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6. BIOMEDICAL LAW AND ETHICS

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I. Introduction

6.1 The year under review saw a professional disciplinary case in which the Court of Three Judges considered for the first time the question of whether medical practitioners can deviate from guidelines promulgated by the Ministry of Health ("MOH"), as well as the dosing regimens and recommended maximum dosages set out in product labels and package inserts when prescribing medication.

II. Professional misconduct: the case of *Ang Yong Guan*

6.2 In *Ang Yong Guan v Singapore Medical Council*[2] ("*Ang Yong Guan*"), the Court of Three Judges overturned the decision of a disciplinary tribunal ("DT") to acquit Dr Ang Yong Guan ("Dr Ang"), a psychiatrist, of professional misconduct for prescribing various medications to his former patient which were not in conformity with the guidelines issued by MOH.

6.3 Dr Ang treated the patient between 2010 and 2012, both as an inpatient and as an outpatient at his clinic or via telephone consultations, for various conditions including insomnia, depression, post-traumatic stress disorder ("PTSD"), obsessional ruminations and anxiety. As the patient's condition required various medication, Dr Ang prescribed him a mixture of antidepressant, anti-anxiety, antipsychotic and hypnotic drugs. At various points in time, Dr Ang prescribed the patient with a combination of approximately six to seven different types of drugs.

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1 The author wishes to thank Vanessa Yong and Theodora Kee for their inputs, and Varun Karthik for his assistance. All errors and omissions remain the author's own. The views expressed herein are those of the author alone, and do not reflect those of the organisations she belongs to.

2 [2024] 4 SLR 1364.

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6.4 The final prescription issued by Dr Ang on about 31 July 2012 was for, among other things, a nightly dose of 60mg of Mirtazapine and a nightly dose of 25mg of Zolpidem Controlled Release ("Zolpidem CR"). Four days later, the patient passed away. The final cause of death was certified as "multi-organ failure with pulmonary haemorrhage, due to mixed drug intoxication". Post-mortem blood concentrations of various drugs including Olanzapine, Duloxetine, Mirtazapine and Bromazepam, all of which had been prescribed by Dr Ang, were found to be elevated beyond the therapeutic concentrations found in living subjects.[3]

6.5 Following the patient's death, the executors of his estate and his insurers entered into a legal dispute over insurance payouts. The central issue in the civil proceedings was whether the patient had intentionally consumed an overdose of drugs which led to his death. The claim went on appeal and the Court of Appeal found that on the balance of probabilities, the patient had ingested no more than the prescribed doses of medication without expecting or anticipating that this would result in his death.

6.6 Shortly after the Court of Appeal issued its decision, the patient's sister filed a complaint with the Singapore Medical Council ("SMC") against Dr Ang in relation to his treatment and care of the patient. The SMC brought three charges against Dr Ang under s 53(1)(*d*) of the Medical Registration Act[4] ("MRA") for professional misconduct and three corresponding alternative charges under s 53(1)(*e*) of the MRA for failing to provide professional services of the quality that was reasonable to expect of him. A summary of the charges provided in the Court of Three Judges' decision is reproduced on the next page

3 *Ang Yong Guan v Singapore Medical Council* [2024] 4 SLR 1364 at [5].
4 Cap 174, 2014 Rev Ed.

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<table>
<tr><th>First pair of charges</th><th>Second pair of charges</th><th>Third pair of charges</th></tr>
<tr><td>Switching between antidepressants without ensuring that each was continued for at least 4 to 6 weeks</td><td>Allowing for long-term chronic use of benzodiazepines by prescribing a 6-months' supply to the Patient on 31 July 2012</td><td>Prescribing a daily dosage of 60mg of Mirtazapine, in excess of the permitted maximum daily dosage of 45mg</td></tr>
<tr><td colspan="2">Concurrently prescribing two or more benzodiazepines to the Patient on various occasions</td><td rowspan="4">Prescribing a daily dosage of 25mg of Zolpidem CR, in excess of the permitted maximum daily dosage of 12.5 mg</td></tr>
<tr><td colspan="2">Prescribing benzodiazepines to the Patient beyond the limit of short-term relief (2 to 4 weeks)</td></tr>
<tr><td colspan="2">Prescribing benzodiazepines to the Patient to treat his insomnia beyond the limit of intermittent use (for example, 1 night in 2 or 3 nights)</td></tr>
<tr><td colspan="2">Prescribing benzodiazepines despite being aware that the Patient was concurrently taking opioid analgesics</td></tr>
</table>

6.7 The DT found that Dr Ang did not have clear medical grounds for issuing any of the prescriptions, but that his conduct did not amount to an intentional or deliberate departure from the relevant standards of treatment as he had shown care and concern for the patient and attempted to meet the standards expected of him. However, the DT concluded that he had failed to meet the acceptable standards of clinical practice applicable to a psychiatrist. Dr Ang was therefore acquitted of the three professional misconduct charges but convicted on the three professional services charges and sentenced to a 24-month suspension.

A. Standard of care in relation to prescription of medication

6.8 On appeal, the Court of Three Judges first considered the relevant standard of care in relation to the prescription of medication in order to determine whether Dr Ang's departures were deliberate and intentional.

6.9 The court accepted that if there is a relevant MOH guideline that sets out a particular standard of care on prescriptions, the SMC would have discharged its burden of establishing the requisite standard of care and the medical practitioner's conduct should be assessed against the relevant MOH guideline. This is because MOH guidelines represent codifications of the standards observed or adopted by the medical profession and are based on the best available evidence at the time of development.

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6.10 In the absence of any relevant guidelines, the court accepted that recommendations on use of the medications as set out in their package inserts would constitute the standard of conduct applicable to prescriptions of these medications. The court reasoned that regulatory approval for local use of the medicines is based on the presumption that there is at least general adherence to the maximum dosages set out in their package inserts, which thus form the applicable standard of conduct governing prescriptions of these medicines. Medical practitioners prescribing the medicines are therefore expected to abide by the recommendations in the package inserts.

B. Deviations from guidelines

6.11 While the guidelines and package inserts set out a presumptive or baseline standard of care, the court acknowledged that this was not to say that a medical practitioner could *never* deviate from the standards codified in MOH guidelines. Guidelines do not have the same force as legislation, and departures are thus permissible in individual cases where there are proper justifications.

6.12 Crucially, the evidential burden falls upon the medical practitioner to demonstrate that the deviation from the relevant standards is justified or supported by good reasons. A deviation from a guideline represents a departure from the standard of care applicable to the medical practitioner, and therefore the burden falls upon the medical practitioner to show that the departure was justified.

6.13 As to the yardsticks to assess whether a departure from applicable standards is justified, the court did not agree with the test used by the DT. The court found that the DT's test focused on whether the doctor subjectively conducted a risk-benefit analysis to come to a reasoned conclusion that a departure was justified in the circumstances. In the court's view, it would be equally important for the doctor's conduct to be seen as objectively justifiable in the circumstances, which would ultimately depend on expert evidence.

6.14 The court also held that there are additional requirements in situations where the possibility of harm is sufficiently high and the potential consequences are of sufficient severity. In such cases, even if the risk is objectively justifiable, it would only be appropriate if the medical practitioner is able to show that he had advised the patient about the departure from guidelines and the inherent risks, and the patient had given his informed consent. That the court would stipulate this additional requirement based on the extent of potential harm and risks to the patient

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should come as no surprise in light of the primacy of the wider doctrine of informed consent in our medico-legal landscape.

6.15 In summary, the relevant principles to be distilled from the judgment are that a doctor 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 that a prospective departure from that standard is justified.

(b) The doctor's conduct is objectively defensible in the circumstances, as determined with reference to the prevailing test for medical negligence.

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

6.16 The first requirement is a subjective test as to whether the medical practitioner conducted a risk-benefit analysis regarding the decision to depart from relevant guidelines. Specific consideration must be given to the underlying rationale behind the medical guidelines that the doctor intends to depart from, and the risks that might materialise from such deviation. The court's emphasis on the centrality of the underlying rationale of the guideline in this risk-benefit analysis can be seen by the court's comment that where the guidelines themselves do not contain any express rationale, medical practitioners contemplating departures are to take reasonable steps to discover the underlying concern behind the guidelines, and take those concerns into account in their decision making.

6.17 The second requirement is an objective inquiry for which the prevailing test for medical negligence in Singapore (*ie*, the *Bolam-Bolitho* test) is to be applied.

6.18 As for the last requirement, it should be noted that the court declined to impose a blanket requirement that medical practitioners must inform patients about every single deviation from guidelines. However, where the intended deviation concerns the prescription of medication, as was the case in *Ang Yong Guan*, the duty of the doctor to appropriately inform patients about the medicines that are prescribed would extend to the fact that the prescription is a departure from prevailing standards, the rationale behind the standard, the risks inherent in the departure and the countervailing benefits that justify the departure. Doctors should

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therefore exercise caution and duly advise their patients accordingly whenever they find themselves in this clinical treatment scenario.

C. Decision of the court

(1) First and second pairs of charges

6.19 In relation to the first and second pairs of charges, Dr Ang explained that he discontinued the antidepressants earlier than the prescribed guidelines because the patient complained of side effects from these medications. The evidence to support this could be found in Dr Ang's clinical notes, which recorded that the patient reported feeling "xian", "feels tired this morning", and had other side effects of giddiness, headache, difficulties with sleeping, and poor mood. The court accepted Dr Ang's reasons for the discontinuation.[5]

6.20 The court also accepted Dr Ang's claim that he had articulated the need for long-term use of benzodiazepines to deal with the patient's chronic insomnia as this was supported by numerous instances where the patient's inability to sleep was documented in the clinical records. The court thus found that it was not inappropriate for Dr Ang to prescribe a 6-month supply of benzodiazepines to the patient. They also accepted that Dr Ang had considered the risks of dependence because he monitored the patient for signs of dependence and addiction through telephone and outpatient consultations and the patient was able to manage his medications responsibly. Dr Ang also had a plan to wean him off the benzodiazepine after certain events and various stressors had been resolved.

6.21 However, in relation to Dr Ang's decision to issue concurrent prescriptions of multiple benzodiazepines and benzodiazepines with opioid analgesics, the court found that Dr Ang had no justification apart from a general claim that the patient had a complex condition and that the benefits outweighed the risks of a concurrent use of drugs. The court found this explanation to be wanting, particularly in light of the evidence from the experts that the combination of these drugs has been well documented to cause significant side effects, including slowed or difficult breathing and even death. Consequently, the first and second professional misconduct charges were made out against Dr Ang on this aspect.

5 *Ang Yong Guan v Singapore Medical Council* [2024] 4 SLR 1364 at [93]–[105].

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(2) Third pair of charges

6.22 The third pair of charges concerns Dr Ang's prescription of a daily dose of 60mg of Mirtazapine and 25mg of Zolpidem CR, in excess of their respective maximum dosages of 45mg and 12.5mg as set out in their package inserts. Despite the fact that Dr Ang himself had conceded that these dosages went to the "edge of the killing range",[6] he was not able to adequately explain why he did so, or why he thought the risks to the patient were worth taking. All that was put forth in his defence was that his prescription was reasonable and appropriate in view of the patient's "multiple complex conditions which include chronic pain, insomnia, anxiety, depression, PTSD and personality issues".[7]

6.23 This proved to be inadequate in justifying the risks taken by Dr Ang. The court made it a point to reiterate that such general claims made without proper explanation of evidence in support of those claims, are not helpful. The court was not persuaded that the risks to the patient were sufficiently ameliorated so as to negate the presumption of inappropriate treatment. Given the number of different medications the patient was on, the potential drug interactions had to be accounted for when assessing if the increase in the prescription beyond the limits stated in the package inserts was justified in the circumstances. However, Dr Ang had not demonstrated that he had even considered it.

6.24 The third professional misconduct charge was thus made out against Dr Ang.

D. Sentencing

6.25 The court's decision on sentencing was handed down in a subsequent judgment that was only issued in 2025. Briefly, the court set aside the sentence imposed by the DT and imposed a suspension of 36 months on Dr Ang. The other orders made by the DT, namely, that Dr Ang was to be censured, that he was to give a written undertaking to refrain from engaging in the conduct complained of, or any similar conduct in the future, were upheld by the court.

III. Commentary

6.26 Dr Ang's conviction on the three charges of professional misconduct caused a bit of a stir within some segments of the medical

6 *Ang Yong Guan v Singapore Medical Council* [2024] 4 SLR 1364 at [145].
7 *Ang Yong Guan v Singapore Medical Council* [2024] 4 SLR 1364 at [137].

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fraternity. Doctors have expressed concerns that when they are asked to sit on committees tasked to propose treatment guidelines, it is never with the intention of making it easier to find fault with colleagues, nor would they want the guidelines to be viewed almost as mandatory requirements that will end up being binding or restrictive on practice. This is especially so in clinical fields of practice (including psychiatry) where there may be a significant number of cases where patients' conditions may not respond well to conventional treatment, and doctors find it necessary to push the boundaries of treatment guidelines in an effort to manage patients' severe symptoms.

6.27 Others have wondered if introducing what they view as legalistic tests to ascertain when a doctor can safely deviate from these guidelines could end up being problematic and impractical for the medical profession, as it could introduce additional considerations that a doctor must now take into account in clinical management. It has even been suggested that it could potentially distract the doctor from fulfilling their paramount duty to the patient—which is to clinically assess and treat patients based on their best interests and based on the patients' specific needs. Some doctors are concerned that they are being asked to undertake a detailed risk-benefit analysis based on "rigid" criteria set out by the courts, which will not only add to the consultation time, but is ultimately motivated by a need to protect oneself from medico-legal risk, rather than serve the patient.

6.28 In my experience, the fact that some within the medical profession have negative reactions in the immediate aftermath of a judgment that has had weighty consequences for the doctor concerned, is hardly surprising. Whenever adverse outcomes in professional discipline cases occur in the context of a challenging clinical setting, it tends to make other doctors worry if they too, may find themselves in similar peril. They end up focusing on the outcome, but may miss the wider message that the court is trying to deliver—that the court *does* understand the challenges doctors face whenever they treat patients who are not responding well to treatment, and appreciate the sense of urgency that doctors feel when they are trying to figure out what drug combinations will provide patients with relief from their symptoms. A proper examination of the court's grounds of decision would put paid to any claim that the courts are trying to foist unrealistic expectations on medical practitioners.

6.29 Some within the medical community have asked if doctors are now expected to laboriously record in their case notes what each guideline prescribes, the underlying rationale behind the particular directive/guideline in question that the doctor is intending to depart from, and the reasons for any departure. However, if we look at the facts of the

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case, it will become clear that these fears are misplaced. What Dr Ang actually documented was simply that the patient was "xian" and "feels tired this morning", and this was enough for the court to accept Dr Ang's explanation that the patient was indeed experiencing side effects from the antidepressants and that was why they were prematurely discontinued. This tells us that the court is not interested in quantity but the quality of the documentation. Doctors will not be penalised simply because they did not write copious notes.

6.30 What the court is trying to ascertain from the documentation is whether the doctor was applying his mind to the patient's circumstances and risks, based on symptoms reported by the patient and other clinical findings. For this very reason, the court may ascribe less weight to general documentation (for example, "risk-benefit analysis was conducted" and "benefits outweighed the risks"). These generalised statements, if used to justify deviations from guidelines (and especially when the deviations carry significant risks to the patient), do not actually tell us what was going on with the patient and what specific factors the doctor was taking into account. It is a timely reminder to the medical profession that they should stop thinking that incorporating generalised boilerplate statements within their medical documentation are necessarily meaningful or helpful. Medical documentation should not be perfunctory. It should inform us as to the doctor's thought process, the considerations that went behind the treatment plan, as well as provide insight into the doctor's appreciation of the risks involved and the clinical considerations that justified the departure from guidelines—in relation to *the particular patient*. What the court really wants to see is meaningful (rather than mechanical) and sufficient (rather than voluminous) documentation specific to the patient.

6.31 Apart from documentation, the Court of Three Judges is also reminding doctors that in the professional disciplinary setting, generalised statements to justify their conduct are unlikely to pass muster. It is incumbent upon doctors to go further and explain the rationale as well as considerations behind their treatment decisions and provide evidence to support their reasoning; all of which will be scrutinised by the tribunal or court.

6.32 At the end of the day, the *Ang Yong Guan* decision cannot be said to impose new or onerous requirements on medical practitioners, both in terms of how they advise and treat patients, and how that process is being documented. Rather, it provides helpful clarifications on why treatment guidelines and directives in medical practice are relevant and important, and it tells us that the court understands that there will be cases where doctors may need to deviate from those guidelines. All that the court asks is that doctors who find themselves in this situation be ready to explain

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why they did so, and they should do so with reference to specific factors that were pertinent to that patient, rather than simply falling back on general explanations and boilerplate statements.

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