moh.gov.sg/content/moh_web/home/pressRoom/pressRoomItemRelease/2016/The-Ministry-of-Health-Response-to-Health-Insurance-Task-Force-Recommendations.html.

143 Managing the Cost of Health Insurance in Singapore, Health Insurance Task Force, 13 October 2016, at page 11.

144 Explanatory Notes – Principles of Revised ECEG at [7] and [8].

145 *SMC v. Wong Him Choon* [2016] 4 SLR 1086 at [99]-[118].

146 www.sal.org.sg/Lists/Speeches/Attachments/136/OLY%202016%20-%20CJ%20Menon.pdf.

147 The Role, Responsibilities and Essential Skills of being a Court-Appointed Medical Assessor, Judge of Appeal Judith Prakash, 22 October 2016 at [9] and [11].

148 www.sal.org.sg/Lists/Speeches/Attachments/136/OLY%202016%20-%20CJ%20Menon.pdf.

Finally, as Singapore continues to experience low fertility rates, the adoption of new methods of fertility assistance has come under active consideration. The BAC has formed a review group to look into the ethical, legal and social issues arising from mitochondrial genome replacement technology,[149] while the MOH is currently reviewing the use of pre-implantation genetic screening and its ethical implications, and will commence a three-year pilot programme in the first half of 2017 to assess its clinical effectiveness.[150]

149 www.bioethics-singapore.org/index/activities/current-projects.html. Mitochondrial gene replacement allows the replacement of mutant mitochondrial gene in unfertilised oocytes or zygotes with normal donor mitochondria, preventing the passing of the condition from mother to child.

150 www.moh.gov.sg/content/moh_web/home/pressRoom/Parliamentary_QA/2016/pre-implantation-genetic-screening--pgs-.html.

Appendix 1

ABOUT THE AUTHORS

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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$1.2million 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: The International Who's Who of Life Sciences Lawyers* 2013.

JACQUELINE CHUA

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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 law suits 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 was specially selected to conduct the Medical Protection Society and Singapore Medical Association training course for medical experts.

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