From the President's Office
Dr Kean-Seng Lim

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Legal and Regulatory Services Branch
NSW Ministry of Health
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By Email: MOH-cosmeticregulation@health.nsw.gov.au

Re: **H19/136229**

Thank you for the opportunity to provide a submission to the draft Poisons and Therapeutic Goods Amendment Regulation 2020, which seeks to improve the safe use of products commonly used in cosmetic procedures in NSW within the remit of the Poisons and Therapeutic Goods Act 1966.
AMA (NSW) made a submission to NSW Health regarding Proposed Changes to the Poisons and Therapeutic Goods Regulation 2008 in September 2018 to provide guidance and relevant clinical context around the use of botulinum toxin and hyaluronic acid dermal fillers and to inform the development of regulations and related policy that reflect best practice standards and ensure patient safety.
AMA (NSW) strongly supported NSW Health's consideration of tailored regulations in relation to medicines in this new classification.

This submission is in response to NSW Ministry of Health's subsequent consultation on the draft Poisons and Therapeutic Goods Amendment Regulation 2020 (the draft regulation) which will amend the Poisons and Therapeutic Goods Regulation 2008 (PTGR).

The main aim of the draft regulation is to improve the safe use of cosmetic medicines in NSW within the remit of the PTGA. The draft regulation is targeted to providing the requirements for the storage, administration and record keeping regarding the following substances:

- Botulinum toxins
- Hyaluronic acid
- Deoxycholic acid
- Polyacrylamide, and
- Polylactic acid.

In particular, that administration of the above substances to a patient outside a hospital/clinical setting will only be legal where it is administered by a nurse acting on the direction of an *authorised practitioner*. The

draft regulation aims to clarify and tighten the regulation of administration, record-keeping and storage of these substances, with a particular focus on certain business and clinical models.

With regard to the Questions for Consideration in the Discussion Paper, AMA (NSW) would like to submit the following responses:

LIMITING THE IMPACT ON NON-COSMETIC USES OF COSMETIC MEDICINES

1. Are there any other situations or groups which should be exempt from the scope of the draft regulation?

No, AMA (NSW) does not recommend an exemption to other situations or groups from the scope of the draft regulation.

2. Will the requirements in the draft regulation impose a significant additional regulatory burden on persons who handle or use cosmetic medicines for non-cosmetic reasons?

No, AMA (NSW) does not believe the requirements in the draft regulation will impose a significant additional regulatory burden on persons who handle or use cosmetic medicines for non-cosmetic reasons.

3. N/A

PROHIBITING ADMINISTRATION OF ILLEGALLY MANUFACTURED OR IMPORTED COSMETIC MEDICINES

4. Are there any circumstances in which prohibition would add an additional burden to businesses or persons in the cosmetic medicine industry?

AMA (NSW) supports the draft regulation prohibiting administration of illegally manufactured or imported cosmetic medicines and feel this will provide necessary safeguards to patients put at risk through the use of illegally imported cosmetic medicines, which are of unknown quality, safety and efficacy.

However, with regard to the pharmacy-compounded products, we note that dermatologists often compound products not available in Australia, using approved ingredients. We support that when used appropriately by trained medical practitioners, this is a safe practice.

RESTRICTING WHO CAN ADMINISTER COSMETIC MEDICINES

5. Is it appropriate to allow ENs to administer cosmetic medicines under the direction of an authorised practitioner (when acting under the direct or indirect supervision of an RN)?

AMA (NSW) does not support the inclusion of ENs to administer cosmetic medicines. This inclusion would allow an RN to supervise an EN outside of the supervision of a medical practitioner. AMA (NSW) recognises that it is standard practice for nurses with the appropriate skills and training to administer injections after a face-to-face consultation with a doctor has occurred. AMA (NSW)

suggests that the prescribing medical practitioner must be contactable and able to respond promptly in the case of an adverse event. Complications such as vascular occlusions are medical emergencies, and the doctor authorising the treatment needs to make sure that proper training and protocols are in place to protect the patient should these complications occur. The doctor needs to be available within a reasonable time to tend to such complications. AMA (NSW) suggests that in circumstances where a nurse is authorised by a doctor to administer a cosmetic treatment, that it is incumbent upon the doctor to ensure the nurse is adequately trained and skilled in delivering the treatment.

6. Are there any other types of health practitioners who should be permitted to administer cosmetic medicines under the direction of an authorised practitioner?
No, AMA (NSW) does not support the inclusion of other types of health practitioners to be permitted to administer cosmetic medicines under the direction of an authorised practitioner.

DIRECTIONS FOR ADMINISTRATION

7. Does allowing oral directions to be given where the authorised practitioners will be on site during the administration pose an unacceptable risk to patients?

AMA (NSW) suggests oral instructions should be accompanied by written instructions to limit the possibility of miscommunication and error.

8. Are the details required to be included in written or oral directions appropriate? Should any details be removed or added to these requirements?

Yes, the details required to be included in written or oral directions are appropriate.

9. Is the maximum 6-month validity for written directions appropriate?

Yes, AMA (NSW) recommends a maximum 6-month period as a patient's medical circumstances can change, therefore it is necessary to keep consultations current and up to date to ensure procedure and treatment is appropriate for the patient. This is in keeping with PBS prescribing practices.

PERSONS PROVIDING COSMETIC SERVICES

10. Is it appropriate for individuals, corporations, partnerships and other legal 'persons' which provide cosmetic medicines services to have obligations in relation to the cosmetic medicines used in their business?

Yes, AMA (NSW) supports that it is appropriate for individuals, corporations, partnerships and other legal 'persons' which provide cosmetic medicines services to have obligations in relation to the cosmetic medicines used in their business.

11. Are there any types of cosmetic medicine service provided that should be added or omitted from the definition of 'responsible provider'?

No, AMA (NSW) has no additions or omissions to make in this regard.

RECORD-KEEPING

13. Are there any details which should be added or omitted from the information RNs and ENs must include in a record of administration?

No, no details to add or omit.

14. Do the draft record keeping requirements impose obligations that are additional to what is generally regarded as best practice in the industry?

No, the draft record keeping requirements do not impose obligations that are additional to what is generally regarded as best practice in the industry.

STORAGE

15. Would you need to make changes to your current procedures or practices to comply with the draft regulation?

N/A

15. N/A

OTHER SUBSTANCES THAT SHOULD BE SUBJECT TO THE NEW REQUIREMENTS

16. Should any other Schedule 2 – 4 or Schedule 8 substances, or other therapeutic goods, be subject to the draft regulation?

Cosmetic medicine is constantly evolving, and new products will emerge that will require regulation. At the moment, AMA (NSW) notes that Calcium hydroxylapatite, a dermal filler, should also be subject to the draft regulation.

17. Should equipment for resuscitation (crash carts) be required to be kept at premises where administration of the regulated substances occur? Should this be the responsibility of the provider?

No, 'crash carts' are not required equipment.

Yours sincerely,

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