



Health

DISCUSSION PAPER

Amendments to the
Poisons and Therapeutic Goods Regulation 2008
Regulation of products commonly used in cosmetic
procedures

Executive Summary

The Ministry of Health is consulting on the draft Poisons and Therapeutic Goods Amendment Regulation 2020 (**the draft regulation**) (**Attachment A**) 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 *Poisons and Therapeutic Goods Act 1966 (PTGA)*. The draft regulation is not intended to respond to all concerns that stakeholders may have in relation to the cosmetic industry and cosmetic medicines. 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, administration of the above substances to a patient outside a hospital/clinical setting¹ will only be legal where it is administered by a nurse acting on the direction of an *authorised practitioner*². Further, 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.

The Ministry of Health would like to hear submissions on the issues raised in this paper. Submissions should be sent via email to MOH-CosmeticRegulation@health.nsw.gov.au or sent in hardcopy to:

Legal and Regulatory Services Branch
NSW Ministry of Health
Locked Bag 961
NORTH SYDNEY 2059

Submissions should include the reference **H19/136229** and must be received by **13 April 2020**.

¹ For example, administration by an authorised practitioner or in a hospital is considered a hospital/clinical setting

² An *authorised practitioner* is a medical practitioner, dentist, nurse authorised under s.17A of the PTGA, optometrist authorised under s.17B of the PTGA or podiatrist authorised under s.17C of the PTGA

Background

Various pieces of Commonwealth and NSW legislation regulate activities involving cosmetic medicines. The primary role of the PTGA is to protect public health and safety by controlling access to, and the availability of, medicines and poisons listed in the ten classes – known as Schedules - of the Commonwealth *Poisons Standard (Poisons Standard)* in NSW.³

All of the current cosmetic medicines are in Schedule 4 of the Poisons Standard. The PTGA and PTGR are intended to restrict the access and availability of Schedule 4 medicines in NSW in accordance with the recommendations in the Poisons Standard. **Appendix B** provides detailed information about the key aspects of the regulatory regime for Schedule 4 medicines for human use.

The PTGA and PTGR controls are based on traditional healthcare and business models. They assume that patients generally obtain Schedule 4 medicines from a hospital or public health clinic; the private practice of their local authorised practitioner (e.g. a medical or dental practice); or their local pharmacy on the prescription of an authorised practitioner.

Many businesses in the cosmetic industry do not follow these traditional models. In many cases, cosmetic medicines are administered at clinics which are not owned or operated by authorised practitioners. Sometimes a clinic may employ or engage the authorised practitioner on a contractual basis to legally obtain and supply the cosmetic medicine, and where the consultation with the patient is commonly by audiovisual link.

Anecdotal evidence reported to the Ministry of Health (**Ministry**), the Minister and in the media, as well as evidence collected during Ministry investigations, suggests that the PTGA and PTGR do not adequately address the risks associated with these business and clinical models.

The Ministry of Health reviewed the regulation of cosmetic procedures

In late-2017, the NSW Minister for Health,⁴ the Hon Brad Hazzard MP, directed the Ministry to review the appropriateness of the NSW regulation of cosmetic procedures for ensuring consumer safety. This followed the death of a woman who underwent a non-surgical breast augmentation in inner-Sydney.

In April 2018, the Ministry released its *Report on the Review of the Regulation of Cosmetic Procedures (Ministry Report)*.⁵ The Ministry Report noted concerns arising from Ministry investigations about the use of medicines and medical devices such as botulinum toxins and hyaluronic acid dermal fillers in the cosmetic industry.

³ The medicines and poisons in the Poisons Standard are used in many industries, and required in many health and veterinary products, but also carry public health and safety risks if misused or diverted for criminal purposes. The Poisons Standard contains recommendations as to the controls that States/Territories should impose on medicines and poisons in the different Schedules of the Poisons Standard. These recommendations are primarily adopted in NSW through the PTGA and the *Drug Misuse and Trafficking Act 1985*.

⁴ Now the Minister for Health and Medical Research

⁵ NSW Ministry of Health *Report on the Review of the Regulation of Cosmetic Procedures* (April 2018)
<https://www.health.nsw.gov.au/patients/cosmetic/Pages/default.aspx>

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The Ministry Report recommended, amongst other things:

- The creation of a new subclass of Schedule 4⁶ medicines used in non-surgical cosmetic procedures in the PTGA, to allow for the introduction of tailored rules in the PTGR relation to the storage, use and administration of these medicines [Recommendation 7];
- Stakeholder consultation occurs before the making of the tailored rules [Recommendation 8];
- Increasing the penalties for breaching the PTGA and PTGR [Recommendation 9].

The PTGA was amended as recommended in the Ministry Report

On 30 May 2018, Part 3 Division 1A was introduced into the PTGA. It allows tailored regulations to be made in relation to botulinum toxins, hyaluronic acid for injection or implantation and any other substance or therapeutic good that may be specified in the PTGR (**cosmetic medicines**).⁷ The regulations can be about possession, manufacture, supply, use, prescription, administration, storage and disposal of cosmetic medicines and carry two types of penalties:

- in the case of a requirement identified in the regulations as a **category 1 requirement**— 1,000 penalty units in the case of a body corporate or 200 penalty units or imprisonment for 6 months (or both) in the case of an individual, or
- in the case of a requirement identified in the regulations as a **category 2 requirement**— 250 penalty units in the case of a body corporate or 50 penalty units in any other case.

Public consultation was undertaken on proposed PTGR changes

The Ministry conducted public consultation about the proposed regulations to be made under the new Division 1A in late-2018. The responses revealed diverse stakeholder views about the appropriate regulation of cosmetic medicines as well as the cosmetic industry more broadly.

The Ministry has prepared the draft regulation for the purpose of further public consultation, having regard to the issues arising from the public consultation that fell within the PTGA remit. The draft regulation is not intended to respond to all concerns that stakeholders may have in relation to the cosmetic industry and cosmetic medicines. Issues outside scope of the draft regulation and this consultation process are detailed at **Appendix A**.

⁶ Substances listed in Schedule 4 of the *Poisons Standard* (Cth), as updated from time-to-time, which is adopted pursuant to the *Poisons and Therapeutic Goods (Poisons List) Proclamation 2016* as Schedule 4 of the Poisons List for the purpose of s.8 of the PTGA

⁷ The Ministry acknowledges that hyaluronic acid is often presented in the form of a medical device rather than a medicine, and that botulinum toxins and hyaluronic acid also have non-cosmetic uses. However, this Discussion Paper uses term ‘cosmetic medicines’ so as to distinguish these products from cosmetic products that are not therapeutic goods (e.g. moisturisers) and reinforce that the focus of the draft regulation is on cosmetic uses of these products.

Content of Regulation and Discussion questions

Limiting the impact on non-cosmetic uses of cosmetic medicines

Draft regulation

The draft regulation does not apply to the:

1. administration of a *relevant substance* in any of the following circumstances—
 - to a patient by an *authorised practitioner* in the lawful practice of the practitioner's profession
 - to a patient in a hospital by a person employed at the hospital on the direction of an authorised practitioner,
 - to an animal by a veterinary practitioner in the lawful practice of the practitioner's profession or by another person on the direction of a veterinary practitioner,
2. storage of a relevant substance for the purposes of administration referred to above; and
3. storage of a relevant substance at a pharmacy.

The draft regulation is only seeking to regulate the risks associated with certain businesses and persons. For example, administration of a cosmetic medicine by an *authorised practitioner*⁸ in the lawful practice of the practitioner's profession does not carry the degree of risk as administration by a person in a non-clinical setting. Therefore, administration to a patient by an *authorised practitioner* and administration (on the direction of an authorised practitioner) in public hospitals and health institutions, licensed private health facilities and nursing homes are excluded from the draft regulation. This is because the PTGR already imposes additional restrictions on administration, storage and record-keeping in these circumstances. Other regulatory regimes control the use of medicines in animals and are therefore also excluded from the application of the regulation.

To the extent the above exclusions do not apply, the draft regulation applies to cosmetic and non-cosmetic uses of cosmetic medicines. This includes the use of botulinum toxins in the treatment of focal spasticity in juvenile cerebral palsy or in adults, or the prophylaxis of headaches in adults with chronic migraine.

As the draft regulation aims to formalise what is generally considered to be good clinical practice, it is expected that the impact for those who administer non-dispensed cosmetic medicines for non-cosmetic uses outside of hospitals will be minimal.

Questions for consideration

1. Are there any other situations or groups which should be exempt 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?
3. If so, how could this burden be minimised in the draft regulation (e.g. by changing the content of the draft regulation)?

⁸ An *authorised practitioner* is a medical practitioner, dentist, nurse authorised under s.17A of the PTGA, optometrist authorised under s.17B of the PTGA or podiatrist authorised under s.17C of the PTGA

Prohibiting administration of illegally manufactured or imported cosmetic medicines

Draft regulation

The draft regulation prohibits the administration of a cosmetic medicine that:

- is not in the Australian Register of Therapeutic Goods (**ARTG**), and
- has not otherwise been lawfully manufactured in, or imported into, Australia for use in Australia pursuant to the *Therapeutic Goods Act 1989* (Cth).

Breaching this provision carries a penalty of up to **1,000 penalty units in the case of a body corporate or 200 penalty units or imprisonment for 6 months (or both) in the case of an individual.**

The *Therapeutic Goods Act 1989* (Cth) ensures the quality, safety and efficacy of therapeutic goods that are available in Australia, by prohibiting therapeutic goods being imported into, or manufactured or wholesale supplied in, Australia unless they have been:

- registered, listed or included in the ARTG, which generally follows an assessment of their quality, safety and efficacy by the Commonwealth Therapeutic Goods Administration (**TGA**), or
- exempted from the ARTG requirement, or
- approved or authorised by the Commonwealth Health Secretary for importation into, or manufacture or supply in, Australia as non-ARTG goods.

In addition, the PTGA prohibits retail supply of medicines which have been imported into, or manufactured in, Australia in breach of the *Therapeutic Goods Act 1989*. The intention is that pharmacy-compounded products could not be administered.

The draft regulation ensures that it will also be an offence for a person who provides the service of administration of cosmetic medicines in the course of a business to allow administration of cosmetic medicines that have been illegally imported into or manufactured in NSW. This will address concerns that some NSW patients are being put at risk through the use of illegally imported cosmetic medicines, which are of unknown quality, safety and efficacy.

Most cosmetic medicines used in NSW will be in the ARTG. The ARTG can be searched on the TGA website and cosmetic medicines in the ARTG should be labelled with an ARTG number (AUST R or AUST L) or ARTG ID. Authorised practitioners, RNs and ENs should contact the TGA or the Ministry if they have questions about whether the cosmetic medicines meet these requirements.

Questions for consideration

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

Restricting who can administer cosmetic medicines

Draft regulation

A person must not (other than in the excluded scenarios outlined above) administer a cosmetic medicine to a human in NSW unless they are:

- an **authorised practitioner**, being a medical practitioner, a nurse practitioner authorised by the Health Secretary, a dentist and, if they have been endorsed by their national Board for Scheduled medicines, a podiatrist, optometrist, or nurse or midwife, or
- a registered nurse (**RN**) or enrolled nurse (**EN**) acting on the direction of an authorised practitioner.¹

Breaching this provision carries a penalty of up to **1,000 penalty units in the case of a body corporate or 200 penalty units or imprisonment for 6 months (or both) in the case of an individual.**

This requirement is consistent with the PTGR requirement for staff of public hospitals and health institutions, private health facilities and nursing homes to only administer Schedule 4 medicines to patients on the direction of an authorised practitioner. It also reflects:

- the Australian Health Ministers Advisory Council *Scheduling Policy Framework for Medicines and Chemicals* which notes that '*[f]or human medicines, a requirement for administration by injection will usually mean medical or dental supervision is required because of the additional risks and complexity of this route of administration*', and
- the sentiment expressed by many stakeholders that non-registered health practitioners should not be administering cosmetic medicines.

The Ministry notes that the draft regulation sets a minimum standard of qualification for those handling cosmetic medicines. Authorised practitioners, RNs and ENs will still be expected to act within their scope of practice, and in accordance with their professional obligations. For example:

- practitioners must ensure they practice within the limits of their competence, having regard to their education, skills and training
- authorised practitioners must ensure that any RN or EN that they direct to administer a cosmetic medicine has adequate training, experience and qualifications and is appropriate supervised; and
- ENs will generally still be expected to act under the direct or indirect supervision of an RN, as per the Nursing and Midwifery Board of Australia *Enrolled Nurse – Standards for Practice*.⁹

Questions for consideration

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)?
6. Are there any other types of health practitioners who should be permitted to administer cosmetic medicines under the direction of an authorised practitioner?

⁹ Nursing and Midwifery Board of Australia *Enrolled Nurse – Standards for Practice* (1 January 2016) <<https://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Professional-standards/enrolled-nurse-standards-for-practice.aspx>> (Last accessed 17 December 2019)

Directions for administration

Draft regulation

The draft regulation sets out the requirements for an authorised practitioner giving a valid direction to an RN or EN.

Firstly, before giving the direction, the authorised practitioner must have personally reviewed the patient either in person or via audiovisual link. Telephone consultation will not be permitted. Breaching this provision carries a penalty of up to **1,000 penalty units in the case of a body corporate or 200 penalty units or imprisonment for 6 months (or both) in the case of an individual.**

Secondly:

- if the authorised practitioner will not be on site when the cosmetic medicine is administered in accordance with the direction, the direction must be in writing
- if the authorised practitioner will be on site when the cosmetic medicine is administered in accordance with the direction, the direction can be given orally or in writing.

Written directions can be communicated in hardcopy or electronic form and can authorise multiple treatment sessions over the 6 month period following the authorised practitioner's consultation with the patient. To be effective, written directions must:

- contain the information in **clause 68E(2)**, including details of the proposed administration (e.g. the number of times, and the intervals at which, the relevant substance is to be administered), and
- be signed (electronically or in ink) by the authorised practitioner.

Oral directions can authorise a contemporaneous treatment only and must contain the information in **clause 68E(5) and clause 68E(8)**. Authorised practitioners are required to make a written record of oral directions (containing the information set out at **clause 68E(8)**) within a reasonable amount of time following the giving of the direction).

Breaching the provisions about form of direction carries a penalty of up to **250 penalty units in the case of a body corporate or 50 penalty units in any other case.**

The Ministry is aware that many cosmetic medicine service providers have developed their own best practice procedures, many of which include written directions. However, as many stakeholders refer to cosmetic injectors 'dispensing' (i.e. administering) cosmetic medicines on 'prescription', in the absence of clear standards in the PTGR some cosmetic medicine service providers may have based their written administration directions on the form of prescription in the PTGR.

This is problematic in that, in the PTGR, 'prescriptions' are orders for pharmacists to supply take home doses of Scheduled medicines. The PTGA prohibits a person other than a pharmacist, or person acting under the personal supervision of a pharmacist, from dispensing a medicine on the prescription of an authorised practitioner.

The form of prescription specified in the PTGR is generally inappropriate for directing administration of a cosmetic medicines. In particular, the PTGR prescription provisions:

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- only allow oral prescriptions to be used in emergency situations, while an oral direction to administer a cosmetic medicine may be entirely appropriate where the authorised practitioner will be onsite during administration,
- do not require prescriptions to contain information needed in a direction to administer cosmetic medicines, such as how much of a particular product should be administered in each area, and
- allow prescriptions to last 12 months from the date they are issued, due to the additional clinical oversight provided by the pharmacist who dispenses the medicine. This validity period is not considered appropriate for directions to administer cosmetic medicines.

The draft regulation aims to formalise and standardise the procedures already adopted by many cosmetic health service providers. This will set a minimum standard of oversight by authorised practitioners and for communication between authorised practitioners and those who administer under their direction. It will also bring cosmetic medicine service providers into line with other health service providers that administer medicines, such as hospitals.

The ability to issue oral directions where the authorised practitioner will be onsite during administration should minimise the impact of the draft regulation on those who administer non-dispensed cosmetic medicines for non-cosmetic purposes.

Questions for consideration

7. Does allowing oral directions to be given where the authorised practitioner will be on site during administration pose an unacceptable risk to patients?
8. Are the details required to be included in written or oral directions appropriate? Should any details be removed or added to these requirements?
9. Is the maximum 6 month validity for written directions appropriate?

Persons providing cosmetic medicine services

Draft regulation

The draft regulation imposes responsibilities on those conducting businesses or enterprises that provide cosmetic medicines services. These are defined in the draft regulation as '**responsible providers**'. A responsible provider is a legal 'person' (which includes an individual, a corporation or a partnership) who provides the service of administering cosmetic medicines for fee or reward, or in the course of a business (whether or not for profit), other than an individual who is:

- involved in providing that service under contract (e.g. an RN that is contracted by the corporate owner of a cosmetic clinic to administer cosmetic medicines), or
- in the course of their employment by another person (e.g. an RN that is employed by an authorised practitioner to administer cosmetic medicines at the practitioner's clinic).

Under the draft regulation, responsible providers will have obligations to ensure that, in their business or enterprise:

- cosmetic medicines are administered in accordance with the requirements of the draft regulation. In particular, to ensure that those medicines are administered by authorised practitioners, or RNs or ENs on the direction of authorised practitioners (issued following a consultation with the patient)
- there are appropriate risk management policies and procedures to protect the health and safety of patients (for example, equipment for resuscitation)
- their business uses cosmetic medicines that have been legally imported into, or manufactured in, Australia pursuant to the *Therapeutic Goods Act 1989* (Cth); and
- the responsible provider keeps records in relation to the directions that are given, and the cosmetic substances that are administered, in the course of their business.

Breaching the first of these requirements carries a **penalty of 1,000 penalty units in the case of a body corporate or 200 penalty units or imprisonment for 6 months (or both) in the case of an individual**. Breaching the other requirements carries a penalty of up to **250 penalty units in the case of a body corporate or 50 penalty units in any other case**.

The Ministry expects that the definition of *responsible providers* will capture a corporation, a franchisee/franchisor, or partnership:

- which runs a business that employs or contracts people to administer cosmetic medicines
- regardless of whether the administration occurs at a clinic that they operate, or at another location (e.g. a salon operated by another person).

The purpose of introducing this concept is to ensure that those who exercise practical control over the provision of the cosmetic medicine service also have responsibilities in relation to the use of the cosmetic medicines even if they are not responsible for administering those medicines. In many cases, cosmetic medicine service providers already take responsibility for these matters. The Ministry is aware that many cosmetic medicine service providers have already implemented policies to ensure that standards of clinical governance and storage are maintained.

Currently, the PTGA and the PTGR tend to focus on individuals that are held legally responsible for the Scheduled medicines, rather than individuals and other legal entities that exercise practical control over the medicines. For example, individual authorised practitioners have storage obligations in relation to the Scheduled substances in their possession, even if they are employed or contracted

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by a medical clinic. This is one aspect of the PTGA that has been identified as potentially requiring broader reform as part of the PTGA review and rewrite.

Questions for consideration

10. Is it appropriate for individuals, corporations, partnerships and other legal ‘persons’ which provide cosmetic medicine services to have obligations in relation to the cosmetic medicines used in their business?
11. Are there any types of cosmetic medicine service provider that should be added or omitted from the definition of ‘responsible provider’?
12. Are the obligations imposed on responsible providers in the draft regulation matters that are reasonably expected to be within the control of cosmetic medicine service providers? If not, why not and are any changes to the draft regulation required to reflect those arrangements?

Record-keeping

Draft regulation

The draft regulation has the following record-keeping requirements in relation to cosmetic medicines.

Authorised practitioners who give directions to administer cosmetic medicines must:

- make a record of any oral direction they give (in accordance with **clause 68E(8)**), and
- retain and keep a copy of any written direction (in accordance with **clause 68E(2)**), or record of any oral direction, that they give.

RNs or ENs who administer cosmetic medicines on the direction of an authorised practitioner must make a record of any cosmetic medicine they administer, containing the details specified in **clause 68F**.

Responsible providers must retain copies of any written directions, records of any oral directions and records of administration that relate to their cosmetic medicine business. Records of administration should be kept together with records of directions.

Where the responsible provider is not the authorised practitioner or RN or EN responsible for making the record, the authorised practitioner, RN or EN must provide a copy of the relevant direction or record to the responsible provider.

Breaching any of these provisions carries a penalty of up to **250 penalty units in the case of a body corporate or 50 penalty units in any other case**.

The requirement for responsible providers to keep centralised records aims to ensure continuity of care and, in particular, reduce the likelihood of administration errors, for patients who may see different authorised practitioners, RNs or ENs at a single cosmetic medicine business.

In accordance with clause 176 of the PTGR, records must be:

- kept as legible instruments written indelibly in English or in some other manner some which such an instrument is readily reproducible, and
- retained for at least 2 years from the latter of the date on which an entry was made in the document or record, or a cosmetic medicine was administered in accordance with, or on the authority of, the document or record, and
- made available for inspection on demand by a police officer or inspector appointed under the PTGA.

Questions for consideration

13. Are there any details which should be added or omitted from the information RNs and ENs must include in a record of administration?
14. Do the draft record keeping requirements impose obligations that are additional to what is generally regarded as best practice in the industry?

Storage

Draft regulation

Any person in occupation or control of premises at which a relevant substance is stored is required to ensure that the cosmetic medicines are stored:

- in a room or enclosure the public cannot access
- apart from human or animal food
- in such a way that, if the container of cosmetic medicine leaks or breaks, it cannot mix with or contaminate any human or animal food, and
- in accordance with any conditions for storage specified on the label of the cosmetic medicine (including cold-chain storage).

Estimating time and cost of transitioning to new requirements

The Ministry understands that transitioning to the requirements in the draft regulation will take some time and may involve costs to some providers. To ensure that the impacts of the draft regulation are appropriately understood, the Ministry requires information about the time and resources required to transition to the new requirements.

Questions for consideration

15. Would you need to make changes to your current procedures or practices to comply with the draft regulation?
16. If changes would be needed, how extensive would these changes need to be? If possible, please provide details of the estimated time of making these changes.

Other substances that should be subject to the new requirements

Draft regulation

The draft regulation currently applies to:

- botulinum toxins for human use,
- hyaluronic acid and its polymers in preparations for injection or implantation
- polyacrylamide
- polylactic acid, and
- deoxycholic acid.

Under s.18C of the PTGA, the scope of the draft regulation can be extended to cover any substance specified in Schedule 2 – 4 or Schedule 8 of the Poisons Standard or any other therapeutic good.

Other substances and therapeutic goods which have been suggested as appropriate to be subject to the draft regulation include:

- platelet rich plasma injections
- hyaluronic acid in dermapens (microneedling)
- hyalase
- adrenaline
- antibiotics; and
- analgesics.

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Many stakeholders have previously raised the issue of regulating lasers, intense pulse light and other similar treatments. It is noted that, in December 2018, the Australian Health Ministers' Advisory Council agreed to refer the issue of regulating these treatments to the Australian Radiation Protection and Nuclear Safety Agency for consideration. These treatments will not be considered for regulation under the draft regulation.

Questions for consideration

17. Should any other Schedule 2 – 4 or Schedule 8 substances, or other therapeutic goods, be subject to the draft regulation?
18. 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?

Submissions

The Ministry of Health would like to hear submissions on the issues raised in this paper. Submissions should be sent via email to MOH-CosmeticRegulation@health.nsw.gov.au or sent in hardcopy to:

Legal and Regulatory Services Branch
NSW Ministry of Health
Locked Bag 961
NORTH SYDNEY 2059

Submissions should include the reference **H19/136229** and must be received by **13 April 2020**.

Individuals and organisations should be aware that generally submissions made in respect of the Discussion Paper may be made publically available under the *Government Information (Public Access) Act 2009*. The Ministry, in considering its response to the Discussion Paper, may also circulate submissions for further comment to other interested parties or to publish parts of the submissions. If you wish your submission (or any part of it) to remain confidential (subject to the *Government Information (Public Access) Act 2009*), this should be stated clearly and marked.

Issues outside scope of draft regulation

Draft regulation does not prohibit video consultation

A prohibition on video consultation is often suggested to address the perceived inadequacy of video consultations conducted by some authorised practitioners in the cosmetic industry, with reports that some do not even take a basic history from the patient and even consult for less than 60 seconds. Most of these reports raise serious professional conduct issues, which are most appropriately addressed through disciplinary processes. Authorised practitioners should be aware that their obligations to their patient are not diminished (and may actually be more extensive)¹⁰ when they consult via video. It is noted that guidelines governing the obligations for video consultations were prepared in 2012 and the use of video consultation has become more prevalent since that date. In this regard, the Medical Board of Australia expects medical practitioners who assign an aspect of a cosmetic procedure to another registered health practitioner (e.g. an RN) to:¹¹

- retain overall responsibility for the patient, and
- ensure that any other person participating in the patient's care has appropriate qualifications, training and experience and is adequately supervised as required.

In its November 2018 *Report into Cosmetic Health Service Complaints in NSW*, the Parliamentary Committee on the Health Care Complaints Commission:

- noted that video consultation is permitted under Medical Board of Australia guidelines and can play a beneficial role in other areas of healthcare, and
- stated that, before suggesting changes to the use of video consultation for cosmetic medicines, broader evaluation and consultation on the effectiveness of the current guidelines is required.

Concerns within the remit of other regulators

Many of the most common concerns about cosmetic medicines fall within the remit of other regulators and are therefore not addressed by the draft regulation.

Unrealistic advertising of results of cosmetic medicines

Advertising of cosmetic medicines is strictly regulated under Commonwealth legislation (see Appendix B). Certain types of public advertisements for cosmetic medicines are entirely prohibited, and advertisements that refer generally to cosmetic medicines must be accurate and not aimed at encouraging excessive use of the cosmetic medicine.

Inadequate training of health practitioners

Registered health practitioners have professional obligations to work within the limits of their competence and scope of practice.¹² This includes ensuring they have adequate knowledge and skill to provide safe clinical care.

¹⁰ For example, see the Medical Board of Australia, *Guidelines – Technology-based patient consultations* (16 January 2012) <<https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Technology-based-consultation-guidelines.aspx>> Last accessed 17 December 2019

¹¹ Medical Board of Australia, *Guidelines for Registered Medical Practitioners who Perform Cosmetic Medical and Surgical Procedures* (1 October 2016) <<https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Cosmetic-medical-and-surgical-procedures-guidelines.aspx>> Last accessed 17 December 2019

¹² For example, see Chapter 2.2 of the Medical Board of Australia, *Good medical practice: a code of conduct for doctors in Australia* (March 2014) <<https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>> Last accessed 17 December 2019

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Importation of counterfeit products

Commonwealth legislation prohibits the importation of counterfeit cosmetic medicines.

Incentive payments

Depending on the circumstances, a registered health practitioner may be engaging in ‘unsatisfactory professional conduct’ under the *Health Practitioner Regulation National Law (NSW)* if they offered or accepted benefits for referring or recommending other health service providers or health products.

The NSW Government will consider issues about the disclosure of commissions and incentive payments by other cosmetic industry employees (e.g. front of house staff) while implementing the Better Business Reforms package. The package, which passed Parliament on 24 October 2018, includes a general requirement for traders to disclose the existence of financial incentives for providing or referring goods or services.¹³

Alleged non-compliance with existing PTGA requirements

The Ministry has received reports alleging there is a culture of non-compliance with the existing requirements in the PTGA in the NSW cosmetic industry, including reports of the following:

- **PTGA licensed wholesalers wholesale supplying cosmetic medicines to unauthorised persons** – it is an offence for a PTGA licensed wholesaler to wholesale supply any Schedule 4 medicine for human use to a person other than those specified in the PTGA. This group generally comprises other PTGA licensees, authorised practitioners, pharmacists, specific officeholders at public hospitals and health institutions, private health facilities and nursing homes and specific health practitioners, first responders, qualified first aiders (limited medicines only).
- **Authorised practitioners wholesale supplying cosmetic medicines without a PTGA licence** – it is an offence for any person, other than a pharmacist in limited circumstances, to wholesale supply (e.g. supply for resupply) any Schedule 4 medicine without a licence under the PTGA. This includes the supply of an authorised practitioner who obtains the cosmetic medicine from the wholesaler, to another authorised practitioner who administers or directs administration of the cosmetic medicine.
- **Non-pharmacists ‘dispensing’ cosmetic medicines on the prescription of authorised practitioners** – under the PTGA, only a pharmacist, or a person under the direction of a pharmacist, is permitted to dispense an Schedule 4 medicine on the prescription of an authorised practitioner, and under the *Health Practitioner Regulation National Law*, the pharmacist must be practising in a registered community pharmacy, or a public hospital pharmacy.

The Ministry will continue to investigate any specific reports of non-compliance that it receives.

¹³ NSW Government, *Response to Parliamentary Committee on the HCCC – Final Report – Cosmetic Health Service Complaints in NSW* (17 June 2019)
<https://www.parliament.nsw.gov.au/committees/inquiries/Pages/inquiry-details.aspx?pk=2476#tab-reportsandgovernmentresponses> Last accessed 17 December 2019

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Key aspects of the PTGA as it relates to cosmetic medicines for human use

Wholesale suppliers must be licensed and can only supply to authorised persons

It is an offence to wholesale supply a Schedule 4 medicine for human use in NSW without a licence from the NSW Health Secretary.¹⁴ Any supply for the purpose of resupply is considered to be a supply by wholesale supply for the purpose of the PTGA.

In addition, licensed wholesale suppliers can only wholesale supply Schedule 4 medicines for human use to persons authorised in or under the PTGA to supply, use or possess the Schedule 4 medicine.

For the purpose of human use, this group is mainly comprised of:

- licensed manufacturers and wholesalers,
- authorised practitioners,
- pharmacists,
- specific officeholders at public hospitals and other health institutions, licensed private health facilities and residential care facilities (e.g. medical superintendent or chief pharmacist),
- specific health practitioners, first responders and first aid officers (limited medicines only).

In most cases, wholesale suppliers are not permitted to wholesale supply S4 medicines to RNs and enrolled nurses (**ENs**) who do not have a Scheduled medicine endorsement on their registration.

Authorised persons cannot wholesale supply without a licence

Authorised persons must handle the S4 medicines they obtain in accordance with the PTGR.

However, these persons are not permitted to wholesale supply (ie. supply for the purpose of resupply) the S4 medicines they obtain unless they are licensed by the Health Secretary.

Only authorised practitioners can issue prescriptions and only pharmacists can dispense

The PTGR provides that only authorised practitioners can issue prescriptions and this must be done in the practice of their profession. It also sets out the details that must be included in prescriptions, unless an exemption has been granted by the Health Secretary.

Under the PTGA, only a pharmacist, or person acting under the personal supervision of a pharmacist, can dispense an S4 medicine on the prescription of an authorised practitioner.¹⁵ Unlike some other jurisdictions, the PTGA and PTGR do not provide for administration to occur on the prescription of an authorised practitioner.

Pharmacists and authorised practitioners have record-keeping obligations in relation to prescriptions for S4 medicines. Authorised persons also have record-keeping obligations in relation to S4 medicines they supply directly to patients.

Wholesale suppliers and authorised persons are responsible for storage of S4 medicines in their possession

The PTGR sets out the requirements for storing Schedule 4 medicines. Wholesale suppliers and authorised persons must meet these requirements for Schedule 4 medicines in their possession.

Wholesalers of medicines are also subject to the *Australian code of good wholesaling practice for medicines in schedules 2, 3, 4, and 8* developed by the TGA. This Code provides for storage, transport, handling and security arrangements regarding medicines.

¹⁴ The PTGR provides for pharmacists to undertake limited form of wholesale supply for the purpose of filling customer orders.

¹⁵ Pharmacists are only permitted to dispense medicines from public hospitals and registered pharmacy premises pursuant to the *Health Practitioner Regulation National Law (NSW)*.

Key aspects of regulatory regime for cosmetic medicines in NSW

ACTIVITY	KEY SOURCE(S) OF REGULATION	GENERAL RULE*
		*Exceptions and exemptions apply in some cases
Manufacture	<i>Therapeutic Goods Act 1989 (Cth)</i>	<ul style="list-style-type: none"> - Manufacturer must be licensed - Product must be in the Australian Register of Therapeutic Goods (ARTG)
Importation and exportation	<i>Therapeutic Goods Act 1989 (Cth)</i>	<ul style="list-style-type: none"> - Product must be in the ARTG
Wholesale supply	<i>Therapeutic Goods Act 1989 (Cth)</i>	<ul style="list-style-type: none"> - Product must be in the ARTG
	<i>Poisons and Therapeutic Goods Act 1966 (NSW)</i>	<ul style="list-style-type: none"> - Wholesaler must be licensed
Non-wholesale supply	<i>Poisons and Therapeutic Goods Act 1966 (NSW)</i>	<ul style="list-style-type: none"> - Person must be authorised to non-wholesale supply - Staff at hospital can only administer under direction of an authorised practitioner
Issuing prescriptions and dispensing on prescription	<i>Poisons and Therapeutic Goods Act 1966 (NSW)</i>	<ul style="list-style-type: none"> - Person issuing prescription must be an authorised practitioner - Person dispensing on prescription must be a pharmacist
	<i>Health Practitioner Regulation National Law (NSW)</i>	<ul style="list-style-type: none"> - Pharmacist must dispense from a registered pharmacy or public hospital - Records to be kept
Conduct of health practitioners	<i>Health Practitioner Regulation National Law (NSW)</i> and standards, codes, guidelines issued by the National Boards	<ul style="list-style-type: none"> - Registered health practitioners must meet standards of appropriate professional conduct or practice. In disciplinary proceedings, standards, codes and guidelines issued by the practitioner's National Board.
	<i>Public Health Act 2010 (NSW)</i>	<ul style="list-style-type: none"> - Non-registered health practitioners must comply with Code of Conduct
Advertising	<i>Therapeutic Goods Act 1989 (Cth)</i> and <i>Therapeutic Goods Advertising Code (No 2) 2018 (Cth)</i>	<ul style="list-style-type: none"> - Prohibition on public advertisements which refer to specific S4 medicines (by substance or trade name) - Advertisements for medicines must be accurate and not misleading and, in particular, must not exaggerate product efficacy or performance or encourage inappropriate or excessive use of the medicine
	Consumer protection and fair trading legislation	<ul style="list-style-type: none"> - General limits on advertising of goods and services