IN THE COURT OF 3 JUDGES OF THE GENERAL DIVISION OF THE HIGH COURT OF THE REPUBLIC OF SINGAPORE

[2025] SGHC 129

Court of 3 Judges of the General Division of the High Court /
Originating Application No 11 of 2024

Between

Lee Pheng Lip Ian

… *Appellant*

And

Singapore Medical Council

… *Respondent*

JUDGMENT

[Professions — Medical profession and practice — Professional conduct]

Lee Pheng Lip Ian
v
Singapore Medical Council

[2025] SGHC 129

Court of 3 Judges of the General Division of the High Court —
Originating Application No 11 of 2024
Sundaresh Menon CJ, Tay Yong Kwang JCA, Judith Prakash SJ
21 January 2025

8 July 2025 Judgment reserved.

Judith Prakash SJ (delivering the judgment of the court):

Introduction

1 Dr Ian Lee Pheng Lip ("Dr Lee") is a medical practitioner who practised out of a private clinic licensed to him known as the Integrated Medicine Clinic ("IMC"). He originally claimed trial to 21 charges of professional misconduct under s 53(1)(*d*) of the Medical Registration Act (Cap 174, 2014 Rev Ed) (the "MRA"), the gravamen of which alleged that he had inappropriately prescribed various forms of hormone replacement therapy to his patients. He was eventually convicted on 17 of those charges by a disciplinary tribunal ("DT") appointed by the Singapore Medical Council ("SMC"). The DT suspended Dr Lee for an aggregate term of 18 months. This judgment is delivered in respect of Dr Lee's appeal against his convictions and sentence.

Facts

The prescriptions

2 We find it helpful to first set out the prescriptions which led to Dr Lee's convictions before the DT and to briefly explain a few terms pertaining to the medications prescribed. We do so with reference to a report adduced by the SMC's expert witness in the proceedings below, one Professor C Rajasoorya ("Prof Rajasoorya"), an endocrinologist at Sengkang General Hospital with over 30 years of experience. Prof Rajasoorya's observations on the nature and composition of the medications prescribed by Dr Lee were not challenged either before the DT or on this appeal.

3 Dr Lee's prescriptions are set out in an agreed statement of facts dated 27 October 2022. The medications that are relevant to this appeal fall within the following four categories of hormones:

(a) Erfa, a thyroid hormone preparation made from desiccated pig thyroid glands containing both the thyroxine (T4) and triiodothyronine (T3) forms of thyroid hormone. Between late-2011 and early-2014, Dr Lee prescribed Erfa on 41 occasions to eight patients (P2, P3, P6, P8, P9, P10, P11 and P19).

(b) Biest and Triest, which are custom compounded formulations containing a mixture of estrogens. Biest contains the hormones estradiol (E2) and estriol (E3), while Triest contains these two hormones as well as estrone (E1). Between late-2011 and early-2014, Dr Lee prescribed Biest on 11 occasions to two patients (P11 and P24), and Triest on three occasions to two patients (P10 and P25).

(c) Testosterone, a hormone produced in both males and females, albeit in much smaller quantities in the latter. Dr Lee faced two charges concerning his prescriptions of testosterone to P17 and P21.

(d) Progesterone, a female sex hormone which plays a crucial part in the menstrual cycle and the maintenance of pregnancy. Dr Lee faced two charges for his prescriptions of progesterone to P20 and P23, who are both women who have gone through hysterectomies.

4 Hormones are substances produced by endocrine glands and may be extracted from glands or may be synthesised artificially. Hormone replacement therapy ("HRT") generally refers to the prescription of hormones to replace hormone deficiencies in patients.

5 The term "bio-identical hormone replacement therapy" ("BHRT"), on the other hand, refers specifically to the use of hormones that are structurally (*ie*, at a molecular level) identical with hormones that are naturally produced within the endocrine glands and circulating in the human bloodstream. An example is the use of soy and yam precursors to produce 17-beta estradiol, a hormone naturally produced in human ovaries. BHRT can also refer to the use of a custom-compounded, multi-hormone mode of administration that has concentrations like those found in normal physiological circumstances. For the purposes of this appeal, nothing turns on the question of whether specific treatments do or do not constitute BHRT.

Background to the dispute

6 In 2013, the Ministry of Health ("MOH") exchanged correspondence with Dr Lee expressing concern over Dr Lee's provision of BHRT to his patients. In August 2013, the MOH wrote to Dr Lee to inform him that the clinic

licence for the IMC would be renewed for six months from 9 September 2013 to 8 March 2014 subject to the licensing condition that BHRT would not be carried out at the IMC. The MOH also notified the SMC of its concerns regarding Dr Lee's conduct. After this notification and having obtained several clarifications from the MOH, the SMC issued a formal letter of complaint against Dr Lee on 14 February 2014 to the chairman of the Complaints Panel pursuant to s 39(3)(*a*) of the MRA.

7 Subsequently, on 7 March 2014 (*ie*, prior to the expiry of the extended clinic licence), the MOH granted a further extension of the clinic licence for a duration of one week (*ie*, until 15 March 2014) to "enable [Dr Lee] to make the necessary arrangements with [his] patients". In response, Dr Lee wrote to the MOH on 11 March 2014 to request that the clinic licence to be further renewed "so that [his] patients' care [would] not be affected". Dr Lee also stated that he would "cease [his] current practise [*sic*] of prescribing BHRT to patients forthwith". The MOH renewed the clinic licence for the IMC two more times, each renewal being for a term of six months, as the MOH was monitoring the IMC's compliance with the licensing conditions the MOH had imposed.

8 Meanwhile, on 15 April 2014, the MOH issued a circular prohibiting the prescription of BHRT by licensed healthcare institutions outside the context of a formal clinical trial approved by the Health Sciences Authority ("HSA"). It is not disputed that this was the first time the MOH had expressly released a circular prohibiting the prescription of BHRT.

9 On 16 March 2015, upon the expiry of the IMC's clinic licence, the MOH did not grant a further renewal. According to the MOH, based on its latest inspections on 10 February 2015 and 9 March 2015, Dr Lee did not exhibit an intention to wean his patients off BHRT. Further, the MOH had discovered that

Dr Lee was prescribing testosterone to patients although these patients had normal testosterone levels and there was no proper documentation of clinical indications of testosterone deficiencies. These allegations formed the subject of a second letter of complaint issued by the SMC on 30 April 2015 to the chairman of the Complaints Panel pursuant to s 39(3)(*a*) of the MRA. These complaints were subsequently laid before a Complaints Committee (the "CC").

10 Dr Lee was invited to submit written explanations in response to each of the complaints pursuant to s 44(2) of the MRA, which he duly provided. In his letters of explanations, Dr Lee generally took the position that he was entitled to prescribe BHRT to his patients.

11 On 12 February 2018, the CC sent a letter to Dr Lee informing him that the CC had completed its inquiry and had ordered an inquiry to be held by a disciplinary tribunal. Dr Lee sought to challenge the CC's decision and, in this connection, he filed HC/OS 514/2018 on 2 May 2018 seeking to quash the CC's order for an inquiry to be held by a disciplinary tribunal. Dr Lee's application was dismissed by the High Court on 4 March 2019, and Dr Lee's appeal to the Court of Appeal in CA/CA 52/2019 was likewise dismissed on 10 February 2020. On Dr Lee's application, the disciplinary proceedings had been stayed pending the final determination of the judicial review proceedings.

12 Following the lifting of the stay of proceedings, the SMC reached out to one Dr Eng Soo Kiang ("Dr Eng") on 4 March 2020, as well as to Prof Rajasoorya on 17 April 2020, to request them to provide expert opinions on the propriety of Dr Lee's prescriptions. Their expert reports were signed and submitted on 11 April 2021.

The charges

13 On 22 April 2021, the SMC's solicitors served a Notice of Inquiry ("NOI") on Dr Lee, which contained a total of 21 charges that the SMC had preferred against Dr Lee under s 53(1)(*d*) of the MRA.

14 Amendments were made to the NOI on 3 September 2021 to reflect, for each original charge, a primary charge and an alternative charge. The primary and alternative charges were based on the same factual substratum but reflected the two different forms of *mens rea* recognised by the Court of Three Judges ("C3J") in *Low Cze Hong v Singapore Medical Council* [2008] 3 SLR(R) 612 ("*Low Cze Hong*") (at [37]) as capable of amounting to "professional misconduct" under s 53(1)(*d*) of the MRA, namely, (a) an intentional, deliberate departure from the standards observed by members of the profession of good repute and competency ("First Limb"), and (b) serious negligence that objectively portrays an abuse of the privileges which accompany registration as a medical practitioner ("Second Limb"). The primary charges were premised on the First Limb and the alternative charges on the Second Limb.

15 In the first to 17th charges, the SMC charged Dr Lee with acting in breach of Guideline 4.1.3 of the SMC Ethical Code and Ethical Guidelines 2002 Edition ("ECEG"). The material part of Guideline 4.1.3 of the ECEG states:

> A doctor may only prescribe medicines that are legally available in Singapore and must comply with all the statutory requirements governing their use.
>
> A doctor shall prescribe, dispense or supply medicines only on clear medical grounds and in reasonable quantities as appropriate to the patient's needs. … Patients shall be appropriately informed about the purpose of the prescribed medicines, contraindications and possible side effects. …

During the course of the proceedings before the DT, the 3rd, 9th and 14th charges were withdrawn by the SMC. The remaining 14 charges each related to a different patient who was treated by Dr Lee. Some of these charges had originally alleged that the medications prescribed by Dr Lee (in particular, Erfa, Biest and Triest) were "*not legally available for prescription in Singapore*", but this allegation was later withdrawn by the SMC as it became apparent that the medications in question had been imported with the HSA's approval. Instead, the SMC was content to proceed on the basis that the hormones prescribed by Dr Lee were "*generally inappropriate*", that there was a lack of "*evidence to support [their] use*" and/or that the prescriptions were given in circumstances where there were "*no medical grounds to do so*". As the particulars of the charges vary according to the patients and the specific prescriptions involved, we will consider them in greater detail in our analysis below.

16 The 18th charge, which Dr Lee was eventually acquitted of, charged him for breaching an undertaking he had provided to the MOH on 11 March 2014 to cease prescribing BHRT to his patients.

17 In the 19th to 21st charges, the SMC charged Dr Lee with acting in breach of Guideline 4.1.4 of the ECEG, the material part of which provides:

> A doctor shall treat patients according to generally accepted methods and use only licensed drugs for appropriate indications. A doctor shall not offer to patients, management plans or remedies that are not generally accepted by the profession, except in the context of a formal and approved clinical trial. …

The SMC's case was that Erfa, Biest and Triest were "non-evidence-based treatment[s]" that could "only be administered in the context of a formal and approved clinical trial". Thus, the prescriptions of these medications each formed the subject of a charge alleging that Dr Lee had offered to his patients a

management plan or remedy that was not generally accepted by the medical profession.

The DT proceedings

18 Prof Rajasoorya and Dr Eng both testified as expert witnesses for the SMC. They were cross-examined on the contents of the expert reports that they had earlier provided. Additionally, the SMC called one Ms Agnes Chan, a director of the Therapeutics Branch of the HSA, to testify on matters relating to the HSA's grant of permission to import unregistered medical products.

19 Dr Lee was given an opportunity to call an expert witness to testify in his defence, but he ultimately did not adduce evidence from any expert witness. One Datuk Dr Selvam Rengasamy furnished an expert report dated 18 August 2022. However, Dr Selvam was not called to testify as a witness and his report was therefore not admitted as evidence before the DT.

20 The defence's witnesses comprised Dr Lee himself and one Ms Wong Kah Yeen ("Ms Wong"), a pharmacist employed at Specialist Compounding Pharmacy Pte Ltd ("SCP").

21 The DT's inquiry took place across two tranches, with the first tranche taking place from 1 to 3 November 2022, and the second tranche taking place from 17 to 19 January 2023. An oral hearing was convened on 6 June 2023 after the parties exchanged their written closing submissions. The DT delivered its verdict on 16 January 2024 and invited the parties to put in their sentencing submissions. On 4 June 2024, the DT ordered the suspension of Dr Lee's registration for a period of 18 months.

Decision below

22 On 13 August 2024, the DT released its grounds of decision in *Singapore Medical Council v Dr Lee Pheng Lip Ian* [2024] SMCDT 3 ("GD"). We summarise these grounds in so far as they are material to the present appeal.

23 First, the DT accepted Prof Rajasoorya's evidence for preferring the use of synthetic thyroxine over Erfa to treat hypothyroidism and other thyroid ailments. Prof Rajasoorya had highlighted that in his 30 years of practice as an endocrinologist, he had seen no more than three cases of a genuine insufficient response to synthetic thyroxine: GD at [34]–[38].

24 Second, the DT found that there were no clear medical grounds for Dr Lee's prescriptions of testosterone to P17 and P21. This was because their testosterone levels fell within the prescribed normal range at the time of Dr Lee's prescription. Although Dr Lee claimed that his prescription of testosterone to P17 was for "*maintenance*", he was unable to produce any patient medical records ("PMRs") to support his claim: GD at [49]–[52].

25 Third, the DT found that women who had undergone hysterectomies should not be prescribed progesterone. This is because the purpose of such prescription is to treat menopausal symptoms and to prevent endometrial thickening, which may predispose the patient to cancers of the uterine lining. Dr Lee's conduct had deviated from the logical basis for prescribing the medication: GD at [55]–[58].

26 Fourth, the DT held that the applicable standard of conduct to treat estrogen deficiency or symptoms of menopause was to use HRT (using synthetics, instead of BHRT) and not to use custom compounded hormones.

Dr Lee had not cited any relevant literature to suggest that Biest and Triest ought to be prescribed: GD at [61]–[64].

27 Consequently, the DT found that Dr Lee had breached Guidelines 4.1.3 and 4.1.4 of the ECEG. The DT thus convicted him on the primary charges: GD at [65] and [76]. The alternative charges thus fell away.

28 As for sentence, the DT first addressed the points raised by Dr Lee in his mitigation plea. The DT found that while there was a delay in prosecuting the complaint against Dr Lee, particularly before the CC, such delay was not unreasonable. A substantial part of the delay was moreover caused by Dr Lee himself. No discount to Dr Lee's sentence was warranted on account of the delay. Likewise, the DT placed no weight on the other factors raised by Dr Lee, including his track record and professional standing, the lack of actual harm and the lack of intention to breach any rules, and the fact that his patients had requested BHRT: GD at [85]–[86].

29 Thereafter, the DT applied the sentencing framework set out in *Wong Meng Hang v Singapore Medical Council and other matters* [2019] 3 SLR 526 ("*Wong Meng Hang*") and affirmed in the *Sentencing Guidelines for Singapore Medical Disciplinary Tribunals* dated 15 July 2020 ("*Sentencing Guidelines*"). The DT found that the charges fell within the slight harm, medium culpability range. The appropriate starting point for each of the charges was therefore a suspension of between three months and one year. The DT imposed varying terms of suspension in accordance with the types of charge on which Dr Lee had been convicted and ordered some to run concurrently while others had to run consecutively. We reproduce in the Appendix [94(a)] of the GD which summarises the periods of suspension imposed by the DT for each charge. In the final analysis, the DT's orders meant that an aggregate suspension term of

18 months was imposed: GD at [92]–[94(a)]. The DT further ordered Dr Lee to furnish a written undertaking to the SMC that he would not, outside of a formal clinical trial, prescribe Erfa, Biest and Triest or prescribe progesterone to hysterectomised women or testosterone where it was not medically indicated: GD at [94(b)]. Dr Lee was also ordered to bear 80% of the SMC's costs and 100% of its disbursements, including the fees of its expert witnesses: GD at [97].

Parties' cases on appeal

Dr Lee's case

30 The crux of Dr Lee's case on appeal is that the DT's conclusions on the applicable standards of conduct are not supported by the evidence. In particular, the DT had overlooked the various concessions given by Prof Rajasoorya in his cross-examination.

(a) On Erfa, Dr Lee contends that Prof Rajasoorya had accepted that (i) Erfa is not less efficacious than synthetic thyroxine for treating hypothyroidism and could be prescribed to patients as long as they had been advised on its risks and benefits; (ii) there was no issue with how Dr Lee had managed his patients apart from his prescriptions of Erfa; and (iii) Erfa carried the same side effects as synthetic thyroxine. Prof Rajasoorya's main concerns were about the standards, quality control and safety of using Erfa but such concerns had no factual basis in relation to Dr Lee's prescriptions because the Erfa dispensed by Dr Lee was imported from reputable sources with the HSA's approval. Consequently, the applicable standard for the treatment of hypothyroidism did not prohibit his prescription of Erfa.

(b) On Biest and Triest, Dr Lee likewise contends that Prof Rajasoorya was primarily concerned with the quality and dosage controls (or lack thereof) of custom-compounded hormones. However, Prof Rajasoorya was unaware of the quality control measures in place in the present case, namely, that the Biest and Triest were dispensed by SCP according to standard formulae. There was also no evidence that the prescriptions of Biest and Triest were unsafe.

(c) On progesterone, Dr Lee takes the position that he was entitled to prescribe progesterone to hysterectomised women to treat menopausal symptoms such as osteopenia and anxiety. Prof Rajasoorya's main concern stemmed from studies which showed that the use of progestin (*ie*, synthetic progestogens) created a higher risk of developing breast cancer. However, Dr Lee had prescribed *progesterone* and not progestin.

(d) On testosterone, Dr Lee reiterates that he prescribed testosterone to P17 for "*maintenance*". As for P21, she had previously been prescribed testosterone by another doctor for menopausal symptoms and Dr Lee had continued the treatment as he thought it would be beneficial to P21. In any event, one prescription of testosterone to each of P17 and P21 could not amount to professional misconduct.

31 Dr Lee also submits that the DT erred in failing to consider the fact that there were other doctors prescribing BHRT at the material time. According to Dr Lee, the MOH had not made clear whether BHRT was prohibited. It would therefore be unjust to punish Dr Lee for departing from the applicable standards of conduct when there was uncertainty on what was generally accepted by the medical profession.

32 As for his sentence, Dr Lee submits that a letter of warning would be the appropriate sentence, as there were other doctors who had prescribed BHRT at the material time who were only issued letters of warning. In the alternative, he submits that a fine would be an appropriate sanction for all the charges. Dr Lee also submits that the DT erred in failing to apply a 50% discount to his sentence on account of the inordinate delay in his prosecution.

The SMC's case

33 The SMC essentially maintains that the DT was correct in convicting Dr Lee. The DT made the correct findings on the applicable standard of conduct in respect of each category of hormones:

(a) On Erfa, the applicable standard of conduct was to prescribe synthetic thyroxine. There is no basis to disagree with Prof Rajasoorya's opinion. Dr Lee admitted to Erfa being a non-standard form of therapy and conceded that more care ought to have been taken in documenting the reasons for switching to Erfa from a standard treatment. That notwithstanding, he readily prescribed Erfa to eight patients within a short period of time.

(b) On Biest and Triest, the applicable standard of conduct was to use synthetic HRT to treat estrogen deficiency or symptoms of menopause. Dr Lee had provided no evidence to justify his prescription of Biest or Triest.

(c) On progesterone, the applicable standard of conduct was that women who had undergone hysterectomies should not be prescribed progesterone because the purpose of prescribing progesterone is to treat menopausal symptoms and to prevent endometrial thickening. There is

no evidence that the prescription of progesterone nullifies the risk of breast cancer. There is also no evidence to suggest that progesterone prescription is indicated for osteopenia or anxiety.

(d) On testosterone, the parties agreed that testosterone should only be prescribed to females suffering from hypoactive sexual desire dysfunction or males with low testosterone levels.

34 Dr Lee's prescriptions were departures from the applicable standards. Dr Lee had not put forward any evidence to justify his departures from the applicable standards. Further, the present case did not involve any uncertainty in the applicable standards and consequently Dr Lee's reliance on various facts suggesting otherwise was misplaced. The DT therefore correctly found Dr Lee guilty of the charges.

35 As for sentence, the SMC submits that the DT correctly assessed the degree of harm and culpability of Dr Lee's actions. The individual and global sentences imposed were guided by the sentencing principles and were not manifestly excessive. The DT had also correctly considered the aggravating and mitigating factors, including whether there was an inordinate delay in Dr Lee's prosecution, the fact that Dr Lee continues to exhibit a lack of remorse, and Dr Lee's seniority and/or eminence among the medical profession.

Issues before this court

36 The elements of each of the charges are not in dispute. As noted above at [14], the primary charges brought by the SMC allege professional misconduct under s 53(1)(*d*) of the MRA and are framed based on the First Limb of *Low Cze Hong*. For such charges to be made out, the following findings must be made:

(a) what the applicable standard of conduct was among members of the medical profession of good standing and repute in relation to the actions that the allegations of misconduct concerned;

(b) whether the applicable standard of conduct required the doctor to do something and, if so, at what point in time such duty crystallised; and

(c) whether the doctor's conduct constituted an intentional and deliberate departure from the applicable standard of conduct without due cause.

37 Once it is shown that a medical practitioner has departed from the applicable standard of conduct, the evidential burden falls upon him to show that such departure was justified or supported by good reasons: *Ang Yong Guan v Singapore Medical Council and another matter* [2024] 4 SLR 1364 ("*Ang Yong Guan*") at [63]. As we explained in *Ang Yong Guan* (at [84]), a medical practitioner can justify his departures from the applicable standard of conduct, if:

(a) he has considered the rationale behind that standard and concluded after a risk-benefit analysis of a prospective departure from it that the departure is justified;

(b) the medical practitioner's conduct is objectively defensible in the circumstances, as determined with reference to the prevailing test for medical negligence; and

(c) at least in certain circumstances, the medical practitioner has first discussed a prospective departure with the patient including any safety measures, and the patient has consented to such a departure.

38 The following issues thus arise for our determination:

(a) First, what is the applicable standard of conduct among members of the medical profession of good standing and repute in relation to the prescriptions contained in each of the charges framed against Dr Lee?

(b) Second, was Dr Lee's conduct an intentional and deliberate departure from the applicable standard of conduct?

(c) Third, assuming there was a departure from the applicable standard of conduct, did Dr Lee prove that his departures were justified or supported by good reasons?

(d) Fourth, assuming Dr Lee's convictions are upheld, what is the appropriate sentence to impose?

39 In the next sections, we structure our analysis on the first three issues according to the types of prescriptions given by Dr Lee which formed the subject of the charges, before turning to consider whether the charges were made out and whether the sentences imposed should be upheld.

The Erfa prescriptions

The applicable standard of conduct

40 We first consider the applicable standard of conduct concerning the prescriptions of Erfa which Dr Lee issued to his patients. There is no real dispute that the patients in question generally suffered from hypothyroidism, a disorder

of the endocrine system in which the thyroid gland does not produce enough thyroid hormones.

41 The general standard of conduct, as set out in Guidelines 4.1.3 and 4.1.4 of the ECEG, is that doctors should only prescribe, dispense and/or supply medicines (a) where there are clear medical grounds to do so; and (b) according to methods which are generally accepted by the medical profession. Guideline 4.1.4 also states that a doctor shall "use only licensed drugs for appropriate indications", although the SMC does not appear to rely on this aspect of the guideline in its framing of the charges (see [46] below).

42 It is common ground that, apart from these general guidelines, there were no specific guidelines or directives issued by the MOH at the material time which codified the standards regarding the use or prohibition of Erfa for the treatment of hypothyroidism or other thyroid-related deficiencies. The burden thus lay on the SMC to prove in the usual way that the prescription of Erfa to patients suffering from hypothyroidism lacked "clear medical grounds" and was not "generally accepted by the profession" at the material time.

43 In this regard, the DT noted at [33] of the GD that the SMC's case was that "the applicable standard of conduct among members of the medical profession of good standing and repute is that conventional synthetic L-thyroxine treatment ought to be the standard of care for hypothyroidism or other thyroid ailments requiring such treatment, absent reasons such as an allergy, side effects or other intolerance of synthetic T4 in the patient". The DT then accepted Prof Rajasoorya's opinion as to why synthetic T4 had to be preferred to Erfa. So it would appear that the DT accepted the applicable standard as enunciated by the SMC. On the appeal, Dr Lee challenged the applicable standard and we thus must consider it anew.

44 The starting point in our analysis is to consider the allegations contained in the particulars of the relevant charges. As an example, the material portion of the first primary charge, concerning Dr Lee's prescription to P2, is set out below:

> 1st Charge
>
> That you, Dr Lee Pheng Lip Ian, are charged that you, between 31 December 2012 and 17 June 2013, whilst practising as a medical practitioner at IMC, had acted in breach of Guideline 4.1.3 of the ECEG in that you prescribed, dispensed and/or supplied medicines without clear medical grounds to [P2], to wit:-
>
> **PARTICULARS**
>
> …
>
> (b) You prescribed, dispensed and/or supplied Erfa on 3 occasions to [P2], particulars of which are set out in Schedule 1 annexed hereto, even though:-
>
> (i) ~~Erfa is not legally available for prescription in Singapore;~~
>
> (ii) Prescription of Erfa constitutes bio-identical hormone replacement therapy ("**BHRT**") which:
>
> 1. is ***generally inappropriate as there are no established benefits over traditional hormone replacement therapy***;
>
> 2. ***poses increased risks*** (such as risks of infection and adverse effects from impurities, and the risk of inconsistent dose delivery), ***which [P2] was not informed about***.
>
> (iii) ***[P2]'s thyroid function tests were observed to be within the normal range while [P2] was taking synthetic thyroxine***,
>
> and your aforesaid conduct constitutes an intentional, deliberate departure from the standards observed or approved by members of the profession of good repute and competency, and that in relation to the facts alleged you are thereby guilty of professional misconduct under section 53(1)(*d*) of the Medical Registration Act (Cap. 174).

[strikethrough in original; emphasis added in bold italics]

45 The charges premised on a breach of Guideline 4.1.3 of the ECEG were generally framed in a similar manner as the first primary charge and contained three essential allegations: (a) that there were no established benefits to Erfa over traditional HRT; (b) Erfa posed increased risks which the patients were not informed about; and (c) the thyroid function tests of the patients in question were normal at the time of Dr Lee's prescriptions and/or while the patients were taking synthetic thyroxine. As stated earlier, the allegation relating to whether Erfa was "legally available for prescription in Singapore" was removed by the SMC in subsequent amendments to the charges.

46 The 19th primary charge, which was premised on a breach of Guideline 4.1.4 of the ECEG, was framed as follows:

> 19th Charge
>
> That you, Dr Lee Pheng Lip Ian, are charged that you whilst practising as a medical practitioner at IMC, had acted in breach of Guideline 4.1.4 of the ECEG in that you ***offered a management plan or remedy that is not generally accepted by the profession to your patients*** … to wit:-
>
> **PARTICULARS**
>
> (a) You did not treat [P2] according to generally accepted methods by prescribing Erfa to [P2] on 3 occasions, particulars are set out in Schedule 1 annexed hereto, even though ***Erfa, which is a form of BHRT, is a non-evidence based treatment and can only be administered in the context of a formal and approved clinical trial***;
>
> …
>
> and your aforesaid conduct constitutes an intentional, deliberate departure from the standards observed or approved by members of the profession of good repute and competency, and that in relation to the facts alleged you are thereby guilty of professional misconduct under section 53(1)(*d*) of the Medical Registration Act (Cap. 174).

[emphasis added in bold italics]

47 The crux of the SMC's case before the DT can be surmised from the charges, namely, that the applicable standard of conduct for the treatment of hypothyroidism was then "traditional hormone replacement therapy", namely, by the prescription of synthetic thyroxine, not the administration of non-evidence-based treatments such as Erfa. The rationale for this standard was that Erfa (a) had no established benefits over traditional HRT, and (b) posed increased risks which the patients were not informed about.

48 We accept the contentions of the SMC on the applicable standard of conduct for three main reasons. First, it is undisputed that Erfa was not licensed for use in Singapore by the HSA at the material time. The importance of using only licensed drugs for appropriate indications is enshrined in Guideline 4.1.4 of the ECEG (see [17] above). While there was, and is, no absolute prohibition against the use of unlicensed drugs such as Erfa, such use falls *squarely* within the definition of "off-label" use and cannot be considered as the "applicable standard" of treatment as such: *Gobinathan Devathasan v Singapore Medical Council* [2010] 2 SLR 926 ("*Gobinathan*") at [49] and [53]–[54]. Thus, notwithstanding that the issue of whether Erfa is "legally available" is not in dispute, the very fact that it was "unlicensed" is a material factor that guides us in our decision regarding the applicable standard of conduct.

49 Second, Prof Rajasoorya testified in his report and on the stand that the use of synthetic thyroxine, which only contains the hormone thyroxine (T4), ought to be the standard of conduct for the treatment of hypothyroidism. Erfa contains a combination of the hormones thyroxine (T4) and triiodothyronine (T3). Its use is controversial for several reasons: (a) patients generally do not require T3 treatment in addition to being given supplemental T4 for

hypothyroidism; (b) even if patients need T3, the dosage can be adjusted individually; (c) there are concerns over the standards, quality control and safety of using Erfa obtained from non-standard sources; and (d) the use of animal products gives rise to concerns of contamination. Thus, absent "clear reason for substitution", there would not be any "clear medical grounds" for the use of a prescription that is not registered in Singapore, nor would such use be considered "generally accepted" by the medical profession.

50 Third, Dr Lee himself conceded multiple times on the stand that the use of synthetic thyroxine was the conventional treatment for hypothyroidism and that Erfa was not licensed for use by the HSA at the material time. We set out some of his admissions below:

> Q And I think Erfa thyroid is made from desiccated pig thyroid, you accept that, right?
>
> A Yes.
>
> Q Do you know that it's not licensed by the FDA?
>
> A Yes.
>
> Q Okay. ***It's also not licensed by the HSA, correct?***
>
> A ***Yes.***
>
> …
>
> Q Okay. But were you aware that concerns then emerged about the consistency and the efficacy of desiccated thyroid hormone?
>
> A Yes.
>
> Q And cases were reported detailing a continued hypothyroidism or iatrogenic thyrotoxicosis.
>
> A Yes.
>
> Q Okay. ***So what then happened was the science developed and the discovery of the conversion of T4 to T3 in humans led to a major transition in clinical practices away from a desiccated thyroid hormone***

> ***to the adoption of L-thyroxine monotherapy as a standard of care.***
>
> A ***Yes.***
>
> Q So that -- ***so the conventional treatment therefore became T4 or L-thyroxine treatment, right?***
>
> A ***Yes.***
>
> …
>
> Q And but ***you would agree that the use of synthetic T4 is the conventional medical treatment, correct?***
>
> A ***Yes.***
>
> …
>
> Q ***Would you agree that LT4 is standard therapy?***
>
> A ***Yes.***
>
> [emphasis added in bold italics]

51 Apart from these concessions, Dr Lee also agreed that using "thyroid extract therapy" such as Erfa "could expose [patients] to certain risks such as elevated serum T3 levels". This appeared to be an express recognition by Dr Lee of the risks inherent in using Erfa as opposed to synthetic thyroxine.

52 Notwithstanding these concessions, Dr Lee submits that the SMC had not shown that synthetic thyroxine was the standard treatment for hypothyroidism, and instead avers that the standard "does not prohibit" the use of Erfa because, among other things, he was assured of the safety of Erfa and his patients had expressed a preference for it. In our view, these submissions are untenable. While there were no specific guidelines or directives setting out or codifying the applicable standards of conduct at the material time, the evidence before the DT clearly showed that the conventional treatment for hypothyroidism at the material time was synthetic thyroxine and not the unlicensed Erfa. Dr Lee provided no evidence to the contrary save for his bare

assertions that "there was nothing wrong with [his] prescription of Erfa" and that Erfa was "one of the options available to [him] at the material time".

53 We highlight that there is a distinction between establishing the applicable standard and *justifying a departure* from that standard (see *Ang Yong Guan* at [63]). In our view, the reasons provided by Dr Lee in support of his submission that the standard "does not prohibit" Erfa, are more properly advanced as justifications for his departures from the standard. The mere fact that a medication is safe, or a patient expresses a preference for it, does not necessarily mean that it falls within the applicable standard of conduct. Whether a prescription falls within the applicable standard of conduct is ultimately a fact-sensitive inquiry. In some cases, such as in *Ang Yong Guan*, the standards are stated expressly in the MOH's codified guidelines or in the package inserts for the relevant prescriptions. In other cases, such as the present, the applicable standard can be inferred from the fact that there are ample on-label medications (*ie*, medications that are licensed and registered under the HSA) available to treat thyroid deficiencies. In *Gobinathan*, the court observed (at [62]) that:

> In any event, where safety of the patient is an element of the charge, the legal burden should still be on the SMC to prove, beyond a reasonable doubt, that the treatment is unsafe for the patient. In such a case, all that the respondent (*ie*, the defending doctor) has to show is that there is a reasonable doubt that the treatment is unsafe for that patient. However, where the safety of the patient is not an element of the charge, as here, and where the charge is for inappropriate treatment because that treatment is not indicated for that condition and not generally accepted by the profession, then ***the evidential burden is on the defending doctor to prove that safety of the patient is a reason to negative an assumption of inappropriate treatment on the analogy of "off-label" treatment***. We are of the opinion that ***where a doctor embarks on a treatment that is not indicated or generally accepted in the profession, but the doctor is of the view that his novel treatment may do some good, but will do no harm to the patient, placing such a burden on him to establish that no harm will come to that patient strikes a***

> ***correct balance*** between two important considerations in medicine, viz, promoting innovation and progress, provided that the patient's well-being is not compromised.
>
> [emphasis added in bold italics]

54 These observations are directly relevant to the present case. The evidential burden was thus on Dr Lee to prove that his prescriptions did not expose his patients to unnecessary risks and/or that his patients' preferences justified his departures from the applicable standard. We would further observe that whether these factors amount to *sufficient* reason to negative an assumption of inappropriate treatment would likewise be a matter that is highly dependent on the facts.

Whether Dr Lee departed from the applicable standard

55 Dr Lee admitted that he did prescribe Erfa to his patients. He has therefore departed from the applicable standard of conduct. We further conclude from the concessions he made on the stand that he was "conscious of the applicable standard" (see *Singapore Medical Council v Wong Him Choon* [2016] 4 SLR 1086 at [53]) when he decided to depart from that standard. We therefore agree with the DT that Dr Lee's prescriptions of Erfa amounted to an intentional and deliberate departure from the applicable standard of conduct.

Whether Dr Lee's departures were justified

56 As the SMC had established before the DT that Dr Lee's prescriptions of Erfa departed from the applicable standard of conduct, the onus lay on Dr Lee to show that his prescriptions of Erfa were justified.

57 In *Gobinathan* (at [53]–[54]), the court recognised that the ECEG does not touch on when the use of off-label prescriptions is allowed. The court drew

guidance instead from the guidelines set out by the British General Medical Council ("GMC") and the American Food and Drug Administration ("FDA"), the relevant passages of which we reproduce below:

> 53 … In its Supplementary Guidance entitled "Good Practice in Prescribing Medicines (September 2008)" …, the GMC dealt with the topic of "Prescribing medicines for use outside the terms of their licence (off-label)", stating:
>
> …
>
> 20 When prescribing a medicine for use outside the terms of its licence you must:
>
> (a) *be satisfied that it would better serve the patient's needs than an appropriately licensed alternative*[;]
>
> (b) *be satisfied that there is a sufficient evidence base or experience of using the medicine to demonstrate its safety and efficacy*; the manufacturer's information may be of limited help, in which case the necessary information must be sought from other sources[;]
>
> (c) take responsibility for prescribing the medicine and overseeing the patient's care, monitoring and any follow up treatment, or arrange for another doctor to do so … [; and]
>
> (d) make a clear accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing the medicine in the patient's notes.
>
> …
>
> 54 Similarly, the FDA in its Information Sheet Guidance entitled ""Off-Label" and Investigational Use of Marketed Drugs, Biologics and Medical Devices" … sets out similar criteria for off-label use in the US:
>
> Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgement. *If physicians use a product for an indication not in the approved labelling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound*

> *medical evidence, and to maintain records of the product's use and effects. …*
>
> [emphasis in original]

58 In *Ang Yong Guan*, we clarified the requirements that the medical practitioner must satisfy in order to justify a departure from the applicable standard of conduct. At [84], we summarised the requirements as follows:

> 84 … A medical practitioner can justify his departures from the applicable standards of care … if:
>
> (a) he has considered the rationale behind that standard and concluded after a risk-benefit analysis of a prospective departure from it that it is justified;
>
> (b) the medical practitioner's conduct is objectively defensible in the circumstances, as determined with reference to the prevailing test for medical negligence; and
>
> (c) at least in certain circumstances, the medical practitioner has first discussed a prospective departure with the patient including any safety measures, and the patient must have consented to such a departure.

59 On the importance of maintaining proper documentation recording the reasons for deviating from the applicable standard, we highlighted (at [88]) that:

> 88 … the burden lies on [the doctor] to show that his conduct was justifiable in the circumstances … While it is not necessarily the case that a doctor will always be found to have failed to properly advise a patient of the risks and benefits of a prescription or obtain their informed consent simply for want of documentation in the clinical record, bare assertions will not suffice for a medical practitioner to discharge the burden of proving that he did in fact do so.

60 Dr Lee's submissions in the present case do not separately address each of the three elements set out in *Ang Yong Guan* at [84] as his arguments were advanced (incorrectly, in our view) in support of his submission that Erfa fell within the applicable standard of conduct for treating hypothyroidism. Broadly speaking, however, he advanced three main justifications for his prescriptions

of Erfa. The first argument is that there is no evidence that his prescriptions were unsafe. The second argument is that he only prescribed Erfa to patients who either asked for Erfa or were already on Erfa at the time when they came to see him. The third argument is an overarching one where he claims that there was a lack of clarity as to the applicable standards at the relevant time and thus he should not be unfairly penalised.

61 As against this, the SMC submits that there is no evidence to suggest that the *Ang Yong Guan* elements are fulfilled. In particular, the PMRs are silent as to whether Dr Lee had considered if there were reasons for prescribing Erfa as opposed to synthetic thyroxine and likewise did not show that he had explained to his patients the risks and benefits of the prospective departure and any safety measures that could be taken.

62 In determining whether Dr Lee's explanations justify his actions, we must weigh them against the underlying rationale for the applicable standard. As we highlighted above (at [47]), the rationale for preferring synthetic thyroxine over Erfa appears to be twofold, namely, that Erfa (a) has no established benefits over synthetic thyroxine; and (b) poses increased risks (such as the risks associated with impurities and the risk of inconsistent dose delivery) which the patients were not informed about.

63 Notwithstanding the fact that the PMRs are silent as to Dr Lee's reasons for prescribing Erfa to his patients, we are prepared to give Dr Lee the benefit of the doubt that he at least considered the rationale behind the applicable standard and concluded after a risk-benefit analysis that the deviation was justified. We say so for three main reasons.

64 First, Dr Lee's case is that he only prescribed Erfa to patients who either asked for Erfa or were already on Erfa at the time when they came to see him. He testified that he prescribed synthetic thyroxine to the majority (80%) of his patients. He did not prescribe Erfa in those cases because, in his view, those patients did not require it. In Dr Lee's view, there were at least three main reasons why he would be entitled to prescribe Erfa over synthetic thyroxine: (a) efficacy, *ie*, Erfa would be prescribed if synthetic thyroxine was not efficacious in treating a patient's symptoms; (b) allergies, *ie*, Erfa would be prescribed if patients were allergic to synthetic thyroxine; and most pertinently; (c) choice, *ie*, Erfa was an option which Dr Lee could provide if the patient asked for it. He continued giving Erfa to his patients because their conditions improved and they had expressed a preference for Erfa. It was also not disputed by the SMC that Dr Lee's patients had requested Erfa.

65 Secondly, Dr Lee's reasons for prescribing Erfa to his patients can also be gleaned from the HSA application forms for the importation of Erfa (the "HSA Forms") which were signed off by Dr Lee. Some of the HSA applications were granted to Dr Lee on the basis that the Erfa was "buffer stock" rather than for a named patient, while other HSA Forms contained the relevant patient's name. In all the HSA Forms, the stated reason for not using a registered product was generally listed as "patient preference and/or insufficient response to [synthetic] thyroxine". This shows that Dr Lee had applied his mind to the reasons for prescribing Erfa to his patients and also corroborates his testimony that he only prescribed Erfa to patients who expressed a preference for it, or whom he believed would benefit from Erfa, for example, due to an insufficient response to synthetic thyroxine.

66 Thirdly, in so far as the rationale behind the standard relates to the safety concerns associated with Erfa, such as the risks associated with impurities and

the risk of inconsistent dose delivery, we accept that Dr Lee had taken steps to mitigate such risks. The Erfa supplied by Dr Lee was manufactured by a reputable company and dispensed by a MOH-licensed compounding pharmacy. In fact, Dr Lee deposed that he was one of the founders of SCP, the compounding pharmacy through which he applied to the HSA for approval to import Erfa into Singapore. He deposed that SCP was "set up to … give support to doctors who wished to prescribe medication not available in retail pharmacies" and that having a provider such as SCP "ensured that the [HSA's] approval was obtained … and that medication that required compounding was done by a fully qualified pharmacist in a registered and audited setting" in order "to avoid patients turning to purchases through the Internet or foreign pharmacies … where there may be risks of variable dosage and quality".

67 In our judgment, however, Dr Lee's explanations do not suffice to provide an objectively defensible justification for his prescriptions of Erfa. We explain.

The first justification: patient safety

68 Dr Lee's first justification is that there is no evidence that his prescriptions were unsafe. He relies on the fact that none of his patients complained and many gave glowing testimonials in his support. He also submits that by showing that the Erfa he supplied was imported with the HSA's approval and from a licensed compounding pharmacy, he had addressed the crux of Prof Rajasoorya's concerns, namely, the issues of "standards, quality control and safety" and potential "contamination of animal products".

69 However, this is not the whole picture. In our view, the evidence suggests that the rationale behind the relevant standard goes beyond the issues

of standards, quality control and safety. Rather, a key reason for preferring synthetic thyroxine as the standard treatment for hypothyroidism over Erfa is that Erfa, which comprises both the T3 and T4 types of thyroid hormones, carries with it an inherently greater risk that a patient may become exposed to excessive serum T3 levels.

(a) First, Prof Rajasoorya's expert evidence was that there is generally no need to prescribe T3 in addition to T4 to treat patients suffering from hypothyroidism. This is because the human body is for the most part able to convert T4 to T3. In his practice, it would be extremely rare for him to prescribe T3 to a patient, because T3 is "very potent" and "has to be given three times a day". In his 30 years of practice, he had only used T3 on two occasions.

(b) Second, the American Thyroid Association's Guidelines for the Treatment of Hypothyroidism (the "ATA Guidelines"), which were adduced before the DT as part of Dr Eng's report, suggest that one of the "main clinical concerns" with the use of desiccated thyroid preparations is the risk of excessive serum T3 levels. The material part of the guidelines reads as follows:

> There are two main clinical concerns with the use of desiccated thyroid preparations, both of which center on their T_3 component. The ratio of T_4 to T_3 in desiccated thyroid preparations is 4.2:1, which is significantly lower than the 14:1 ratio of secretion by the human thyroid gland. This relative excess of T_3 leads to supraphysiologic levels of T_3 … In addition, due to the shorter half-life of T_3, fluctuations of T_3 occur over the course of the day, with peak levels shortly after dosing … Thus, there is concern for thyrotoxicosis if thyroid extract therapy is not adjusted according to the serum TSH.

Dr Lee himself conceded on the stand that these guidelines came from a "pretty authoritative source" and amounted in substance to "clinical practice guidelines".

(c) Third, as we highlighted above (at [51]), Dr Lee agreed that one of the risks of using thyroid extract therapy (*ie*, Erfa) was that it could expose patients to elevated serum T3 levels. He likewise agreed that Erfa contains a greater concentration of T3, relative to T4, when used to replace thyroid hormones in humans.

70 It is also evident from the facts of the 11th charge, concerning Dr Lee's prescriptions of Erfa to P19, that the risk of elevated serum T3 levels would have weighed on Dr Lee's mind when deciding to prescribe Erfa to his patients. This is because P19's thyroid function test results on 12 March 2012 showed that her T3 levels were above normal. Yet, Dr Lee decided to prescribe Erfa to her on 24 May 2012, although he justified this by saying that the patient was already on desiccated thyroid extract therapy, and he had in fact prescribed to her a much lower dosage of Erfa. This does not appear to us to be the correct approach. As a matter of logic, it would have made more sense for P19 to be prescribed a medication which *did not contain any T3 at all*, rather than a smaller dosage of a medication that is known to contain a "relative excess of T3" as compared to what the human body would otherwise produce.

71 In sum, therefore, we do not consider Dr Lee's first justification to be objectively defensible. His attempts to reduce the concerns of Prof Rajasoorya about the prescription of Erfa to that of quality control, contamination and dosage inconsistency do not reflect a true picture of what Prof Rajasoorya, and indeed the wider medical community, considered to be the rationale for preferring the use of synthetic thyroxine over Erfa.

The second justification: patient preference and insufficient response to synthetic thyroxine

72 Dr Lee's second submission is that he only prescribed Erfa to patients who either requested Erfa or were already on Erfa at the time when they came to see him. For example, P2, who had previously taken synthetic thyroxine, had emailed Dr Lee to inquire about trying a "different thyroid replacement therapeutic approach" and asked if there was any "other medication" she could be prescribed. He does not dispute that there was generally no indication from his patients' thyroid function test results suggesting that synthetic thyroxine was inefficacious. However, in the HSA Forms he submitted to obtain permission to import Erfa into Singapore, his reason for importing Erfa was stated as "patient preference and/or insufficient response to thyroxine".

73 We first deal with the question of whether patient preference can justify Dr Lee's departures from the applicable standard of conduct. The Endocrine Society's Scientific Statement, which was adduced before the DT through Prof Rajasoorya's expert report, states as follows:

> Some consider desiccated thyroid products bioidentical because they are not synthetic but instead come from animal thyroid glands and contain other thyroid molecules such as thyroglobulin and thyronamines. However, they have a T_4 to T_3 molar ratio of approximately 4:1 rather than the physiological human secreted T_4 to T_3 ratio of 14:1. At present, they have no demonstrated therapeutic value beyond the better-standardized, nonbiologically derived preparations; ***however, they are clearly preferred by some patients, and clinicians can prescribe these products safely if TSH levels are regularly monitored.*** …
>
> Current evidence indicates that LT_4 therapy alone is a sufficient treatment for most patients with hypothyroidism. Combination LT_4/LT_3 therapy, whether given as synthetic preparations or desiccated thyroid hormone, is not necessary for most hypothyroid patients but may benefit a small subset. …
>
> [emphasis added in bold italics]

74 While this statement may seem to suggest that a medical practitioner is entitled to prescribe desiccated thyroid hormones to patients who express a preference for it, this must be understood in its proper context. In this regard, the ATA Guidelines further elaborate upon the meaning of patient preference in the following manner:

> Goals of care should be guided by autonomous patients' preferences, but there are limits to what practitioners may offer if patients are demanding therapies that are outside the standard of care or potentially harmful. In the context of hypothyroidism, patients may express a preference to feel well and be restored to euthyroid levels, yet refuse synthetic LT_4 therapy because it is not "natural". This stated preference could indicate the patient does not understand and appreciate the pharmacologic properties of LT_4, which can be explained as restoring natural physiologic function. In this common example, the patient's preference can be understood as a preference not to have drug side effects or be harmed. ***Respecting the patient's preference, in this context, would be to ensure the patient has a truer understanding of hypothyroidism and LT_4 action; only when the patient understands and appreciates that choosing thyroid extract therapy rather than LT_4 could expose them to certain risks such as elevated serum T_3 levels would this constitute informed refusal of standard therapy.***
>
> [emphasis added in bold italics]

75 During cross-examination, Dr Lee agreed with the propositions set out in the ATA Guidelines. As we highlighted in *Ang Yong Guan* at [82], whether the doctor has an obligation to inform the patient of the fact and risks associated with a departure from the applicable standards would depend on the probability of the risk and the magnitude of the harm which the patient would suffer if the risk were to materialise. In the present case, given Dr Lee's concessions, he had tacitly agreed that the risks of elevated serum T3 levels were risks that his patients were reasonably likely to have attached significance to, in arriving at a decision as to whether to consent to a departure from the standard treatment.

76 Thus, for Dr Lee to be justified in prescribing Erfa to his patients on the basis of their preference, he had to show that his patients properly understood the risks involved in such a prescription. Indeed, as counsel for the SMC put it to Dr Lee in cross-examination, he had to show that there was more than just an expression that the patient "want[ed] something natural as opposed to something synthetic".

77 In this regard, Dr Lee testified that he "would have discussed everything with patients before ever starting any kind of treatment". As against this assertion, neither the PMRs nor Dr Lee's email correspondence with his patients contained anything to indicate that the risks of elevated T3 levels were discussed and further, that the patients were informed that Erfa was *not a licensed drug registered for use by the HSA*. There was no evidence at all that the patients had provided informed consent to receiving Erfa. We reiterate, as we did in *Ang Yong Guan* at [88], that the evidential burden was on Dr Lee to show that his departures from the codified standards were justifiable in the circumstances and in this regard, bare assertions did not suffice for him to discharge that burden. Dr Lee, however, put forward no evidence at all to suggest that he had highlighted the risks of using Erfa to his patients.

78 As for the argument that Dr Lee's patients (in particular, P3, P6 and P19) were already on Erfa at the time when they were referred to him, this argument was plainly a non-starter. Guideline 4.1.3 of the ECEG makes it clear that it is the duty of every doctor to ensure that there are clear medical grounds for the prescriptions provided to his or her patients.

79 Apart from patient preference, Dr Lee also highlighted that he had prescribed Erfa to several of his patients (namely, P8, P9 and P11) because they continued to present with symptoms of hypothyroidism such as abdominal

dyspepsia and constipation even while they were on synthetic thyroxine. Prof Rajasoorya's evidence was that he would not base a diagnosis or treatment purely on symptoms but would instead have to look at the biochemical supportive data. He also testified that it was extremely rare for a patient to have a genuine insufficient response to thyroxine and that in his 30 years of practice, he had only seen three such cases. Dr Lee disagreed, contending that while a person's biochemistry was an "important factor", it was not the "only factor". In our judgment, there is no basis for interfering with the DT's decision to prefer Prof Rajasoorya's evidence over Dr Lee's assertions. The DT had specifically considered both Prof Rajasoorya and Dr Lee's evidence on this point before accepting Prof Rajasoorya's opinion: GD at [36]–[38]. We highlight that the threshold for appellate intervention prescribed in s 55(11) of the MRA is a high one which requires the appellant to show that the DT's decision was unsafe, unreasonable or contrary to the evidence. Having regard to the arguments run in the proceedings below, Dr Lee's arguments on the alleged inefficacy of synthetic thyroxine have no merit.

80 Consequently, Dr Lee's second justification does not provide him with an objectively defensible basis for departing from the applicable standard.

The third justification: lack of clarity as to applicable standards

81 Dr Lee's third justification is based on an alleged lack of clarity in the applicable standards at the material time because there was a body of reputable medical practitioners who considered it acceptable to prescribe Erfa to patients without the need for any additional justifications. He seeks to draw an analogy with the case of *Low Chai Ling v Singapore Medical Council* [2013] 1 SLR 83 ("*Low Chai Ling*"), where the eponymous doctor was acquitted by the C3J on five charges of professional misconduct stemming from her provision of

aesthetic medicine. According to Dr Lee, the present case is similar because, at the material time, there were no codified guidelines on the prescription of BHRT and there were moreover other doctors who similarly prescribed BHRT but did not face any serious sanctions.

82 The *Low Chai Ling* case involved a general practitioner who carried out various non-invasive aesthetic treatments in 2007. She faced seven charges before the disciplinary committee ("DC") on the basis that she had breached Guideline 4.1.4 of the ECEG by having offered and performed the impugned treatments outside the context of a formal and approved clinical trial, with the material period of misconduct stated in each charge being the period "prior and up to 20 September 2007" (at [16]). The DC found her guilty on five out of the seven charges against her on the basis that the treatments in question did not meet the standards of evidence-based medicine ("EBM").

83 These convictions were overturned on appeal by the C3J. Before setting out its conclusions, the court made the point that a distinction ought to have been drawn between determining whether a particular treatment met the standards of EBM, and whether a failure to meet the standards of EBM amounted to professional misconduct under the MRA. The relevant passages are at [42]–[43] of the decision and are worth setting out in some detail as Dr Lee seeks to rely on these paragraphs in support of his submissions:

> 42 … given the lack of guidance on the propriety of the impugned procedures, which were widely practised at the material time, it is unsatisfactory that any medical practitioner should be singled out and charged with professional misconduct solely for administering such procedures, which were only clearly deemed by the SMC not to be evidence-based well after the alleged transgressions. *It is a cardinal tenet of the rule of law that a person should only be punished for offending laws, regulations or professional practices that are both known and clearly established at the time of offending; no person should be punished retrospectively.* Unfortunately, the manner in

> which the case against the applicant was framed at the DC hearing raises troubling questions as to what she was really being punished for. What is now clear on hindsight cannot be presumed to have been present in the minds of doctors with the same clarity during the period before the regulators took a firm stand on the practice of aesthetic medicine in July 2008 with the publication of the first edition of the Guidelines on Aesthetic Practices for Doctors ("the July 2008 Guidelines").
>
> 43 More crucially, while it is important for the guidance of the medical profession to determine whether or not the five procedures set out at [42] above were in fact evidence-based treatments, in so far as the current proceedings are concerned, it should not be the primary issue, given the uncertainty prevailing at the material time about the proper practice of aesthetic medicine and the legitimacy of some of the treatments that were then widely administered. Rather, given that the charges against the applicant were for professional misconduct, what should really have been the focus of the DC was the actual conduct of the applicant apropos her patients, and whether it was so out of line with what was professionally expected of her that she should be convicted …

84 Having set out the distinction, the court went on to consider the expert evidence in that case. The expert had opined in his report that there were certain guidelines for offering treatments of low or very low evidence-based grades such as those offered by the doctor in question. However, these guidelines were not applied by the DC in coming to its decision to convict the doctor of the charges. As the court put it, the DC instead "adopted an 'EBM or nothing' approach by flatly condemning any treatment that failed to meet the exacting requirements of EBM" (at [49]). Upon examining the doctor's conduct, the court concluded that the charges were not made out. While the court recognised that doctors "had a duty to practise medicine that was clearly EBM, and the onus rested on them to ensure that the procedures which they performed were not prohibited", it considered the situation in the instant case to be fairly problematic for various reasons, including the fact that there were no established standards or official standards prescribed by either the MOH or the SMC for the practice of aesthetic medicine at the material time, coupled with the fact that

there were many other prominent doctors engaged in similar practices with no steps being taken by regulators to curtail such activities (at [54]–[56]). It was therefore inappropriate to rigidly apply Guideline 4.1.4 of the ECEG to the doctor's practice of aesthetic medicine during the material period (at [76]).

85 In our judgment, the analogy that Dr Lee seeks to draw between the present case and *Low Chai Ling* is an inapt one. In *Low Chai Ling*, the permissibility of an entire area of practice (*ie*, aesthetic medicine) was shrouded in mystery. It was expressly recognised by the court in *Low Chai Ling* (at [27], [77(a)]) that the ethical parameters for the practice of conventional medicine and those for the practice of aesthetic medicine do not coincide in all respects. This is because, unlike conventional medicine, aesthetic medicine does not have as its primary objective the curing of any existing illness or disease (at [28]).

86 In so far as BHRT is viewed by some as an alternative or complement to conventional medicine, it is not considered to be a *distinct field* of medicine in the same way as aesthetic medicine. Ultimately, when a medical practitioner opts to prescribe BHRT to his patients, his primary aim is to cure the patient's ailments. In that regard, it is targeted at the *same primary objective* as conventional medicine. Thus, while Dr Lee seeks to draw a comparison to the lack of clear guidelines in *Low Chai Ling* by suggesting that this was also the case where BHRT was concerned, this is a false comparison. Where conventional medicine is concerned, the correct analogy to be drawn must be to consider whether there was any uncertainty regarding the applicable standard for *the diagnosis, treatment and prevention of the particular disease* of the patient, which in the present instance relates to the treatment of hypothyroidism. If there was a proven, safe and available treatment option, a medical practitioner would typically *not* be allowed to prescribe experimental and unlicensed

treatments to his patients save in exceptional circumstances. That to us is the core rationale of Guidelines 4.1.3 and 4.1.4 of the ECEG.

87 As we have explained above (at [47]–[52]), there was no uncertainty at the material time as to the standard practice for treating hypothyroidism. The evidence which the DT accepted was that a medical practitioner should generally use synthetic thyroxine unless the patient is allergic or if synthetic thyroxine is genuinely inefficacious. Alternatively, where a patient expressed a strong preference for non-synthetic products, it would have been open for a medical practitioner to prescribe a non-synthetic option *provided that true informed consent* was obtained.

88 We therefore agree with the DT that the mere fact that other doctors were prescribing Erfa to patients was *irrelevant* to Dr Lee's charges. It is entirely possible that those doctors had very good reasons for the prescription of Erfa, for example, if their patients were allergic to synthetic thyroxine.

89 To bolster his case that BHRT was recognised as a treatment alternative in Singapore, Dr Lee also relies on the fact that continuing medical education points were awarded for courses related to BHRT, as well as the fact that an article which recognised the existence of BHRT was published on the website of a premier healthcare group in Singapore. We do not see the relevance of these facts and are not persuaded that they have any bearing on the applicable standard of treatment for hypothyroidism at the material time.

Conclusion on the Erfa prescriptions

90 In sum, we agree with the DT that Dr Lee's prescriptions of Erfa were an intentional and deliberate departure from the applicable standard of conduct, which required him to prescribe synthetic thyroxine. He was not able to provide

an objectively defensible justification for his departures from the relevant standard and was therefore guilty of professional misconduct on the Erfa-related charges.

The Biest and Triest prescriptions

The applicable standard of conduct

91 We turn to consider Dr Lee's prescriptions of Biest and Triest. To recapitulate, Biest and Triest are custom compounded formulations containing a mixture of estrogens. Biest contains the hormones estradiol (E2) and estriol (E3), while Triest contains these two hormones plus a third, estrone (E1). It is common ground that Dr Lee had prescribed Biest and Triest intending to treat estrogen deficiencies in his patients. It is also undisputed that Biest and Triest were not registered on the HSA's list of approved medical products at the material time.

92 As with Erfa, there were no specific guidelines or directives issued by the MOH at the material time which codified the standards regarding the use of Biest or Triest to treat estrogen deficiencies. Instead, the SMC's case as set out in the charges was that there was "no evidence to support its use". As the SMC once again relied generally on Guidelines 4.1.3 and 4.1.4 of the ECEG to establish its case, it bore the burden of proving in the usual way that the prescriptions of Biest and Triest to patients suffering from estrogen deficiencies lacked "clear medical grounds" and was not "generally accepted by the profession" at the material time.

93 The SMC relied on Prof Rajasoorya's evidence that the use of custom-compounded hormones should generally be limited to those situations in which a patient is either allergic or does not tolerate any of the FDA-approved

preparations of a substance that is necessary for his or her health. His evidence in turn referenced the guidelines issued by major international medical societies. In particular:

(a) The Endocrine Society's Scientific Statement expressly states that "[t]here is no scientific or clinical rationale for the use of compounded estrogen preparations of unknown pharmacokinetics when there are ample on-label pharmaceutical preparations".

(b) The 2012 Hormone Therapy Position Statement of the North American Menopausal Society ("NAMS") provides that:

> Custom-compounding of [hormone therapy] may combine several hormones (eg, estradiol, estrone, and estriol) and use nonstandard routes of administration (eg, subdermal implants). Some of the hormones are not government approved (estriol) or monitored and some of the compounded therapies contain nonhormonal ingredients (eg, dyes, preservatives) that some women cannot tolerate. … ***There may be increased risks to the women using these products. Custom-compounded formulations … have not been tested for efficacy or safety; product information is not consistently provided to women along with their prescription … and batch standardization and purity may be uncertain.*** …
>
> … For most women, government-approved [hormone therapy] will provide appropriate therapy without the risks of custom preparations. ***Therefore, NAMS does not generally recommend compounded [estrogen therapy] unless necessary because of allergies to ingredients contained in government-approved products.***
>
> [emphasis added in bold italics]

(c) The American College of Obstetricians and Gynecologists ("ACOG") published a Practice Bulletin in January 2014 on the management of menopausal symptoms, which states that:

> Bioidentical hormones include commercially available products approved by the FDA, such as micronized progesterone and estradiol, as well as compounded preparations that are not regulated by the FDA. ***Because of a lack FDA oversight, most compounded preparations have not undergone any rigorous clinical testing for either safety or efficacy, so the purity, potency and quality of compounded preparations are a concern. In addition, both underdosage and overdosage are possible because of variable bioavailability and bioactivity. Evidence is lacking to support superiority claims of compounded bioidentical hormones over conventional menopausal [hormone therapy]*** … Conventional [hormone therapy] is preferred given the available data.
>
> [emphasis added in bold italics]

(d) In an earlier opinion published in August 2012 by the ACOG's Committee on Gynecologic Practice and the Practice Committee of the American Society for Reproductive Medicine (the "ACOG's Committee Opinion"), it was explained that:

> Examples of compounded hormones include Biest (biestrogen) and Triest (triestrogen) preparations. The name Biest commonly refers to an estrogen preparation based on a ratio of 20% estradiol and 80% estriol on a milligram-per-milligram basis. A similar preparation, Triest, usually contains a ratio of 10% estradiol, 10% estrone, and 80% estriol. These ratios are not based on each agent's estrogenic potency but on the milligram quantity of the different agents added together …
>
> …
>
> The American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice and the Practice Committee of the American Society for Reproductive Medicine make the following conclusions and recommendations:
>
> - Evidence is lacking to support superiority claims of compounded bioidentical hormones over conventional menopausal hormone therapy.
>
> - Customized compounded hormones pose additional risks. These preparations have

> variable purity and potency and lack efficacy and safety data.
>
> - Because of variable bioavailability and bioactivity, both underdosage and overdosage are possible.
> - Conventional hormone therapy is preferred over compounded hormone therapy given the available data.
> - Despite claims to the contrary, evidence is inadequate to support increased efficacy or safety for individualized hormone therapy regimens based on salivary, serum, or urinary testing.

94 In our judgment, the medical literature amply supports the conclusion that Prof Rajasoorya reached in his report. The applicable standard of treatment would have been to use "standard estrogen preparations" which were registered for use in Singapore.

95 Dr Lee himself appeared to agree with this standard during cross-examination. We reproduce the material aspects of his testimony containing his admissions below:

> A … yesterday morning, you asked me whether I was aware that [Estrone] and Estriol are not registered, and I said "Yes". My answer should be I don't know about Estrone, but yes, ***I am aware that Estriol is not registered.***
>
> Q And this would be your state of knowledge back in 2013/2014, right?
>
> A Yes.
>
> …
>
> Q … ***If you don't use Biest and Triest, the conventional treatment is to use estrogen, right?***
>
> A ***No, treatment would be to use Estradiol, which is E2***.
>
> [emphasis added in bold italics]

96 Having considered both Prof Rajasoorya's evidence as well as Dr Lee's own testimony, we do not think it can be seriously disputed that the applicable standard of treatment was to prescribe the hormone estradiol (E2) rather than custom-compounded treatments which contained Estriol, a hormone which was not registered for use in Singapore.

Whether Dr Lee departed from the applicable standard

97 As with the Erfa prescriptions, it is not disputed that Dr Lee did in fact prescribe Biest and Triest to his patients. As these prescriptions were not licensed for use in Singapore, he had departed from the applicable standard of conduct. Based on his testimony (as set out at [95] above), he was clearly conscious of the applicable standard when he decided to deviate from it. We therefore agree with the DT that Dr Lee's prescriptions of Biest and Triest amounted to an intentional and deliberate departure from the applicable standard of conduct.

Whether Dr Lee's departures were justified

98 This leaves us to consider whether Dr Lee's departures were justified, bearing in mind the three requirements set out in *Ang Yong Guan* (at [84]).

99 Dr Lee provided three main justifications for his prescriptions of Biest and Triest. These justifications mirrored his submissions in respect of the Erfa prescriptions, namely, patient safety, patient preference and a general lack of clarity in the applicable standards. As with his arguments on Erfa, these submissions were brought in the context of arguing that the applicable standard of conduct included the prescriptions of Biest and Triest to patients with estrogen deficiencies. However, for the same reasons that we provided in the context of Erfa at [53]–[54] above, we find it more appropriate to deal with these

arguments under the rubric of considering whether Dr Lee's departures were justified.

100 We first consider the rationale for the applicable standard as that will inform the rest of our analysis. Based on the charges framed against Dr Lee, the allegation that there is no evidence to support the use of Biest and Triest would suggest that the prescriptions of Biest and Triest were *not medically indicated* to treat patients with estrogen deficiencies. In other words, as the medical literature suggests, Biest and Triest "have not been tested for efficacy". A second rationale that emerges from the medical literature, as well as Prof Rajasoorya's cross-examination, is that the prescriptions have also not been tested for safety. Thus, the "purity, potency and quality of compounded preparations are a concern". A third rationale, also recognised by Prof Rajasoorya, is the risk of both underdosage and overdosage which arises because of "variable bioavailability and bioactivity". Bioavailability, as we understand it, refers to the extent to which a substance or drug enters the systemic circulation thereby accessing the intended biological destination, whereas bioactivity refers to the ability of a drug or substance to elicit a favourable response from that biological destination. As set out in the ACOG's Committee Opinion, the standard ratios used by compounding pharmacies for Biest and Triest are not based on the potency of the individual hormones but rather on the milligram quantity of the different hormones. It goes on to explain that:

> … underdosing of estrogen can lead a woman to believe that she is protected against osteoporosis when, in fact, bone resorption is progressing. Estriol is substantially less bioactive than estradiol, and large quantities must be used to achieve any biological effect. The potential for overdosage also exists, which can lead to increased risks of endometrial hyperplasia, endometrial cancer, and venous thromboembolism.

101 Bearing these rationales in mind, we consider that none of the justifications provided by Dr Lee can withstand scrutiny.

The first justification: patient safety

102 First, Dr Lee contends that Prof Rajasoorya's main concern was not the prescription of Biest and Triest *per se* but rather the safety concerns related to custom-compounded hormones in general. In Dr Lee's view, this concern was not borne out on the facts because the Biest and Triest his patients received was dispensed by SCP, the MOH-licensed compounding pharmacy that Dr Lee himself had founded to ensure that the relevant safety standards were met (see [66] above).

103 In our judgment, Dr Lee's reliance on the fact that the Biest and Triest were dispensed by a regulated compounding pharmacy is wholly misplaced. There are three main reasons why we consider this to be so.

104 One, we have highlighted above that the rationale behind the applicable standard is threefold. Even if we accept Dr Lee's argument that he had addressed Prof Rajasoorya's concerns about safety by ensuring that the compounding was done according to standard formulae, this would at best address the second and third rationales we have identified. It does not address the first (and in our view, key) rationale for the applicable standard, which pertains to the *efficacy* of Biest and Triest in treating estrogen deficiency. In this regard, the burden fell upon Dr Lee to show that there was a body of medical opinion supporting his subjective opinion that Biest and Triest were efficacious, and that such medical opinion had a logical basis: *Ang Yong Guan* at [75], citing *Khoo James and another v Gunapathy d/o Muniandy and another appeal* [2002] 1 SLR(R) 1024 at [63]–[65]. We highlight that it is crucial that the medical

opinion has a logical basis because, as the court explained in *Low Chai Ling* (at [42]), *illegitimate practices are not legitimised merely because large numbers of doctors engage in them*.

105 In the present case, we find it striking that Dr Lee could not obtain *any* expert witness to testify on his behalf to explain, logically and rationally, why they held the opinion that Biest and Triest were efficacious. Instead, Dr Lee simply referred to the fact that there were other doctors prescribing these medications at the material time and that there were regulated compounding pharmacies permitted to dispense the medications. He also relied on Prof Rajasoorya's testimony that there was a body of medical opinion who considered that BHRT was acceptable and that there was a fair number of doctors who saw advantages to BHRT. With respect, these arguments fall far short of providing a logical and defensible justification.

106 Two, we do not think that the safety concerns surrounding the use of Biest and Triest can completely be eradicated by ensuring that the hormones were compounded by licensed pharmacies. As with Erfa, the medical literature appears to suggest that there are additional risks that arise from the use of Biest and Triest due to characteristics that are *inherent* in the medications concerned. In particular, the risk of underdosage and overdosage arises because of "variable bioavailability and bioactivity", as well as "variable purity and potency". This does not appear to be a factor that can be mitigated by using set formulae in the compounding process, as the standard ratios for such compounding do not account for the potency of the individual hormones (see [100] above). Furthermore, as Ms Wong of SCP explained before the DT, the compounding pharmacy merely followed the instructions of the prescribing doctor as regards the amount of each agent that was to be included in the custom-compounded hormone:

> Q … So but what you get from the doctor, only thing you get from the doctor then, in relation to let's say something like Biest is a prescription.
>
> A Yes.
>
> Q ***And the doctor will give you the -- doctor will tell you, I want how much Estriol, how much Estradiol, how much Estrone.***
>
> A ***Yes***.
>
> …
>
> Q well, the pharmacy then assumes and they are entitled to assume that the doctor has got his prescription right.
>
> A Yes.
>
> Q As long as it doesn't overstep certain boundaries that the pharmacy has, you will compound it and dispense it?
>
> A Yes.
>
> [emphasis added in bold italics]

107 Three, the evidence showed that the safety concerns that Prof Rajasoorya had went far beyond the risks associated with compounding pharmacies. Dr Lee submits that Prof Rajasoorya conceded that, subject to the safety of the medication, a medical practitioner could prescribe a medication and monitor the patient for symptoms. However, this submission does not answer the question of *how* one would be assured of the safety of a given medication. In this regard, Prof Rajasoorya's evidence was as follows:

> Q Okay. So, we can, we can say that a doctor must follow your entire hierarchy of studies only, or we can also say a doctor can consider things, we will again put aside the legally available point, we will be coming back to that. Give it to the patient, observe the patient, treat symptoms and monitor what's going on, am I right?
>
> A That's correct, ***as long as whatever you gave the patient is safe enough to give***.
>
> Q Okay.

> A And ***where you have data on its safety, where it has been studied***.
>
> Q Okay. So it must be safe.
>
> A Yes.
>
> [emphasis added in bold italics]

108 Prof Rajasoorya's evidence shows that the safety of a medication would necessarily be premised on *sufficient tests* having been conducted on the medication such that there would be adequate data to support its safe prescription. Such tests had *not* been conducted on Biest and Triest.

109 Thus, the first justification raised by Dr Lee fails on multiple fronts. Not only did Dr Lee fail to discharge the evidential burden of proving that Biest and Triest were safe, but he also failed to prove their efficacy in treating estrogen deficiency.

The second justification: patient preference

110 Secondly, Dr Lee explained that he prescribed Biest and Triest because he "generally preferred to use BHRT for menopausal patients" and/or because the patients expressed a preference for it. In the cases of P11 and P25, Dr Lee was merely continuing another doctor's prescription. In the cases of P24 and P25, they had signed consent forms prior to the prescriptions which set out the risks of BHRT in detail and acknowledged the absence of "large scale, double blinded, placebo controlled trials".

111 The SMC's case was that patient preference, and even the signed consent forms, would be irrelevant where the prescriptions in question are not medically indicated. Thus, unlike the case for Erfa, where the SMC accepted that there was no blanket prohibition against its prescription, it took a different position in respect of Biest and Triest because, in the SMC's view, there is no

evidence to support the *efficacy* of Biest and Triest. It therefore does not matter that the patients had signed the consent forms.

112 This court has said before that the presence of a signed consent form alone is not determinative of whether informed consent was truly obtained: *Jen Shek Wei v Singapore Medical Council* [2018] 3 SLR 943 at [104]. It should be pointed out that the consent forms signed by P24 and P25 referred to BHRT in a *generic* sense. They contain a declaration stating that the patient "specifically and knowingly decline[s] to be prescribed and/or use synthetic hormones as from previous experience, these did not suit [the patient] and/or improve [the patient's] symptoms". However, the consent forms did not bring to the patient's attention the fact that the standard treatment for estrogen deficiency was the prescription of on-label estradiol, and that the prescription of Biest and Triest was a departure from standard treatment. They also failed to highlight that Biest and Triest contained hormones which were not licensed for use by the HSA. Likewise, the PMRs contain no indication that these facts were discussed with Dr Lee's patients. Thus, the consent forms alone do not persuade us that the DT's convictions might be unsafe.

113 More fundamentally, beyond the question of whether the patients provided informed consent to the departure from the applicable standards, we agree with the SMC's submissions that the responsibility lies on the attending doctor to ensure that what he is asking the patient to consent to is in fact medically indicated. In our judgment, where the charge alleges that the medical practitioner had no grounds for pursuing a certain course of action, the fact that a patient requested a particular treatment cannot in itself be an objective justification for the medical practitioner's actions. This follows from our holding in *Ang Yong Guan* (at [75]) that a medical practitioner's deviation from the applicable standards of conduct can only be justified if it was *objectively*

warranted in the circumstances of the patient's case. In the present case, the evidence suggested that there was a lack of data regarding the efficacy of Biest and Triest. Given that there were ample on-label medications to treat estrogen deficiencies, Dr Lee had to explain why he considered it objectively warranted to prescribe a novel treatment that lacked data on safety and efficacy. In our view, he has not satisfactorily answered this question.

The third justification: lack of clarity as to applicable standards

114 Dr Lee's third argument is a general one alleging that there was a lack of clarity on the applicable standards at the relevant time, to the effect that "there was never any concern about using BHRT". Dr Lee focuses on the fact that compounding pharmacies such as SCP were legally allowed to dispense Biest and Triest at the material time.

115 As we explained at [85]–[89] above, we do not accept Dr Lee's explanations on the alleged lack of clarity in the applicable standards. We repeat the observations made above. It is also clear from Ms Wong's evidence that the role of the compounding pharmacy in dispensing Biest and Triest is predicated upon a prior prescription by a doctor, and therefore cannot be used to justify the prescription in question.

Conclusion on the Biest and Triest prescriptions

116 In sum, we agree with the DT that Dr Lee had intentionally and deliberately departed from the applicable standard of conduct when he prescribed Biest and Triest to his patients. He was not able to provide an objectively defensible justification for these prescriptions. Therefore, he was correctly found guilty of professional misconduct on the charges relating to Biest and Triest.

The progesterone prescriptions

The applicable standard of conduct

117 The alleged misconduct that Dr Lee was charged with under the 12th and 15th charges concerned one prescription of progesterone to P20 and P23, notwithstanding that each of them had undergone a hysterectomy, and their progesterone levels were observed to be within the normal range.

118 The DT found that the applicable standard of conduct among members of the medical profession of good standing and repute is that hysterectomised women should not be prescribed progesterone. This is because the purpose of progesterone prescription is to treat menopausal symptoms and to prevent endometrial thickening, which may predispose one to cancers of the uterine lining: GD at [55].

119 Dr Lee submits that the DT's finding is contrary to the available evidence. Instead, the applicable standard does not prohibit the prescription of progesterone to hysterectomised women. Dr Lee's evidence was that progesterone can also be used to treat hot flushes and mood disorders.

120 We do not think that the DT's findings on the applicable standard were contrary to the available evidence. The SMC's case as supported by Prof Rajasoorya's opinion is that the purpose of progesterone prescription is to treat menopausal symptoms and to prevent endometrial thickening, which may otherwise predispose one to cancers of the uterine lining. In his examination-in-chief, Prof Rajasoorya testified that it was the standard recommendation of all major societies not to prescribe progesterone to hysterectomised women because women who have had a hysterectomy have no uterus (and therefore no uterine lining). Among other risks, the prescription of progesterone to

hysterectomised women would increase the risk of breast cancer. Further, as progesterone has androgenising properties, it would also result in masculinity, acne, and mood disturbances.

121 Before proceeding further with the rest of our analysis, we find it helpful to define a few terms which are not in dispute between the parties. The category of hormones known as "progestogens" can be defined to include both "progesterone" and "progestin". Progesterone can be obtained from synthetic or natural sources, whereas progestin is always synthetic. Dr Lee prescribed progesterone from natural sources. Where the term "progestogens" is used in the medical literature, it is generally understood as referring to all forms of progestogens including both progesterone and progestin.

122 Prof Rajasoorya relied on the 2012 Hormone Therapy Position Statement of the NAMS to support his opinion that hysterectomised women should not be prescribed progesterone. The material part of the position statement states as follows:

> **Progestogen indication**
>
> The primary menopause-related indication for progestogen use is to negate the increased risk of endometrial cancer from systemic ET [*ie*, estrogen therapy] use. All women with an intact uterus who use systemic ET should also be prescribed adequate progestogen. With occasional exceptions (eg, history of extensive endometriosis), postmenopausal women without a uterus should not be prescribed a progestogen with systemic ET.

123 Notably, the phrase used in the NAMS position statement is that women without a uterus should not be prescribed a "progestogen", a category of hormones which would include progesterone.

124 Dr Lee's response is twofold. The first prong of his submissions is premised on hysterectomised women obtaining a *benefit* from the prescription of progesterone. In other words, progesterone can be prescribed to hysterectomised women if it is *efficacious*, for example, in treating hot flushes and mood disorders.

125 According to Dr Lee, Prof Rajasoorya had conceded in cross-examination that it could also be worth taking progesterone for the relief of menopausal symptoms, in addition to preventing endometrial thickening. However, this is factually untrue. While Prof Rajasoorya agreed that progesterone would have an effect on "symptom relief", he in fact clarified that he would "need data" to support a prescription of progesterone to patients purely for symptom relief:

> Q Second statement, ***progesterone can be given to women who have had a hysterectomy in terms of treating, symptomatically, mood issues.***
>
> A ***I need data on that.***
>
> Q You need data on that, okay.
>
> A Yes.
>
> Q You can't say yes or no?
>
> A I can't say at the moment --
>
> Q Okay.
>
> A -- because I have never looked at as an issue.
>
> …
>
> A Because I understand that even progesterone can cause disturbed mood issues.
>
> [emphasis added in bold italics]

126 The only evidence tendered by Dr Lee in support of his argument that progesterone may be prescribed to women purely for symptom relief is a paper

published in February 2017 by Michael Schmidt, titled "Progesterone Administration in Postmenopausal and Hysterectomized Patients". In our view, the DT was entitled to prefer Prof Rajasoorya's evidence to this paper for several reasons. First, the article was published February 2017 and therefore appeared after the time period in which the alleged misconduct occurred. Dr Lee therefore could not have relied upon it at the time when he made the relevant prescriptions to P20 and P23. Secondly, the article does not fall within what the parties agreed to be the "apex of the evidentiary pyramid", namely, clinical practice guidelines, meta-analysis systematic review, or randomised double-blind controlled trials. In fact, the article itself highlights that "large, randomized controlled trials are needed to substantiate progesterone's effectiveness at treating mood disorders and depression". Thirdly, the article does not go so far as to endorse the prescription of progesterone to hysterectomised women. It merely suggests that progesterone "can have beneficial effects even in postmenopausal women or women without a uterus". This says nothing about the potential *risks* that may be associated with such practice or the availability of on-label alternatives that might be able to provide the relief that the prescription of progesterone is alleged to offer. It therefore cannot be read as an endorsement of prescribing progesterone to patients purely for symptom relief.

127 In our judgment, the mere fact that patients may obtain a *benefit* cannot in itself suggest that a particular prescription is indicated for specific symptoms. As we alluded to in the context of our discussion on the prescriptions of Erfa, whether a prescription falls within the applicable standard of conduct is ultimately a fact-sensitive inquiry. A key factor that we consider to be relevant in the present case is *the presence of ample on-label treatments for the relevant*

symptoms. In this regard, we highlight the following passage from the NAMS position statement:

> ET [*ie*, estrogen therapy] with or without a progestogen is the most effective treatment of menopause-related vasomotor symptoms and their potential consequences, such as diminished sleep quality, irritability, difficulty concentrating, and subsequently reduced quality of life (QOL). … ***Progestogen alone also reduces vasomotor symptoms but not as effectively as estrogen does***.
>
> [emphasis added in bold italics]

128 This, in our view, is the end of the inquiry in so far as *establishing the applicable standard of conduct* is concerned. If there are ample on-label treatments for a condition, the prescription of an off-label alternative necessarily becomes a matter for the prescribing doctor to justify in accordance with the *Ang Yong Guan* requirements.

129 Nevertheless, for convenience, we deal with the second prong of Dr Lee's submission here. Dr Lee's submission is premised on the *absence of risks*. In particular, he argues that the risks of progesterone prescription which Prof Rajasoorya was most concerned with, namely, the increased risk of breast cancer, were built on a false premise. In most of the studies referred to in Prof Rajasoorya's expert report, there were concerns that the risk of breast cancer may be related to *progestin*, as opposed to *progesterone*. Further, Prof Rajasoorya agreed that there was observational data suggesting that progesterone was not associated with the increased risk of breast cancer, as opposed to synthetic progestogens.

130 This argument does not assist Dr Lee for two main reasons. Firstly, the risk of breast cancer was not Prof Rajasoorya's only concern. Prof Rajasoorya testified that there were other side effects, besides the risks of breast cancer,

which would make the prescription of progesterone to hysterectomised women inappropriate. These side effects stem from the androgenising properties of progesterone. This evidence was not controverted by Dr Lee.

131 Secondly, we do not think that the evidence suggests that progesterone is not associated with the increased risk of breast cancer. In fact, the NAMS position statement clarifies that there is a lack of data on "whether the specific agent used influences the degree of breast cancer risk":

> ***Estrogen-progestogen therapy***
>
> Diagnosis of breast cancer increases with EPT use beyond 3 to 5 years. … Studies have not clarified whether the risk differs between continuous and sequential use of progestogen, with observational studies suggesting that risk may be greater with continuous use of progestogen. ***It is also not clear whether there is a class effect with progestogens or whether the specific agent used influences the degree of breast cancer risk***. Data from a large observational study suggest that EPT with micronized progesterone carries a low risk of breast cancer with short-term use but carries an increased risk of breast cancer with all EPT formulations with long-term use.
>
> [emphasis added in bold italics]

132 During the course of the DT proceedings, Dr Lee tendered a study published in 2016 titled "Progesterone vs. synthetic progestins and the risk of breast cancer: a systematic review and meta-analysis", which concluded that there were observational studies which suggested that "in menopausal women taking estrogen, progesterone use may be associated with lower breast cancer risk compared to synthetic progestin". When this study was shown to Prof Rajasoorya, he conceded that progesterone is safer than progestin in terms of the risk of breast cancer. We make two observations.

133 One, stating that progesterone carries a lower risk of breast cancer than progestin is not quite the same as saying that progesterone is *not associated* with

the risk of breast cancer. Indeed, even the study that Dr Lee relies on suggests that progesterone has an impact on breast cancer risk:

> Both progesterone and synthetic progestins and the dosing regimen may impact breast cancer risk. In the E3N cohort study, MHT [menopausal hormone therapy] regimens containing estrogen and progesterone or dydrogesterone were not associated with a statistically significant increase in breast cancer risk. All other progestins were associated with an increased risk, with no difference between various progestins.

134 Two, the study that Dr Lee relies on itself recognises in no uncertain terms that the purpose of prescribing progesterone is to prevent endometrial thickening. This corroborates the SMC's case that, for women without a uterus, there is no logical basis for prescribing progesterone. We set out a few extracts from the paper below:

> Menopausal hormone therapy (MHT) is highly effective for the treatment of symptoms related to menopause. MHT regimens typically include estrogen and, for women with an intact uterus, a progestin to protect the endometrium from hyperplasia caused by unopposed estrogen.
>
> …
>
> Progestin is utilized in MHT regimens for women with an intact uterus to prevent endometrial hyperplasia.
>
> …
>
> Women with an intact uterus require the use of progesterone for endometrial protection when using systemic estrogen therapy for the management of menopausal symptoms.

135 Bearing in mind the high threshold for appellate intervention as set out in s 55(11) of the MRA, we conclude that there is no basis to disturb the DT's findings on the applicable standard.

Whether Dr Lee departed from the applicable standard

136 There is no dispute that Dr Lee prescribed progesterone to P20 and P23, who had both undergone a hysterectomy. Dr Lee's evidence is that he had prescribed progesterone to P20 to treat anxiety and osteopenia, whereas he treated P23 for menopausal symptoms.

137 We agree with the DT that his prescriptions were a departure from the applicable standard as he had deviated from the logical basis for the prescription of progesterone. Progesterone was simply not medically indicated for P20 and P23. Furthermore, based on our analysis above, it is clear that Dr Lee had not discharged the evidential burden of showing that his prescriptions were objectively defensible. Dr Lee provided little to no evidence to support his bare assertion that progesterone could be prescribed to women who had undergone a hysterectomy. As Dr Lee was conscious of the requirement to ensure that there were clear medical grounds for his prescriptions, the departure in question must be regarded as intentional and deliberate.

138 We therefore conclude that Dr Lee's conviction on the progesterone-related charges cannot be impugned.

The testosterone prescriptions

The applicable standard of conduct

139 Dr Lee faced two charges concerning his prescription of testosterone. The 10th charge stated that he had prescribed testosterone to P17 (a male) "notwithstanding [P17]'s testosterone levels in the blood were observed to be within normal range", while the 13th charge simply stated that he had prescribed

testosterone to P21 (a female) "notwithstanding that there were no medical grounds to do so".

140 The parties agree that a trial of testosterone therapy is appropriate for females with hypoactive sexual desire dysfunction ("HSDD") and for males with low testosterone levels (*ie*, testosterone deficiency).

141 Dr Lee's case on appeal is that the applicable standard of conduct does not limit the prescription of testosterone to the aforementioned situations. In the case of male patients, he submitted that a medical practitioner is entitled to continue prescribing testosterone if the patient "is already on treatment" for testosterone deficiency. As for female patients, he submitted that there was evidence to show that testosterone could be prescribed for conditions other than HSDD, namely, for menopausal symptoms, depression and osteopenia. We are unable to accept Dr Lee's submissions, which appear to rest on various excerpts of Prof Rajasoorya's evidence that have been taken wholly out of context. We explain.

142 First, Prof Rajasoorya's expert report stated that:

> 88. Generally, ***one has to first demonstrate testosterone deficiency and then try to find the cause if possible so that besides replacement of any deficiency, the cause can be addressed.*** The tests could include measuring other pituitary hormones like FSH, LH and Prolactin. As the disorder may sometimes arise from disorders involving the glands secreting these listed hormones, sometimes further imaging studies like an MRI may be indicated.
>
> 89. ***As long as patients find beneficial responses to treatment (when indicated) and do not have significant side effects, the prescription can be continued long term with clinical monitoring. In those where it is not indicated, it should be stopped.***
>
> [emphasis added in bold italics]

143 During cross-examination, Prof Rajasoorya reiterated the importance of addressing the root cause of a patient's testosterone deficiency before continuing a prescription of testosterone:

> Q Now, if Dr Raymond Wong had in fact been giving testosterone, would I be correct to say that as long as patients find beneficial responses to the treatment and do not have significant side effects, the prescription can be continued longer term with close monitoring.
>
> A ***If there was testosterone deficiency was noted and it was not due to other factors, because sometimes illness itself can reduce testosterone. And if it was started and continued, maintained, that would be the normal practice.***
>
> [emphasis added in bold italics]

144 He further explained that, in order to determine whether there was an indication of testosterone deficiency, one would have to rely on "current level hormones":

> Q Okay. So when say the -- for [P17], it was not indicated, we come back to a situation where we have Dr Lee giving a one-off prescription, not continuing it, where there were some indications for it.
>
> A Can I try to understand what you meant by "some indications"?
>
> Q Previous doctor has said borderline. Some of the symptoms would suggest improvement with testosterone.
>
> A ***So this is where one has to rely on current level hormones, and if current hormone levels are normal, it would not be indicated***.
>
> [emphasis added in bold italics]

145 Contrary to Dr Lee's submission, Prof Rajasoorya's evidence cannot stand for the proposition that "it is normal practice to continue treatment" as long as the patient is already on treatment for a documented testosterone deficiency. As a full examination of Prof Rajasoorya's evidence reveals, the

propriety of continuing a prescription of testosterone would be subject to a continued indication of testosterone deficiency, *based on the hormone levels identified in a patient's latest test results*.

146 Second, in so far as female patients are concerned, Prof Rajasoorya's opinion was that there was no evidence to support the use of testosterone for symptoms or medical conditions other than HSDD. He relied primarily on a paper published by the Endocrine Society titled "Global Consensus Position Statement on the Use of Testosterone Therapy for Women", which found after conducting randomised controlled trials and meta-analyses that the "only evidence-based indication for the use of testosterone in women is for the treatment of postmenopausal women who have been diagnosed as having HSDD after formal biopsychosocial assessment". The same study also highlighted that the available data showed "no effect of testosterone therapy" on, among other things, "general wellbeing", "depressed mood" and "bone mineral density" among postmenopausal women. During Prof Rajasoorya's examination-in-chief, he also explained that the prescription of testosterone to women would also cause problems such as "acne", "a change in voice" and "hirsutism", which he explained was a condition "where a lady gets extra hair in areas that are not supposed to have this extra hair".

147 Dr Lee pointed the DT to a page in Dr Eng's reference materials which contained citations of various articles that allegedly provided support for his submission that testosterone could be prescribed to treat women with conditions other than HSDD. With respect to Dr Lee, however, it quickly became apparent that he had no idea what propositions those articles were advancing:

> Q … what evidence did you rely on in 2013, 2014 for testosterone to be prescribed to women to treat depression?

A Maybe you can look at 4AB 358 -- I think it's better to look at 4AB 378 in the second half, there's a big heading that says "Testosterone and psychic well-being in women"; you're there?

Q Yes, I'm there.

A And near the bottom:

> Depression in women: the association with lower testosterone levels.
>
> …
>
> Depression in women: the improvement with testosterone treatment.

Q Okay.

A On the following page, AB 379, you got "Anxiety in women: the association with lower testosterone" and the improvement with testosterone".

Q ***Where are these reports?***

A Sorry?

Q So these must be referring to various papers, right?

A Yes.

Q ***Where are these papers?***

A ***I don't have them.***

Q ***Are they anywhere in your bundle?***

A ***I don't know.***

…

Q ***So it's got a list of various, I suppose, essays or papers, but you don't have the papers and we don't know what the papers say, right?***

A ***The specifics.***

Q ***Yes. We don't have the specifics.***

A ***No.***

Q We don't know exactly what tests were done whether it was randomised or whether it was a cohort study or whether it was a case control, right?

A Yes.

[emphasis added in bold italics]

148 It is plain from this portion of his cross-examination that Dr Lee was simply reading off the titles of various articles without having adduced those articles before the DT. This being the case, there is simply no evidence before us to rebut Prof Rajasoorya's expert opinion, which was amply supported by studies falling within the apex of the evidentiary pyramid.

149 In an earlier portion of his cross-examination, Dr Lee also relied on a paper by the Hull & East Committee Riding Prescribing Committee, which states that testosterone "may also be prescribed for treatment of menopausal symptoms in women". This was once again taken out of context. The same paper cautions that the testosterone preparations for women are "unlicensed".

150 It is clear to us, therefore, that the applicable standard would require medical practitioners to conduct themselves as follows:

(a) In the case of male patients, there is a need to ensure that the patient in question suffers from testosterone deficiency, based on the hormone levels found in the latest tests. Sufficient tests must also be conducted to rule out other possible causes for the low levels of testosterone.

(b) In the case of female patients, there is no evidence to support the use of testosterone for any symptoms or medical conditions other than HSDD.

Whether Dr Lee departed from the applicable standard

151 Dr Lee prescribed testosterone to P17 on 4 December 2014. The most recent tests from P17, taken on 16 October 2014, showed that P17's testosterone

levels fell within the prescribed normal range although, based on P17's PMR dated 4 December 2014, there is a marking stating "TT" with an arrow pointing downwards next to it, suggesting that P17's testosterone levels had dropped. These facts were highlighted to Prof Rajasoorya during cross-examination, but he remained resolute in his conclusions:

> Q Right. So let's assume and this is based on evidence, that 2012 was 295, below range. On treatment, 2013, 702. 2014, dropped, still within range, but 462. Now in those circumstances, giving a single maintenance dose, is that improper conduct?
>
> A Conduct, as I said, is not for me to decide. But the indication here, ***if the testosterone is normal, there's no reason to give testosterone.***
>
> Q ***Even though it's dropping?***
>
> A If it's within normal range because --
>
> Q No, my point is even though it's dropping.
>
> A Where it varies, ***testosterone varies when you measure it at different times of the day.***
>
> Q Yes.
>
> A ***So even though it's dropping, it doesn't put as an indication to treat it***.
>
> [emphasis added in bold italics]

152 Dr Lee's evidence was that he prescribed testosterone for "maintenance" as P17 was previously diagnosed by another doctor as having borderline testosterone levels. He relied on test results which showed an improvement in P17's testosterone levels, based on test results in 2013 and 2014. However, it is not disputed that the PMRs adduced before the DT do not show P17 being on testosterone therapy at the time of Dr Lee's prescription. During cross-examination, Dr Lee explained that there "was documentation" but the notes before the DT were "incomplete". No explanation was provided for why these notes were not before the DT. In these circumstances, we do not

think that the DT's finding as to whether P17 was on testosterone therapy prior to Dr Lee's prescription can be said to be contrary to the available evidence.

153 In any event, this finding of fact does not change the decision on misconduct. In our judgment, given that the testosterone levels indicated in P17's latest test results fell within the normal range, Dr Lee should not have readily prescribed testosterone to P17 without conducting further tests to ensure that P17 was indeed suffering from testosterone deficiency. Thus, even if P17 was on testosterone therapy at the material time, there would have been sufficient indications to Dr Lee suggesting that the testosterone therapy ought to have been stopped. Thus, Dr Lee's prescription of testosterone to P17 departed from the applicable standard of conduct as set out at [150(a)] above.

154 As for P21, Dr Lee prescribed testosterone to her on 3 February 2015. The most recent test results from P21 taken on 25 November 2014 showed that her testosterone levels fell within the prescribed normal range. Based on the PMRs, there was no indication that she suffered from HSDD, nor was it ever advanced as part of Dr Lee's case that she suffered from HSDD. Dr Lee's prescription of testosterone to P21 is a departure from the applicable standard of conduct.

155 Dr Lee's evidence was that P21 was previously prescribed testosterone by another doctor for menopausal symptoms, depression and osteopenia. His prescription was a continuation of her treatment protocol which he considered was beneficial to P21. As highlighted at [146] above, the Global Consensus Position Statement found that there is no effect of testosterone on general wellbeing, depressed mood or bone mineral density. Dr Lee's reasons therefore do not suffice to provide an objectively defensible justification for Dr Lee's prescription.

156 Dr Lee was conscious of the need to ensure that there were clear medical grounds for his prescriptions of testosterone to P17 and P21. His departures were therefore intentional and deliberate. We therefore agree with the DT that that Dr Lee was guilty of professional misconduct on the 10th and 13th charges.

Conclusion on convictions

157 For the reasons given above, there is no basis on which we can interfere with any of the DT's determinations of Dr Lee's guilt on the 17 charges considered in the appeal. The convictions on those charges must stand.

The appropriate sentence

The applicable legal principles

158 It is well-established that an appellate court will not ordinarily disturb the sentence imposed by a lower court unless it is satisfied that (*Public Prosecutor v UI* [2008] 4 SLR(R) 500 at [12]): (a) the trial judge erred with respect to the proper factual basis for sentencing; (b) the trial judge failed to appreciate the materials placed before him; (c) the sentence was wrong in principle; or (d) the sentence was manifestly excessive or manifestly inadequate, as the case may be.

159 The parties are in agreement that the framework set out in *Wong Meng Hang* applies to the present case. The applicable principles were recently summarised in *Ang Yong Guan v Singapore Medical Council and another matter* [2025] 3 SLR 135 at [11]–[15]. For convenience, we briefly set out the principles below.

160 The first step entails evaluating the seriousness of the offence, having regard to the levels of harm and culpability within which the case falls. Harm is

determined with reference to the type and gravity of the *actual* harm caused to a patient as a result of the offence but also includes *potential* harm of which there was a sufficient likelihood, even if no actual harm materialised. Culpability, on the other hand, refers to the "degree of blameworthiness disclosed by the misconduct", determined with reference to the offender's involvement in causing the harm; his or her state of mind when committing the offence; the extent to which the offending conduct departed from standards reasonably expected of a medical practitioner; and all other circumstances surrounding the commission of the offence.

161 The second step entails identifying the applicable indicative sentencing range based on the level of harm and culpability based on the following matrix:

Harm / Culpability	Slight	Moderate	Severe
Low	Fine or other punishment not amounting to suspension.	Suspension of three months to one year.	Suspension of one to two years.
Medium	Suspension of three months to one year.	Suspension of one to two years.	Suspension of two to three years.
High	Suspension of one to two years.	Suspension of two to three years.	Suspension of three years or striking off.

162 The third step entails identifying the appropriate starting point within the indicative sentencing range having regard to the level of harm and culpability.

163 Fourth, the indicative starting point may be further calibrated based on offender-specific aggravating and mitigating factors.

164 Finally, after the appropriate individual sentence for each of the charges is determined, the overall sentence should then be calibrated by applying the one-transaction rule and the totality principle: *Singapore Medical Council v Ling Chia Tien* [2024] 6 SLR 217 ("*Ling Chia Tien*") at [52] and [70].

The parties' submissions

165 Based on the *Wong Meng Hang* framework, Dr Lee submits that his offences all fell within the slight harm, low culpability end of the matrix. This is because none of his patients suffered actual harm from his treatments and he was only motivated by his patients' welfare.

166 Dr Lee's submissions on sentence then proceed in a tiered fashion. First, he submits that the DT erred in relying on precedents involving the prescription of benzodiazepines and other hypnotics in deriving the appropriate sentence. He submits that those cases are markedly different because in those case, there are established guidelines for prescription and a departure from such guidelines carries significant risks. Instead, he argues that he should be issued a letter of warning, because there were three other doctors who had prescribed BHRT at the material time who were only issued letters of warning.

167 The second tier of Dr Lee's submissions, assuming that the first tier is rejected, is that fines should be imposed instead of a suspension, with the quantum of the fine depending on the number of prescriptions set out in each charge, with each prescription attracting a fine of $500. The third tier, which applies if the court intends to uphold the sentence of suspension on Dr Lee, is that only four sentences ought to run consecutively, instead of the five ordered by the DT. He also submits that his sentence ought to be reduced by 50% on account of the inordinate delay in prosecuting his case.

168 The SMC, in essence, seeks to uphold the decision of the DT. The global suspension period of 18 months is not substantially above the normal level of sentences for the most serious of the individual offences committed and cannot be said to be crushing when viewed in light of the number of charges that Dr Lee was convicted of. Further, there is no general proposition that a delay in prosecution would automatically merit a discount in sentence, particularly as the delay in question was largely caused by Dr Lee himself. The inquiry was also far more complex than precedent cases given the number of patients involved and the multiple types of hormones prescribed to the patients.

Our decision on sentence

169 In our judgment, the DT had correctly applied the *Wong Meng Hang* framework in coming to its decision on the individual sentences to impose on Dr Lee. Further, the global sentence imposed by the DT was not manifestly excessive.

Application of the Wong Meng Hang *framework*

170 Firstly, the parties agree that no actual harm was caused to Dr Lee's patients by his prescriptions. There is no dispute that the harm here was slight. However, we wish to dispel any notion that the present case involved *no potential harm*, as Dr Lee seemed to suggest in his written submissions. These submissions were premised on his earlier arguments that he had fully mitigated the risks which Prof Rajasoorya was concerned about. We have explained why we do not agree with those arguments. Based on the evidence, the potential harm that could have arisen due to Dr Lee's prescriptions ranged from the inconvenient (*eg*, hirsutism) to the life-threatening (*eg*, thyrotoxicosis, breast cancer).

171 Secondly, we agree with the DT's assessment of Dr Lee's culpability. Dr Lee's submissions on culpability are premised on the alleged lack of clear standards at the material time. We have explained why we reject this submission. The ECEG has always been clear that medical practitioners should only prescribe medications where there are clear medical grounds to do so and according to methods that are generally accepted by the medical profession. In our judgment, a finding of medium culpability is consistent with similar cases involving the prescription of inappropriate medications.

172 In *Ling Chia Tien*, the errant doctor was convicted of 29 charges of professional misconduct, of which 12 charges related to his inappropriate prescriptions of benzodiazepine and codeine. The doctor in question did not make the inappropriate prescriptions for improper financial gain but rather, held strong patient-centric views. However, while he honestly believed that he was acting in his patients' best interests, the court found that this did not justify his departure from the applicable standards in the manner and to the extent to which he did (at [93]–[94]). Accordingly, his culpability was assessed to fall within the medium range (at [95]). This bears certain similarities with the present case, where the evidence does not suggest that Dr Lee was motivated by improper financial gain or other improper motives. However, while he may have been motivated by his own misguided beliefs as to the propriety of his prescriptions (notwithstanding his knowledge that such prescriptions were non-conventional) and subjectively believed that he was doing so out of concern for his patients' welfare, this does not reduce his culpability significantly. Viewed as a whole, his offending conduct spanned a total of four years and one month, during which time he made 41 prescriptions of Erfa, 11 prescriptions of Biest, three prescriptions of Triest, and two unwarranted prescriptions for each of

progesterone and testosterone. This was a significant number of inappropriate prescriptions and a long duration of offending.

173 Thirdly, we see no reason to disturb the DT's decision on the aggregate sentence imposed on Dr Lee. It bears noting that the position taken by Dr Lee on appeal would reduce his suspension term from 18 months to 15 months. This, in our view, fails to cross the necessary threshold for appellate intervention. He has not suggested that the DT made any errors of law or principle in deciding to suspend him for 18 months. Indeed, the DT was careful to ensure that it did not offend the one-transaction rule: GD at [91]. The DT had also carefully considered each of the offender-specific mitigating factors raised by Dr Lee in his submissions: GD at [86]. Consequently, we uphold the DT's decision on the aggregate period of suspension.

Inordinate delay in prosecution

174 One aspect of Dr Lee's submissions on sentence which warrants further discussion is the question of whether a discount ought to be granted on account of an inordinate delay in prosecuting his offences. The offences in question took place over a decade ago and it cannot seriously be disputed that Dr Lee has had to live with the spectre of disciplinary proceedings for a very long time.

175 The applicable legal principles were summarised by this court in *Ling Chia Tien* at [119]–[121] and [124] as follows:

> 119 A court may extend leniency to an offender and exercise its discretion to discount the sentence if there is a significant delay in investigation and/or prosecution. The following cumulative conditions must be satisfied before a court may decide to apply a discount (*Ang Peng Tiam* at [109], and *Wong Poon Kay v Public Prosecutor* [2024] 4 SLR 453 ("*Wong Poon Kay*") at [66]):

> (a) there has been a significant delay in the investigation and/or prosecution of the matter;
>
> (b) the delay has not been contributed to in any way by the offender; and
>
> (c) the delay has resulted in real injustice or prejudice to the offender.
>
> 120 We agreed with the SMC's submissions that the delay has to be *inordinate*. For a delay to be inordinate, it must be unusually long and inexplicable on reasonable grounds: *Wong Poon Kay* at [68]. … Furthermore, as suggested in *Wong Poon Kay*, the defendant ordinarily bears the burden of proving that there was an inordinate delay in the prosecution and that the delay resulted in real injustice or prejudice to the defendant. Nevertheless, it would promote the expeditious conduct of proceedings if the Prosecution (here, the SMC) provides information about matters that occurred some time ago in the past to the defendant and to the court or tribunal at an earlier stage of proceedings: *Wong Poon Kay* at [77] and *Ang Peng Tiam* at [117].
>
> 121 The underlying rationale for discounting the sentence in such cases is fairness to the offender. Where there is an inordinate delay in prosecution, the sentence should reflect the fact that the matter has been pending for some time, likely inflicting undue suffering that stems from the prolonged agony, suspense and uncertainty: *Wong Poon Kay* at [66].
>
> …
>
> 124 We add that the reference to "investigations" in *Ang Peng Tiam* does not, in our minds, refer strictly to delays up to the point in time before the start of DT proceedings. A court may, in an appropriate case, even consider the delays during DT proceedings that were occasioned by the SMC's far from seamless approach to prosecuting the matter.

176 We highlight that whether a discount is ultimately granted to an offender is a matter of discretion and the onus falls on Dr Lee to show us on appeal that the DT exercised its discretion wrongly.

177 In this regard, the DT found that while there was a delay in prosecuting the complaint against Dr Lee, the delay in question was not unreasonable. Further, a substantial part of the delay was caused by Dr Lee himself, for

example, by Dr Lee's submission of multiple requests for an extension of time between 19 May 2021 to 18 August 2022 in order to submit an expert report which ultimately was not put into evidence before the DT: GD at [82] and [85]. The DT also considered the reasons proffered by the SMC for the delay, namely that the complaint was "complex" and the CC "spent significant resources to conduct its inquiry", and that the SMC's Investigation Unit had conducted extensive investigations under the direction of the CC, including having reached out to Dr Lee, various medical bodies, and endocrinologists in the process: GD at [81].

178 We do not think that the DT erred in declining to exercise its discretion to grant a sentencing discount to Dr Lee. The length of time involved in the present case must be viewed in light of the following chronology of events.

179 The SMC filed its first complaint with the Complaints Panel on 14 February 2014. This was placed before a CC which then sent a notice of complaint to Dr Lee on 1 September 2014. These proceedings, however, were held in abeyance because additional concerns with Dr Lee's practice had come to light. This gave rise to a second notice of complaint filed on 22 June 2016, which Dr Lee responded to on 15 September 2016. Several months later, on 30 May 2017, the CC came back to request further information from Dr Lee, specifically regarding his prescriptions of testosterone. Dr Lee replied to the request on 23 August 2017. The CC then informed Dr Lee on 12 February 2018 that it had completed the inquiry into the complaints against him and had ordered a formal inquiry against him. This chronology of events supports the SMC's position that the present case was "complex" and required "significant resources". New evidence came to light during the course of investigating the first complaint. At this stage, before the DT proceedings had commenced, the

investigation involved a detailed study of the PMRs of 25 patients and eight different prescriptions.

180 Furthermore, we agree with the DT that a substantial part of the delay was caused by Dr Lee. The proceedings before the DT were held in abeyance because of Dr Lee's unsuccessful judicial review proceedings from 2 May 2018 to 10 February 2020. Subsequently, Dr Lee spent around 16 months searching for an expert to produce a report, which was ultimately not adduced in evidence. In total, Dr Lee's own conduct resulted in a delay of around three years. Seen in this light, the delays that arose in the course of these proceedings were not inordinate and do not justify a discount in the sentence.

Conclusion

181 For the reasons that we have set out above, we dismiss the appeal. Costs of the appeal fixed at $50,000 are to be paid by Dr Lee to the SMC. Finally, we also uphold the DT's decision on the costs of the DT proceedings.

182 With regard to the commencement of Dr Lee's period of suspension, we are cognisant that Dr Lee may need some time to deal with his affairs. Therefore, we order that the suspension shall only commence on the date falling two weeks from today or such other date as we may, on application, order.

Sundaresh Menon
Chief Justice

Tay Yong Kwang
Justice of the Court of Appeal

Judith Prakash
Senior Judge

Narayanan Sreenivasan SC, Adorabelle Tan
(Sreenivasan Chambers LLC) (instructed);
Charles Lin, Tracia Lim and Daniel Poh
(Charles Lin LLC) for the appellant;
Thio Shen Yi SC, R Arvindren and Ryan Yap Cheah Jin
(TSMP Law Corporation) for the respondent.

Appendix

94. Having fully considered all the facts and circumstances, the respective submissions of the parties, the sentencing precedents cited by the parties, and applying the totality principle, the DT orders that:

(a) Dr Lee's registration be suspended for a **total period of 18 months** made up as follows –

(i) Suspension of three (3) months in respect of the 1st, 2nd, 4th, 5th, 6th, 7th, and 11th Amended Charges, the periods of these suspensions to run concurrently.

(ii) Suspension of six (6) months in respect of the 8th Amended Charge, this period of suspension to run consecutively to the sentences in respect of 1st, 2nd, 4th, 5th, 6th, 7th and 11th Amended Charges.

(iii) Suspension of three (3) months in respect of the 10th Amended Charge this period of suspension to run consecutively.

(iv) Suspension of three (3) months in respect of the 12th Amended Charge, this period of suspension to run consecutively.

(v) Suspension of three (3) months in respect of the 13th Amended Charge, this period of suspension to run concurrently.

(vi) Suspension of three (3) months in respect of the 15th Amended Charge, to run concurrently.

(vii) Suspension of three (3) months in respect of the 16th Amended Charge, this period of suspension to run consecutively.

(viii) Suspension of three (3) months in respect of the 17th Amended Charge, this period of suspension to run concurrently.

(ix) Suspension of eight (8) months in respect of the 19th Amended Charge, this period of suspension to run concurrently.

(x) Suspension of four (4) months in respect of the 20th Amended Charge, this period of suspension to run concurrently.

(xi) Suspension of four (4) months in respect of the 21st Amended Charge, this period of suspension to run concurrently.