G.N. 3964

MEDICAL REGISTRATION ORDINANCE (Chapter 161)

ORDER MADE BY THE INQUIRY PANEL OF THE MEDICAL COUNCIL OF HONG KONG

DR MAK WAN LING (REGISTRATION NO.: M15434)

It is hereby notified that after due inquiry held on 8 June 2022 in accordance with section 21 of the Medical Registration Ordinance, Chapter 161 of the Laws of Hong Kong, the Inquiry Panel of the Medical Council of Hong Kong ('Inquiry Panel') found Dr MAK Wan Ling (Registration No.: M15434) guilty of the following disciplinary charge:—

'That she, being a registered medical practitioner, was convicted at the High Court on 1 December 2020 of the offence of manslaughter by gross negligence, which is an offence punishable with imprisonment, contrary to Common Law and punishable under section 7 of the Offences against the Person Ordinance, Chapter 212, Laws of Hong Kong.

In relation to the facts alleged, either singularly or cumulatively, she has been guilty of misconduct in a professional respect.'

Dr MAK Wan Ling's name has been included in the General Register from 1 July 2007 to the present and her name has never been included in the Specialist Register.

By a letter dated 3 December 2020, Dr MAK informed the Medical Council (the 'Council') through her solicitors of her conviction after trial by a jury on 1 December 2020 of the offence of manslaughter by gross negligence.

Dr MAK was originally tried together with 2 other defendants, namely, CHOW Heung-wing and CHAN Kwun-chung, each facing one count of manslaughter. After a trial which took 100 days in 2017, the jury convicted the latter 2 defendants but was unable to reach a verdict in respect of Dr MAK. Dr MAK had to face a retrial on her own and she pleaded not guilty to the charge but was found guilty unanimously by a jury of 9.

Dr MAK lodged an appeal against her conviction. However, her application for leave to appeal was unanimously dismissed by the Court of Appeal on 9 March 2022.

In support of the Secretary's case, the Legal Officer also relied on the following court documents relating to Dr MAK, copies of which were placed before the Inquiry Panel for consideration:—

(1) Extracts from the transcript of proceedings at the retrial of Dr MAK;
(2) Reasons for Sentence by Mrs Justice Barnes dated 8 December 2020;
(3) Certificate of Conviction and Sentence dated 8 January 2021; and
(4) Judgment of the Court of Appeal dated 9 March 2022.

It was evident to the Inquiry Panel from reading the Certificate of Conviction and Sentence dated 8 January 2021 that Dr MAK was convicted by a jury after trial on 1 December 2020 of one count of 'Manslaughter (of xxx by gross negligence)' and she was sentenced on 8 December 2020 to imprisonment for 3 years 6 months.

The Inquiry Panel also noted from reading the Reasons for Sentence by Mrs Justice Barnes that:—

'4. This case centres upon a procedure known as CIK Therapy launched and marketed by the DR Group at the price of about $59,500 per treatment to customers including the deceased xxx.

5. At the material time, the DR Group was operating 38 beauty centres throughout Hong Kong, including the DR Esthetic Centre (Causeway Bay) Limited, Hong Kong Mesotherapy Centre Limited and a laboratory named Asia Pacific Stem Cell Science Limited (APSC).

6. The DR Group was owned and controlled by Chow Heung-wing. Chan Kwun-chung (Billy Chan) was employed by Chow Heung-wing as a technician working at APSC. The defendant was a qualified medical doctor (a GP) employed to work at clinics under the DR Group.

7. CIK Therapy involved the drawing of a quantity of blood from a client of the DR Group at a clinic. The blood was then sent to APSC for processing. The processing involved the use of cytokine to induce the growth of killer cells for a period of around 14 days, at a temperature of 37

degrees Celsius and 100% humidity. The processed blood product was then infused back into the same client.

8. Three women, xxx, Wong Fung Kwan (WongFK) and Wong Ching Bor (WongCB), had their blood extracted by the defendant on 12 September 2012 at the Causeway Bay clinic. Explanation about the CIK Therapy was given by the defendant during consultation to each of the three women prior to the extraction of blood. The extracted blood was sent to APSC for processing.

9. Evidence before this Court showed that most people working at APSC were not aware of the fact that CIK processing was taking place there. Evidence also showed that Billy, the person responsible for the processing of CIK cells, did not cause processed blood products to undergo any sterility tests, including bacterial tests, despite the fact that there were persons qualified and equipment available at APSC to carry out such tests.

10. Evidence also showed that during the processing at APSC of the blood extracted from the three women, and other women including Chow Yan Yan (ChowYY) who was the elder sister of Chow Heung Wing, their blood products became contaminated with bacteria known as Mycobacterium Abscessus.

11. Due to the lack of any bacterial tests, the presence of Mycobacterium Abscessus was not detected and the contaminated blood products, including the blood product of xxx, were sent out of APSC on 3 October 2012 to the Causeway Bay clinic for infusion.

12. The defendant did not check with APSC to see whether bacterial tests had been conducted on the processed blood products of the three women prior to infusion. She said in evidence that she trusted APSC and expected that such a basic and fundamental step would have been carried out by the laboratory.

13. The contaminated infusate of each of the three women was infused directly into their blood streams by the defendant on 3 October 2012.

14. In the case of xxx, she went home after the infusion and felt unwell. She went to consult a doctor in private practice that same night, accompanied by her daughter. She was still unwell in the next morning, complaining to her daughter that the pain was worse than being in labour when giving birth. Her daughter accompanied her to go to the Causeway Bay clinic to look for the defendant. As the defendant was conducting an operation in another clinic in Mongkok, an ambulance was called and xxx was sent to the Ruttonjee Hospital.

15. xxx was diagnosed to be suffering from septicaemia, shock, disseminated intravascular coagulopathy, and adult respiratory distress syndrome. Blood culture of her blood confirmed she was suffering from systemic bacterial infection caused by Mycobacterium Abscessus.

16. Despite efforts by the doctors at the ICU, she died on 10 October 2012, a week after the infusion. The cause of death was 'Multi-organ Failure' due to 'Mycobacterium Abscessus septicaemia'.

17. The defendant was charged with the unlawful killing of xxx by Gross negligence. There was no dispute that the defendant was a properly registered doctor responsible for administering the CIK blood product to xxx and that she owed a duty of care to xxx, her patient.

18. There were four particulars of breach alleged in the indictment:—

2(a) failure to ensure a properly accredited laboratory or a properly qualified person was responsible for the preparation and production of the processed blood product of xxx;

2(b) failure to ensure bacteria tests had been conducted on the said blood product and that such tests had been documented prior to administering it to xxx;

2(c) administering the CIK Therapy to xxx without first having obtained from xxx a proper consent by reason of the defendant's failure to inform xxx:—

(i) that CIK Therapy was still experimental for cancer patients and its efficacy was unproven or uncertain;

(ii) there was no scientifically proven benefit to be derived from CIK Therapy on healthy patients such as xxx;

(iii) the preparation of CIK Therapy involved culturing of blood cells in a medium exposed to open air during a period of time thus it carried a risk of infection or contamination of the patient on whom it was administered;

(iv) the administration of CIK Therapy had risks of adverse effects or reactions which could be life-threatening;

(v) there were various safe and non-invasive alternative means for enhancing or improving immunity in human bodies and the use of CIK Therapy was not necessary or medically indicated; and finally.

2(d) failing to give sufficient regard for the fact that the intended use of CIK Therapy on xxx ought not to have been carried out in the circumstances.

19. As the jury unanimously found the defendant guilty of manslaughter by gross negligence, having been directed on the 5 ingredients that the prosecution had to prove so as to make them sure of the defendant's guilt, namely:—

(1) The defendant owed an existing duty of care to the deceased;

(2) The defendant negligently breached that duty of care;

(3) It was reasonably foreseeable that the breach of that duty gave rise to a serious and obvious risk of death;

(4) The breach of that duty caused the death of the deceased; and

(5) The circumstances of the breach were truly exceptionally bad and so reprehensible as to justify the conclusion that it amounted to gross negligence and required criminal sanction.

The jury must have found that the defendant was in breach of her duty to xxx, that it was reasonably foreseeable that the breach of that duty gave rise to a serious and obvious risk of death and indeed caused the death of the deceased xxx. They must have also been satisfied that the circumstances of the breach were truly exceptionally bad and so reprehensible so as to justify the conclusion that it amounted to gross negligence and required criminal sanction…

45. In the case of the victim xxx, she was a healthy woman of 46 at the time… When xxx consulted the defendant on 12 September 2012, before her blood was extracted, xxx was not told that CIK Therapy was an experimental treatment for cancer patients and its efficacy had not be(en) proven; she was not told that there was no scientific proof that CIK therapy was of benefit to a healthy person; she was not told of the risk of bacterial contamination during the processing at a laboratory; nor was she told of the risk of adverse reaction upon infusion due to contamination or infection; she was also not advised that were simple and non-invasive alternative methods for boosting her immunity instead of the CIK Therapy. If xxx had been told of all of the above, I venture to say it would be highly unlikely that she would have consented to the treatment.'

For the purpose of sentencing, Mrs Justice Barnes was prepared to assume that 2(b) to (d) but not 2(a) of the particulars of breach had been proved on the strength of the evidence adduced.

In dismissing the Defendant's application for leave to appeal, the Court of Appeal aptly pointed out in its Judgment (at 51) that it is a matter of common sense that 'a doctor does not simply infuse a blood product which comes into his possession without knowing its provenance and integrity'.

The Court of Appeal also quoted in its Judgment (at 7), amongst others, the following evidence of one of the prosecution experts, whose research field was concerned with haematology, oncology and stem cell transplantation, regarding the Defendant's failure to obtain informed consent:—

'…Professor Li was further of the opinion that, despite the fact that the deceased had signed a consent form and a note about the injection, the information provided to the customers of the DR Group (including the deceased) concerning CIK treatment was insufficient and misleading for a number of reasons, inter alia…:—

'There was no information about manipulation of the cells in a laboratory with addition of cytokines and other reagents, and also culture and expansion of cells in a sterile environment';

and…

'(The applicant) did not give (the deceased) any information on potential serious side effects of this experimental treatment;

and…

'…CIK cell infusion in this particular setting is experimental and did not have any evidence supporting its medical value. If the doctor wants to study an experimental therapy, it should be performed in the setting of clinical research with proper approval. The possible side effects, including common, uncommon and rare, should be elaborated in the consent form. Patients must be protected from being harm(sic.) during the research… Patients must be provided with sufficient information to make a decision of accepting the treatment or not, otherwise the consent will not be valid.'

Since Dr MAK's application for leave to appeal had already been unanimously dismissed by the Court of Appeal, the Inquiry Panel was entitled to take her conviction as conclusively proven against her. Accordingly, the Inquiry Panel found Dr MAK guilty of the disciplinary offence as charged.

The Inquiry Panel emphasized that unless the jury found all the 5 ingredients of the offence proved beyond reasonable doubt, Dr MAK ought to be acquitted. It followed that in convicting Dr MAK of the offence of manslaughter by gross negligence, the jury should have found Dr MAK's conduct 'fell so far short of what could reasonably be expected of her' as a registered medical practitioner in Hong Kong and was 'so bad as to warrant criminal sanction'.

The Inquiry Panel echoed the view of the Court of Appeal that it is a matter of sense that *'a doctor does not simply infuse a blood product which comes into his possession without knowing its provenance and integrity'* and supplemented that the first principle in medical practice is to *'do no harm to the patient'*.

Manslaughter is no doubt one of the most serious crimes and Dr MAK had brought the medical profession into disrepute. Not only did she fail to obtain informed consent from the Patient, worse still, Dr MAK had exposed the Patient to significant risks of bodily harm by giving her 'an experimental treatment for cancer patients and its efficacy had not been proven' on healthy persons.

Taking into consideration the nature and gravity of this case and the mitigation plea on her behalf, the Inquiry Panel ordered that the name of Dr MAK be removed from the General Register for a period of 5 years.

Pursuant to the Inquiry Panel's orders, Dr MAK's name has been removed from the General Register on 29 July 2022.

The order is published in the *Gazette* in accordance with section 21(5) of the Medical Registration Ordinance. The full decision of the Inquiry Panel of the Medical Council is published in the official website of the Medical Council of Hong Kong (http://www.mchk.org.hk).

LAU Wan-yee, Joseph *Chairman, The Medical Council of Hong Kong*