G.N. 7753

MEDICAL REGISTRATION ORDINANCE (Chapter 161)

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

DR HAU MELANIE (REGISTRATION NO.: M18140)

It is hereby notified that after due inquiry held on 31 October 2023 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 found Dr HAU Melanie (Registration No.: M18140) guilty of the following charges:

> *"That on 1 March 2018, she, being a registered medical practitioner, disregarded her professional responsibility to her patient Madam LEE ("the Patient"), in that :*
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> *(i) she prescribed Denosumab (Xgeva) to the Patient without clinical indication; and/or*
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> *(ii) she failed to properly advise the Patient on the risks and/or potential side effects of Denosumab (Xgeva).*
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> *In relation to the facts alleged, either singularly or cumulatively, she has been guilty of misconduct in a professional respect."*

2. The Patient was admitted to Queen Mary Hospital ("QMH") for right pleural effusion from 15 to 18 September 2017 and was confirmed through pleural fluid cytology to be EGFR exon 19 mutated lung adenocarcinoma. She was reviewed by QMH respiratory team on 27 September 2017. Erlotinib 150mg per day was prescribed to treat Stage IV non-small cell lung cancer based on finding of malignant pleural effusion. Reduction in size of lung tumour and amount of pleural effusion on the same side indicated a favourable response on PET-CT imaging performed on 31 January 2018.

3. On 13 February 2018, the Patient saw a Professor MOK ("Prof. MOK") at Hong Kong Sanatorium & Hospital Comprehensive Oncology Centre for a second opinion. Consultation Notes of Prof. MOK showed that Prof. MOK recommended the Patient to consider a dose reduction of Erlotinib 150mg per day to 100mg per day should the skin toxicity of the drug become intolerable. No discussion was documented regarding Denosumab nor associated topics of osteopenia, osteoporosis of bone abnormalities.

4. On 23 February 2018, the Patient had a blood test, including blood calcium levels. Her calcium levels were normal.

5. On 1 March 2018, the Patient returned to QMH Respiratory Clinic for review and consulted Dr HAU. Dr HAU prescribed the Patient with Denosumab (Xgeva). A nurse at the clinic then administered Denosumab (Xgeva) injection on the Patient on the same day.

6. For several days after the Denosumab (Xgeva) injection, the Patient felt more skin rash, dry mucosal membranes (mouth, eyes and skin), diarrhea, and mild epistaxis, as well as a generalized feeling of heat and chills.

7. On 8 March 2018, the Patient went back to QMH Respiratory Clinic and saw a Dr WANG, an Associate Consultant. Dr WANG told the Patient that there was no indication for Denosumab given the lack of bone metastases all along on the Patient's PET-CT scans since her lung cancer

diagnosis.

8. By way of a statutory declaration made on 23 January 2019, enclosing her complaint letter dated 20 March 2018, the Patient lodged a complaint against Dr HAU with the Medical Council.

9. The Inquiry Panel agreed with the Secretary's expert report that Denosumab (Xgeva) is licensed for the management of bone metastases or hypercalcemia of malignancy, both of which could occur in the setting of lung cancer, but was never confirmed by blood test nor whole-body PET-CT scans for the Patient. There was therefore no clinical indication for the Denosumab (Xgeva).

10. By prescribing Denosumab (Xgeva) to the Patient without clinical indication, Dr HAU had in the view of the Inquiry Panel fallen below the standards expected of medical practitioners in Hong Kong. Accordingly, Dr HAU was found guilty of misconduct in a professional respect under charge (i).

11. The Inquiry Panel gratefully adopted as its guiding principles the following statements of law expounded in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11:-

> *"87. ... The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.*
> *...*
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> *90. ... the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible ..."*

12. The Secretary's expert told in her report that Denosumab (Xgeva) is associated with potential side effects of low blood calcium levels (hypocalcemia), which could be serious. Patients should be warned about symptoms of hypocalcemia prior to and after receiving Denosumab (Xegeva). There are small but real risks of allergic reactions, osteonecrosis of the jaw with Denosumab (Xgeva). Atypical subtrochanteric and diaphyseal femoral fractures have been reported after Denosumab, but these conditions are at best rare. With the exception of hypercalcemia of malignancy, there is no other urgent indication to prescribe Denosumab (Xgeva). Patients should be recommended to undergo dental check-up and preventive intervention prior to receiving the drug. The Inquiry Panel agreed with the view of the Secretary's expert.

13. According to the Patient's complaint letter, during the consultation with Dr HAU on 1 March 2018, the Patient had asked Dr HAU if the injection of Denosumab (Xgeva) would have any adverse effect. The Patient said that Dr HAU told her that there would not be any bad effect. In any event, it was noted that Dr HAU had never documented in her clinical record that she had advised the Patient of the risks and/or potential side effects of Denosumab (Xgeva). Further, Dr HAU admitted before the Inquiry Panel that she had failed to properly advise the Patient on the risks and/or potential side effects of Denosumab (Xgeva).

14. The Inquiry Panel was satisfied that Dr HAU had not properly advised the Patient of the risks and potential side effect of Denosumab (Xgeva). Dr HAU had in the view of the Inquiry Panel fallen below the standards expected of medical practitioners in Hong Kong. Accordingly, Dr HAU was found guilty of misconduct in a professional respect under charge (ii).

15. Taking into consideration the nature and gravity of the case against Dr HAU and what the Inquiry Panel had read and heard in mitigation, the Inquiry Panel made a global order in respect of disciplinary charges (i) and (ii) that the name of Dr HAU be removed from the General Register for a period of 1 month, and that the operation of the Order be suspended for a period of 6 months.

16. The orders are published in the Gazette in accordance with section 21(5) of the Medical Registration Ordinance. 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*