Report on the Review of the Regulation of Cosmetic Procedures

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Review of the regulation of cosmetic procedures

1. Overview

There are a large variety of cosmetic procedures that aim to alter or modify a person's body or appearance and the procedures vary greatly in risk to patients or clients. High risk procedures include major cosmetic surgery and the use of certain scheduled medicines. On the other end of the scale, there are relatively low risk cosmetic surgery procedures (such as mole removal for a cosmetic purpose) and low risk procedures that do not involve the use of surgery or medicines, such as hair removal.

There is a range of regulation affecting persons and premises carrying out cosmetic procedures. The review by the Ministry of Health has considered whether the current regulation of cosmetic procedures is appropriate to ensure the safety of patients/clients and makes a range of recommendations to improve the regulatory environment. However, the issue of the regulation of cosmetic procedures is likely to continue to remain an area of concern. As such, the Ministry will continue to monitor the issues, including implementation of the recommendations, and any other issues that arise following investigations that are currently underway, to determine if further action is necessary.

2. Regulation of cosmetic surgery and facilities

Cosmetic surgery ranges from minor cosmetic surgical procedures that are carried out in a medical practitioner's rooms through to high risk procedures, such as breast augmentation, that must be carried out in licensed private health facilities.

Regulation of facilities

The Private Health Facilities Act 2007 and Regulation 2017 requires facilities that carry out certain procedures to be licensed and comply with a range of licensing standards. These standards are aimed at protecting patients and relate to the safety of the premises (such as complying with the relevant sections of the Building Code of Australia and Australasian Health Facility Guidelines) and clinical care and patient safety (such as engaging with the National Standards and Accreditation Scheme, having procedures for the transfer of patients who require higher levels of care, minimum staffing requirements and appropriate equipment). While the Private Health Facilities Act provides extensive regulation in respect of licensed facilities, it only applies to facilities that carry out procedures that fit within one of the classes of private health facilities.

One of the relevant classes is the surgical class. However, the surgical class only requires facilities to be licensed if the surgery is undertaken using general, epidural or major regional anaesthetic or sedation resulting in deeper than conscious sedation.[1] The use of general or major regional anaesthesia can create significant risks to patients. These risks can be associated with airway management (in the case of general anaesthesia) and/or risks associated with the immobility of the patient. These risks can be appropriately mitigated by way of licensing requirements.

[1] Other than sedation provided in connection with dental procedures: cl 3 of the Private Health Facilities Regulation

Facilities that perform surgical procedures using local anaesthesia or conscious sedation are not required to be licensed in the surgical class[2] as they are generally considered to be of lower risk and the facility in which the procedures take place is not seen as requiring licensing as generally professional standards, such as relating to infection control, can mitigate the risk.

The Royal Australasian College of Surgeons (RACS), the Australian and New Zealand College of Anaesthetists (ANZCA) and the Australian Society of Plastic Surgeons (ASPS) recently released a position paper on Day Surgery in Australia[3]. The Colleges recommend increased standards for day surgery clinics that use intravenous sedation or significant amounts of local anaesthesia in day surgery clinics.

The Ministry of Health has considered the position paper and considers that the current licensing requirements for facilities under the Private Health Facilities Act and Regulation are generally appropriate.

Licensing requirements for facilities are extensive and impose a regulatory burden on business. Licensing requirements should only be imposed if there is a health and safety risk that can only be appropriately mitigated by way of requiring facilities to be licensed. All procedures that involve the use of sedation or local anaesthesia will carry a risk to patients. However, in some cases that risk can be mitigated by way of professional responsibilities and competencies required by the individual practitioner. For example, some minor cosmetic surgical procedures, using conscious sedation or local anaesthesia, can be safely carried out by a medical practitioner in an unlicensed private health facility eg mole removal for a cosmetic purpose. If multiple moles were being removed, it would be expected that a medical practitioner would assess the patient and whether or not adequate local anaesthetic could be administered safely in an unlicensed facility. This consideration would, among other things, take into account the cumulative toxicity of the local anaesthetic administration required for the multiple mole removals. Failure to properly consider these issues could be grounds for taking disciplinary action against the practitioner.

However, the Ministry of Health also recognises that reliance on the level of anaesthesia and/or conscious sedation to determine licensing requirements will not always be a sufficient criterion for determining whether or not a facility should be licensed. This is particularly the case with cosmetic surgery where some procedures that carry high risks to patients can be carried out using local anaesthesia and/or conscious sedation.

As such, in 2016 the Private Health Facilities Regulation was amended to create a new class of private health facilities, being the cosmetic surgical class.

Under the Regulation, certain cosmetic surgical procedures are required to be carried out in a licensed private health facility (or a public hospital). These surgical procedures are:

a) any cosmetic surgical procedure that is intended to alter or modify a person's appearance or body and that involves anaesthesia (including a Biers Block), or

[2] However, depending on the procedure, the facility may be required to be licensed in a different class eg gastrointestinal endoscopy

[3] https://www.surgeons.org/media/25520947/2017-10-09_pos_fes-pst-061_day_surgery_in_australia.pdf

b) any of the following surgical procedures (however described): (i) abdominoplasty (tummy tuck), (ii) belt lipectomy, (iii) brachioplasty (armlift), (iv) breast augmentation or reduction, (v) buttock augmentation, reduction or lift, (vi) calf implants, (vii) facial implants that involve inserting an implant on the bone or surgical exposure to deep tissue, (viii) fat transfer that involves the transfer of more than 2.5 litres of lipoaspirate, (ix) liposuction that involves the removal of more than 2.5 litres of lipoaspirate, (x) mastopexy or mastopexy augmentation, (xi) necklift, (xii) pectoral implants, (xiii) penis augmentation, (xiv) rhinoplasty, (xv) superficial musculoaponeurotic system facelift (SMAS facelift), (xvi) vaginoplasty or labiaplasty,

but does not include any dental procedure.

There are two categories of cosmetic procedures that are required to be conducted in licensed facilities:

- cosmetic surgical procedures that use high levels of anaesthesia or more than conscious sedation; or
- certain listed surgical procedures, regardless of the level of anaesthesia or sedation used.

Requiring certain listed procedures to be carried out in a licensed private health facility (or public hospital) recognises that there needs to be a broader consideration of risks of cosmetic surgery other than just the level of anaesthesia or sedation used.

The current list of procedures that are required to be carried out in a licensed private health facility was determined in 2016 following extensive consultation. Whether a cosmetic surgical procedure is required to be carried out in a licensed private health facility is based on the risks to the patient, being:

- The risk of the procedure itself (such as the inherent risks of the procedure eg risk of significant blood loss or other complications, whether there are significant risks the patient may need to be transferred to a higher level of care facility and whether the type of procedure is likely to mean that a patient would be non-ambulatory if they needed to be evacuated during an emergency), and
- the risk that the procedure will require high levels of anesthesia or sedation such that there is a significant risk of the patient inadvertently becoming unconscious and/or significant risk of local anesthesia toxicity.

The listed procedures are considered to be appropriate. However, a listed procedure is only required to take place in a licensed facility if the procedure is a surgical procedure. The Ministry is aware that some of the listed procedures, such as breast augmentation and penis augmentation, can also be carried out non-surgically. Such non-surgical procedures generally involve the injection of fillers (such as collagen) or, in some cases, a transfer of fat from one part of the body to another.

All procedures, whether surgical or not, carry risks. As noted above, licensing requirements should only be imposed if there is a health and safety risk that can only be appropriately mitigated by way of requiring facilities to be licensed. If the listed procedures are carried out non-surgically, the risks are different than if the procedures are carried out surgically. Non-surgical procedures do not generally carry a risk that the patient will be non-ambulatory and the risk of the patient becoming unconscious due to high levels of anaesthesia or sedation is lower. However, if there is an incorrect

administration of the filler, then there are risks of drug toxicity. Further, if a local anaesthetic is injected along with a filler, there is a risk of toxicity from the local anaesthetic if excessive doses are used.

There are risks associated with the use of all drugs and requiring any procedure and requiring procedures to be conducted in a licensed private health facility should only occur where a licensing requirement is proportionate to the risk.

In the case of non-surgical procedures involving the use of drugs, would be expected that the risks would be mitigated by way of professional responsibilities and competencies required by the individual practitioner and the normal regulation in relation to the use of medicines. It is noted that product information for prescription-only fillers provide detailed warnings about incorrect administration which all practitioners would be expected to consider and that medicines regulation limits who can access drugs. Therefore at this stage no substantive changes to the Private Health Facilities Regulation are considered necessary. However, as detailed later in the report, the Ministry recommends that additional regulation should be put in place in respect of the use of medicines commonly involved in cosmetic procedures. As part of the consultation on the detail about the additional regulation of medicines used in cosmetic procedures, the Ministry will also **consult with stakeholders as to whether any non-surgical cosmetic procedures should be required to take place in a licensed facility**.

More generally, as the definition of cosmetic surgery in the Private Health Facilities Regulation relies on a list of specific procedures, and the types of procedures may change over time (or the risks of the procedures can change) the Ministry will keep the definition under review to ensure that the list remains appropriate and, if necessary, changes to the Regulation can be pursued.

Carrying out procedures in an unlicensed facility

Section 33 of the Private Health Facility makes it an offence for a person to "conduct a private health facility" unless the facility is licensed. The offence only applies to a person who is running the facility itself. There is no offence for a medical practitioner to provide prescribed treatment or services (such as cosmetic surgery within the meaning of the Act), that should only be carried out in a licensed facility, in an unlicensed facility.

Medical practitioners should assure themselves that the facility is appropriate for the services they are providing and medical practitioners who provide prescribed treatment or services should ensure that the facility they are providing the services in is licensed. It is noted that private health facilities are required to display a copy of their license in their facility. In order to ensure that medical practitioners do not carry out prescribed treatments and services in unlicensed facilities, it is proposed that a **new offence be created for medical practitioners who provide prescribed services and treatments in unlicensed facilities.**

It is noted the offence in s33 applies to the person who is "conducting" the private health facility. Proving who is "conducting" an unlicensed facility may be difficult. In many cases, it would be expected that the occupier of the premises would be the person "conducting" the unlicensed facility. However, this will not always be the case, such as if a person other than the occupier had day to day control over the operation of the premises. This is an area that the Ministry will continue to monitor as part its ongoing investigations.

Recommendations

1. The Private Health Facilities Regulation is amended to create an offence for a medical practitioner to provide prescribed services and treatments in an unlicensed facility.
2. The Ministry consult with stakeholders regarding whether any non-surgical cosmetic procedures should be required to take place in a licensed facility.
3. The Ministry keep the definition of cosmetic surgery under consideration to ensure that it continues to remains appropriate.

3. Regulation of registered practitioners

Regulation of registered health practitioners

Medical practitioners and nurses are regulated by the Health Practitioner Regulation National Law.

All medical practitioners must be registered with the Medical Board of Australia and comply with relevant standards, codes and guidelines issued by the Board. The Medical Board's *Good medical practice: a code of conduct for doctors in Australia* [4] requires medical practitioners to:

- Recognise and work within the limits of their competence and scope of practice, and
- Have adequate knowledge and skill to provide safe clinical care.

The Medical Board of Australia has issued guideline[5]s for any medical practitioner providing cosmetic medical or surgical treatment. These guidelines cover matters such as:

- Providing patients with a cooling off period for cosmetic surgery,
- Proper patient assessment and discussion of other options available,
- Requiring under 18s, when major cosmetic surgery is proposed, to be referred to an independent psychologist, psychiatrist or general practitioner to identify any significant underlying psychological problems, and
- Guidelines for post procedure management.

Nurses involved in a cosmetic procedure are also required to be registered with the Nursing and Midwifery Board of Australian and comply with relevant standards, codes and guidelines issued by the Board.

Failure to comply with the standards, codes and guidelines set by the Board can result in disciplinary action being taken against a registered health practitioner under the Health Practitioner Regulation National Law by the Health Care Complaints Commission (HCCC) or the relevant health professional Council, such as the Medical Council of NSW. The HCCC and Councils can take action against a

[4] Medical Board of Australia's *Good medical practice: a code of conduct for doctors in Australia: http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx*

[5] Medical Board of Australia's Guidelines For Registered Medical Practitioners Who Perform Cosmetic Medical And Surgical Procedures: http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Cosmetic-medical-and-surgical-procedures-guidelines.aspx

registered health practitioner who poses a risk to the public, including suspending the practitioner's registration.

In addition, private health facilities are responsible for credentialing appropriately qualified and skilled medical practitioners to provide services in their facility and setting any limits on the scope of the practitioner's practice. Public hospitals are also responsible for credentialing medical practitioners.

The regulation of individual medical practitioners and nurse is extensive and focused on public protection. As such, it is considered appropriate and no changes are proposed. However, if new concerns arise from current investigations by the Ministry and the implementation of the recommendations of this review suggesting that the current guidelines relating to provisions of cosmetic medical or surgical treatment are no longer considered adequate, the Ministry will write to the Medical Board to ask the Board to consider reviewing and revising their guidelines.

Use of the title surgeon or cosmetic surgeon

The use of titles by health practitioners is regulated by the Health Practitioner Regulation National Law. The National Law is consistent across the States and Territories with respect to registration and title protection.

Specialist titles for medical practitioners are protected if Health Ministers, on recommendation of the National Board, approves a speciality for the profession and approves a specialist title. "Surgeon" in and of itself is not a recognised speciality or a restricted title. There is no recognised speciality of cosmetic surgery.

However, with respect to medical practitioners, a number of general and specific surgical specialties have been approved, such as:

- Plastic surgery,
- Oral and maxillofacial surgery,
- Orthopaedic surgery.

There are also restrictions on the use of the title "specialist surgeon" as well as a number of other terms, such as "specialist plastic surgeon" or "specialist neurosurgeon".

With respect to podiatry, the field of podiatric surgery has been approved as an area of specialist registration, with the title "podiatric surgeon" protected. The use of the title surgeon is also used by dentists and veterinarians.

While there have been calls to restrict the use of the title surgeon to only medical practitioners who hold a specialist registration in a surgical field, this is not supported at this stage. There are a range of practitioners who use, and have done so historically, the title surgeon. Further, a range of medical practitioners, such as general practitioners, perform surgery within their accepted scope of practice.

However, in respect of the title "cosmetic surgeon", the use of this title can be seen to imply that a medical practitioner has a form of specialist registration and could be seen as misleading to patients. It is recommended that consideration be given to restricting the title "cosmetic surgeon". As any

protected title would apply across all States and Territories, the Minister has already **raised the issue of protecting the title cosmetic surgeon with the COAG Health Council.**

Recommendations

4. The Minister raise the issue of protecting the title "cosmetic surgeon" with the COAG Health Council.

4. Regulation of non-registered health practitioners

Cosmetic procedures can be carried out by both registered health practitioners and persons who are not registered health practitioners.

Non-registered health practitioners are regulated via a negative licensing scheme. Under the scheme, non-registered health practitioners must comply with the Code of Conduct for non-registered health practitioner. The Code sets the standards with which non-registered health practitioners must comply[6]. These standards include matter such as:

- Practising in a safe and ethical manner,
- Adopting appropriate infection control precautions, and
- Not misinforming clients or making claims about the efficacy of treatments and services if the claims cannot be substantiated.

The HCCC can investigate complaints against non-registered health practitioners and if the HCCC considers that there has been a breach of the Code and the practitioner poses a risk to the health or safety of the public, the HCCC can issue a prohibition order[7]. A prohibition order can direct the practitioner not to provide a health services or place conditions on the practice of the health service.

In general, the negative licensing scheme for non-registered health practitioners is appropriate. Under the Public Health Act, the Code applies to health practitioners who are not registered health practitioners or registered health practitioners are provide health services unrelated to their registration.[8] In defining "health practitioner", the Public Health Act relies on the definition in the Health Care Complaints Act, which relevantly defines a health practitioner to mean "a natural person who provides a health service"[9].

The Health Care Complaints Act defines health service[10] as:

> *health service includes the following services, whether provided as public or private services:*
> *(a) medical, hospital, nursing and midwifery services,*

[6] See s100 of the Public Health Act 2010. The Code of Conduct is set out in Schedule 3 of the Public Health Regulation 2012.
[7] Division 6A of Part 2 of the Health Care Complaints Act 1993
[8] Section 100 of the Public Health Act
[9] Section 4 Health Care Complaints Act
[10] Ibid

(b) dental services,

(c) mental health services,

(d) pharmaceutical services,

(e) ambulance services,

(f) community health services,

(g) health education services,

(h) welfare services necessary to implement any services referred to in paragraphs (a)–(g),

(i) services provided in connection with Aboriginal and Torres Strait Islander health practices and medical radiation practices,

(j) Chinese medicine, chiropractic, occupational therapy, optometry, osteopathy, physiotherapy, podiatry and psychology services,

(j1) optical dispensing, dietitian, massage therapy, naturopathy, acupuncture, speech therapy, audiology and audiometry services,

(k) services provided in other alternative health care fields,

(k1) forensic pathology services,

(l) a service prescribed by the regulations as a health service for the purposes of this Act.

The definition of a health service is an inclusive one. The examples of health services set out in paragraphs (a)-(l) are inclusive, and is *not* an exhaustive list of the categories of health services. Other services that are properly considered health services will still fall within the definition even if the service is not specifically listed.

The Code of Conduct for non-registered health practitioners will only apply to persons who carry out cosmetic procedures if the procedures fall within the definition of "health service". This will depend on the type of procedure being performed. Some cosmetic procedures are more akin to beauty procedures would not be, and should not be, seen as a health service, for example hair removal.

Non-registered health practitioners[11], as well people who are not health practitioners, are also subject to the skin penetration provisions in the Public Health Act 2010 and the Public Health Regulation 2012 if they perform a procedure that penetrates the skin. The skin penetration provisions are aimed at minimising the spread of blood borne viruses, such as HIV or Hepatitis C, and include infection control standards relating to not reusing needles, wearing gloves and sterilising equipment for less complex procedures such as piercing or tattooing. It is an offence not to comply with the skin penetration provisions.

One area of cosmetic procedures that raise particular issues of concern is extreme body modification procedures. Body modification involves the deliberate altering of a part of the body in the same way that cosmetic procedures are designed to do. Extreme body modification includes procedures such

[11] Registered health practitioners are subject to infection control standards as part of their professional obligations.

as the insertion of subdermal implants of a variety of shapes (such as snowflakes and hearts), tongue splitting and scarification. Extreme body modification procedures are not always seen as a health service. However, when the procedure, such as the insertion of subdermal implants, involves incisions through the skin and/or sutures, it is likely to be considered a health service and therefore the Code of Conduct will apply. Even if it is not considered a health service, as there is penetration of the skin, the infection control standards in the Public Health Act and Regulation will apply.

On review, the Ministry considers that additional regulation is required for more extreme forms of body modification that involve surgical incisions and/or sutures.

Extreme body modification procedures that involve surgical incisions and/or sutures involve serious risks other than the risk of blood borne viruses. Risks include that inserted foreign bodies will act as a focus for bacterial infections, and of damage to other tissues such as nerves or bone, which can result in paralysis or life-threatening infections. In addition, where the procedure involves the insertion of a foreign object, there are additional infection risks as well as potential risks involving chemical and immunological reactions to the implant.

These risks are over and above the risks of the spread of blood borne viruses which the Public Health Regulation deals with. The Code of Conduct has provisions relating to practitioners not providing care that is outside of the practitioner's experience or training and to practitioners accepting the right of clients to make informed choices. However, there are no specific provisions in either the Code or the skin penetration provisions in the Public Health Regulation that relate to informing clients of these risks and the measures taken to mitigate the risks. Further, there are no limits on performing such procedures on vulnerable groups such as children or intoxicated persons.

It is noted that some jurisdictions have more specific regulation in relation to body modification. For example, the South Australian Summary Offences Act and Regulation has specific provisions relating to body modification[12]. The South Australian legislation applies to a number of body modification procedures including body implantation, tongue splitting and scarification (where such procedures are not performed in the course of medical treatment) and sets the following requirements:

- Body modification procedures must not be performed on minors or intoxicated persons,
- There must be a written agreement between the client and the person performing the procedure,
- The written agreement must include details about how to care for the area of the body and other prescribed information,
- The premises at which a body modification procedure is performed must display prescribed information, and
- Record keeping requirements in relation to the written consent and evidence of age.

The Ministry considers that a **more comprehensive set of regulation relating to extreme body modification that is carried out by non-medical practitioners is required** to ensure that clients are appropriately aware of the risks, the measures to be taken to mitigate those risks and that such procedures are not performed on vulnerable groups. This regulation should be based on the South

[12] Part 4, Summary Offence Act 1953 (SA) and Part 3 of the Summary Offences Regulation 2016

Australian legislation. However, it would also be beneficial to include additional requirements, such as requiring:

- A cooling off period between the client agreeing to the procedure and the procedure actually being performed,
- The person who performs the procedure to advise the client to contact a medical practitioner prior to the procedure to discuss the risks of the procedure, and
- The person who performs the procedure to advise clients to contact a medical practitioner if complications from the procedure arise.

The Ministry will consider further which legislation the additional regulation should sit within.

It is also noted that many of the issues relating to cosmetic procedures, including body modification, relate more to consumer protection and fair trading issues, for example the advertising of products and procedures, targeting of children and young people and representations as to the skills of the persons undertaking the procedure. These matters generally fall outside of NSW Health's portfolio. However, the issue should be raised with NSW Fair Trading and NSW Health should seek to work collaboratively with NSW Fair Trading on this matter.

Recommendations

5. That additional regulation be imposed for extreme body modification procedures relating to informing clients about the risks of the procedure, the measures taken to mitigate the risks and preventing body modification procedures being undertaken on minors.
6. The Minister write to NSW Fair Trading to raise consumer protection relating to cosmetic procedures.

5. Use of medicines in cosmetic procedures

The Poisons and Therapeutic Goods Act and Regulation places controls on the use, storage, administration, prescription and supply of poisons and scheduled medicines. The controls differ depending on the category of scheduled medicines. For example, Schedule 3 medicines are pharmacist only medicines, while Schedule 4 medicines can only be accessed with a prescription.

The Commonwealth also plays a role in regulating medicines, with the Therapeutic Goods Act 1989 (CTH) requiring that medicines to be registered on the Australian Register of Therapeutic Goods (ARTG) in order to be marketed and used in Australia. There are some exemptions which allow non-registered medicines to be used with special authorisation or in other circumstances but these are not relevant to this review. The Commonwealth also places controls on the importation of medicines through regulations made under the Customs Act 1901 (CTH).

Botulinum toxin and injectable hyaluronic acid dermal fillers are Schedule 4 (S4) medicines. The Act and Regulations currently provides that:

- As a S4 medicine, botulinum toxin and injectable hyaluronic acid dermal fillers need to be prescribed by an authorised practitioner (medical practitioner, dentist),[13]
- A wholesaler can only supply S4 medicines to an authorised practitioner or other person authorised to possess the medicine,
- Any person who is assisting in the care of a person can administer botulinum toxin and injectable hyaluronic acid dermal fillers to a patient, in accordance with the authorised practitioner's prescription. Injectable Schedule 4 medicines are not distinguished from medicines ingested or applied topically. It is a matter of professional responsibility for the medical practitioner who prescribes the Schedule 4 medicine to ensure that the person who is to administer the medicine is able to competently do so, and
- S4 medicines must be stored in a room or enclosure to which the public does not have access.

Based on a number of investigations by the Pharmaceutical Regulatory Unit, **the Ministry is concerned as to whether medical practitioners who prescribe these medicines used in cosmetic procedures, such as botulinum toxin and injectable hyaluronic acid dermal fillers, have appropriate oversight over the receipt, storage, access, use and administration of these medicines at cosmetic clinics**. In addition there are also concerns that certain cosmetic clinics are in breach of the Act and Regulation by importing medicines from overseas, without going through licensed Australian wholesalers.

Accordingly, there is a need for **stronger regulation of certain types of S4 medicines that are used in cosmetic procedures**. Stronger regulation will better ensure that medical practitioners who prescribe these medicines have appropriate oversight over the receipt, storage, access, use and administration of these medicines at cosmetic clinics and that appropriate action can be taken against persons who breach the Poisons and Therapeutic Goods Act and Regulation.

In order to strengthen regulation of the use of S4 medicines that are being used in cosmetic procedures, it is proposed to create a new subclass of S4 medicines, with regulations tailoring the rules relating to the storage, use and administration of the medicines, as well as requiring additional consumer protections. It would be expected that the **exact regulatory rules would be subject to consultation with stakeholders** but could include matters such as:

- Requiring that a medical practitioner or dentist who prescribes botulinum toxin and injectable hyaluronic acid dermal fillers must directly consult with the patient,
- Providing that botulinum toxin and injectable hyaluronic acid dermal fillers can only be accessed at premises when a medical practitioner is present during operating hours, and
- Placing limitations on who, such as a registered health practitioner, may administer the medicines in the course of providing a service.

[13] The Act doesn't prescribe the level of contact that a medical practitioner must have in assessing the patient. This is a matter of professional responsibility for the medical practitioner. However, the Medical Board of Australia's guidelines provide that a medical practitioner must not prescribe S4 cosmetic injectables unless they have had a consultation with the patient, either in person or by video

The regulatory rules could also include matters relating more broadly to consumer protection, such as information given to patients. During consultation on the regulatory rules, consultation would occur with Fair Trading.

There are other types of S4 medicines that can be prone to misuse or supplied outside of normal medical models of care. Such medicines often provide for a lucrative business model, which can in turn fuel a black market. As such, similar concerns about inappropriate use arise and these medicines could be included in the new subclass. Examples of such medicines, include Sildenafil (Viagra), human growth hormone and injectable peptides (which can be used for performance improvement).

In addition, it is noted that the Poisons and Therapeutic Goods Act is 50 years old and the penalties applying to breaches of the Act and Regulation are not in keeping with the seriousness of the offences under the Act and Regulation. It is therefore **recommended that the penalties in the Poisons and Therapeutic Goods Act be increased**. It is noted that issues relating to penalties are being considered more broadly as part of the review of the Poisons and Therapeutic Goods Act.

The Ministry's recent investigations have also uncovered concerns about the illegal importation of prescription medicines for use in cosmetic procedures the lack of appropriate labelling of hyaluronic acid dermal fillers product, which can contain lidocaine local anaesthetic. These are matters that concern the Commonwealth Therapeutic Goods Act. The Minister has already written to the Commonwealth Minister about these concerns. In addition, the Minister has already placed on the COAG Health Council agenda the issue of the use of medicines in cosmetic procedure so that other jurisdictions are aware of the issues.

Recommendations

7. That a new subclass of S4 medicines used in non-surgical cosmetic procedures in the Act should be created. This would allow regulations to tailor rules relating to the storage, use and administration of the medicines, as well as requiring additional consumer protections. This subclass could also apply to other S4 medicines that are prone to misuse or supplied outside of normal medical models of care.
8. That consultation occurs with stakeholders before the regulatory rules for the new subclass of S4 medicines are made.
9. That the penalties for breaches of the Poisons and Therapeutic Goods Act and Regulation be increased.