Submission No 10

COSMETIC HEALTH SERVICE COMPLAINTS IN NEW SOUTH WALES

Organisation: Health Care Complaints Commission

Name: Ms Sue Dawson

Position: Commissioner

Date Received: 6 April 2018

JOINT PARLIAMENTARY COMMITTEE INQUIRY INTO COSMETIC SERVICE COMPLAINTS

Submission by the Health Care Complaints Commission

April 2018

Contents

1. Cosmetic Services – Issues and challenges 2

2. Role and responsibilities of the Commission 3

2.1 Health Care Complaints Commission functions and powers 3

2.2 What complaints have been received by the Commission 7

2.3 How has the Commission managed these complaints 10

3. The roles and responsibilities of other Commonwealth and state regulators 11

3.1 NSW Professional Councils 11

3.2 NSW Ministry of Health 12

3.3 NSW Fair Trading 12

3.4 The Australian Health Practitioner Regulation Agency (AHPRA) and National Boards 13

3.5 Commonwealth role in regulating supply of medicines: Therapeutic Goods Administration (TGA) and Australian Border Force 13

4. Opportunities for Collaboration 14

4.1 Policy Development 14

4.2 Joint Operations with NSW Health 14

4.3 Improved co-ordination within NSW 15

4.4 Working alongside AHPRA 15

4.5 Broader National Collaboration 15

5. Adequacy of Powers and Functions 16

5.1 Differences in complaints management powers 16

5.2 Working with private facilities following investigations 17

5.3 The health regulation framework 17

5.4 Further strengthening national collaboration 18

Attachments 19

1. Cosmetic Services – Issues and challenges

The Health Care Complaints Commission ('the Commission') welcomes this Joint Parliamentary Committee Inquiry into Cosmetic Health Services Complaints.

The first challenge in considering the nature and adequacy of the regulatory framework in this area is that the term "cosmetic services" has no clear definition. It is a term that can capture a wide range of services and procedures, with varying degrees of invasiveness and risk.

These services do have the common characteristic that the service or procedure does not typically involve curing or preventing an illness, but rather involves achieving changes in appearance. The term can therefore capture minor, non-invasive treatments (such as laser treatments, hair removal, skin whitening, and addressing minor skin blemishes) through to more invasive procedures (such as breast or buttock reduction/augmentation, body modification, and implants of varying types). The latter may have more of a surgical character, by virtue of aspects such as anaesthetisation, surgical incisions and suturing.

The types of services that are currently of particular concern to the Commission include beauty and body modification clinics, where the business objective is primarily commercial and not curative or care oriented and there are potential risks to consumers that may arise from a number of factors:

- These services may require administration of prescription medications such as Botox – and the prescription should only be provided by a registered health practitioner who conducts a proper heath assessment prior to prescribing – this may not be occurring.
- The service may be making unsubstantiated claims about the efficacy of certain treatments. Advertising may suggest results that are not achievable for some consumers and may be directed at vulnerable consumers.
- The practitioners involved may be undertaking procedures that are beyond their scope of practice and/or for which they do not have training.
- Surgical procedures may be being delivered without appropriate expertise, licensing and/or equipment.
- There may be risks to the treatment that are not being explained or for which there is not informed consent.
- The services may be using non ARTG registered devices or medicines.
- Devices and medicines that are being used may be illegally imported and not quality controlled.
- The services may not be using appropriate infection control practices.
- Consumers may be offered cost reductions or other incentives to have treatment – e.g. low cost loans from lending entities in which the practitioner/facility has a financial interest.

These services pose regulatory challenges for a number of reasons:

- The sector is diffuse, with risky procedures delivered alongside other non-risky treatments and in a commercial rather than clinical environment, often within business structures which do not have clinical governance practices embedded.
- The services will continue to take many different forms. The nature of services delivered by cosmetic health providers to change appearance are developing rapidly and now include procedures such as eyelid suturing, nose bridge lifts, face lifts, the administration of Botox and dermal fillers, facial threading, and sub dermal implants.
- The services may be beyond the usual definitions of health services – posing questions about the jurisdiction of health regulators and the suitability of health regulation frameworks to successfully address the problems and risks.

2. Role and responsibilities of the Commission

2.1 Health Care Complaints Commission functions and powers

The Health Care Complaints Commission is an independent body established under the *Health Care Complaints Act 1993* (the Act)**.** The Act requires that public health and safety are the paramount considerations in the exercise of all Commission functions.

The Act defines the scope of the Commission's work, which is to:

- receive and assess complaints relating to health service providers in NSW;
- resolve or assist in the resolution of complaints;
- investigate serious complaints that raise questions of public health and safety; and
- prosecute serious complaints.

The Commission is able to use its regulatory powers to respond to complaints about cosmetic services in the following way.

2.1.1 Who can make a complaint and what can be the subject of a complaint?

A complaint may be made by any person and includes but is not limited to the client concerned, a relative, carer or patient representative, and/or a health organisation.

Under section 8 of the Act, the Commissioner is able to make a complaint (typically referred to as an own-motion complaint). This may be done if:

- it appears to the Commissioner that the matter that is subject to the complaint raises a significant issue of public health or safety, significant issues as to the appropriate care or treatment of a patient by a health service provider, or
- there would be grounds for disciplinary action against a health practitioners if substantiated.

Under section 7 of the Act, the Commission may receive complaints that relate to the delivery of a health service by:

- registered practitioners (such as doctors and nurses)
- non-registered practitioners (such as persons administering medicines, beauty therapists, body modification technicians)
- health organisations (such as cosmetic and beauty clinics).

A health service is defined under section 4 of the Act, as follows:

health service *includes the following services, whether provided as public or private services:*

(a) medical, hospital, nursing and midwifery services,

(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.

2.1.2 Assessment of a complaint

On receipt of a complaint, the Commission will typically seek relevant records and responses from the provider and if there is no co-operation, the Commission has powers to require provision of relevant information and documents under section 21A of the Act.

The Commission considers the relevant evidence and must assess the complaint to decide whether:

- the complaint should be investigated
- the complaint should be referred to the Secretary of Health under section 25 or 25A
- the complaint should be referred to another body or person under section 25B or 26
- the Commission should decline to entertain the complaint.

For registered practitioners, the assessment will consider care and treatment and conduct having regard to the standards, guidelines and codes of conduct that apply to each profession and their legal obligations.

For non-registered practitioners, the assessment will consider care and treatment and conduct having regard to the *Code of Conduct for Unregistered Health Practitioners* (the Code) and their legal obligations. The Code is a legislative instrument under Schedule 3 of the Public Health Regulation 2012, and came into effect in NSW on 1 August 2008. It sets the minimum practice and ethical standards with which non-registered health service providers are required to comply. It also informs consumers about what they can expect from practitioners and the mechanisms by which they may complain about the conduct of, or services provided by, a non-registered health service provider. Some key aspects of the Code are that the non-registered health practitioner must:

- provide health services in safe and ethical manner
- ensure that he or she practises in a manner that does not put clients at risk
- not make claims to cure certain serious illnesses
- adopt standard precautions for infection control
- not dissuade clients from seeking or continuing with treatment by a registered medical practitioner
- not practise under the influence or alcohol or drugs or with certain physical or mental conditions
- have an adequate clinical basis for treatments
- not engage in a sexual or improper personal relationship with a client
- comply with relevant privacy laws
- keep appropriate records and insurance.

In assessing a complaint about a non-registered practitioner, the Code is used as a key reference point to assess the standard of clinical care and treatment and/or the professional conduct of the health practitioner, to determine whether any breaches of the Code have occurred and if so, the severity of the departures and the action to be taken.

For health organisations, their legal obligations and the policies and systems that are in place to ensure the safety and quality of health service delivery are considered in the assessment process.

An assessment outcome may also involve:

- referring the matter to either local resolution (if the facility is a public health organisation) or the Commission's Resolution Service
- discontinuing the complaint.

Under section 12, the Commission must consult with the relevant professional council for complaints about registered practitioners.

2.1.3 Investigation powers and outcomes

The Commission must investigate a complaint if:

- The relevant Professional Council is of the opinion it must be investigated (section 13(1))
- Following the assessment of a complaint, it appears to the Commission that the complaint:
  - raises a significant issue of public health or safety
  - raises a significant question as to the appropriate care or treatment of a client by a health service provider
  - if substantiated, would provide grounds for disciplinary action against a health practitioner; or would involve gross negligence on the part of a health practitioner
  - if substantiated, would result in the health practitioner being found guilty of an offence under Division 1 or 3 of Part 7 of the *Public Health Act 2010*.

Under sections 32 and 33 of the Act, the Commission has powers of entry, search and seizure that may be exercised either with consent or with a search warrant. These powers apply only to complaints under investigation.

Under section 34, the Commission has powers to compel people to give information, produce documents or give evidence during an investigation.

2.1.4 Prosecution powers for registered practitioners

Following an investigation into a registered health provider, where a significant departure in clinical care and treatment and/or professional conduct has been established, the complaint may be referred to the Director of Proceedings (DoP).

The DoP determines whether disciplinary action is warranted and if so whether the prosecution should be before a Professional Standards Committee or the NSW Civil and Administrative Tribunal (NCAT). The DoP is independent and not subject to the direction of the Commissioner. In determining whether to prosecute the matter, the Director of Proceedings must consider the factors set out in section 90C of the Act: the protection of public health and safety; the seriousness of the allegation; and, the prospects of a successful prosecution.

Where there has been poor care or treatment by a registered practitioner, but not to an extent that would justify prosecution and where there is no risk to public health and safety, the Commission may refer them to the relevant Professional Council for its management or make comments to the practitioner.

2.1.5 Prohibition orders (interim and permanent) for non-registered practitioners

For non-registered practitioners, the Commission has full jurisdiction and determination over such complaints. In these scenarios, the Commission may make a prohibition order (either interim or permanent) preventing the practitioner from providing health services (or a specific health service) or placing conditions on the provision of those services for a period of time.

- **Interim prohibition order**

Under section 41AA of its Act, the Commission may, during any investigation of a complaint against a non-registered health practitioner, make an interim prohibition order only if it:

(a) has a reasonable belief that the health practitioner has breached the code of conduct for non-registered health practitioners, and

(b) is of the opinion that:

(i) the health practitioner poses a serious risk to the health or safety of members of the public, and

(ii) the making of an interim prohibition order is necessary to protect the health or safety of members of the public.

An interim prohibition order remains in force for eight weeks or a shorter period if specified in the order. The Commission must notify the health practitioner of the Interim Prohibition Order and provide a written statement of the decision that sets out the grounds for the Order as soon as practicable after the decision is made.

- **Permanent prohibition order**

Sections 41A to 41D enable a permanent prohibition order to be made at the conclusion of investigation using similar criteria as above, noting that conviction of a relevant offence also provides grounds. A non-registered practitioner has a right of appeal to NCAT.

Under section 41A of the Act, the Commission may also make a public statement that identifies and gives warnings or information about an unregistered health practitioner and their health services.

2.1.6 Comments and recommendations to health organisations

At the conclusion of an investigation of a health organisation and if prosecution is not proposed, the Commission is able to make comments or recommendations to it under section 42 of the Act. Comments may be made in circumstances such as where the health care was inadequate, but the organisation has already taken measures to prevent a re-occurrence in the future.

The Commission would typically make recommendations where there has been poor health service delivery and system improvements are required. Recommendations are communicated to the Secretary of Health and the Clinical Excellence Commission. For public health organisations, implementation is monitored and if necessary audited. If the Commission is not satisfied with implementation, it may make a special report to the NSW Parliament.

2.1.7 Public statements and warnings to health consumers

In 2015 the Commission was given a new power under section 94A(1) of the Act to issue a public warning about a particular unsafe treatment or health service that poses a risk to public health and safety, that is detected *during* the course of an investigation. Previously the Commission could only issue such a warning at the end of an investigation.

2.1.8 Referral to other bodies and information sharing

At the point of assessment, the Commission is able to refer the complaint to another appropriate regulatory or investigative body for action under sections 26, in addition to or instead of investigating the matter.

Aside from co-operation on individual complaints, under section 99B of the Act, the Commission has the ability to share information arising from its complaints management function with other bodies regulating health services in Australia and other investigative bodies, provided that this is necessary in the public interest and provided that the interest in protecting the confidentiality of information and the privacy of any person to who the information relates does not outweigh the public interest.

Entities to whom the Commission would refer matters or information associated with cosmetic and beauty clinics could include both Commonwealth and state entities with relevant jurisdiction and powers, including: NSW Police, the Ministry of Health, NSW Fair Trading, the Australian Health Practitioner Regulation Agency, the Therapeutic Goods Administration and the Australian Competition and Consumer Commission. The jurisdictions of these entities and the Commission's operational connection with them is discussed in more detail below.

2.2 What complaints have been received by the Commission

Due to the diffuse nature of cosmetic services, the data must be regarded as indicative of the issues and trends rather than definitive and it is difficult to collate and analyse the data in a comprehensive way. For instance, if a complaint is made about anaesthetic during a cosmetic procedure, it may be classified as a complaint about anaethetisation in day surgery – rather than as a complaint about a cosmetic procedure and this would not be captured in the data extracted for cosmetic services.

2.2.1 Complaints data

The number of complaints classified as complaints about cosmetic services is relatively small but the overall trend is an increase in number. Table 1 shows the complaints received by the Commission since 2012-13 where the primary classification of the complaint was cosmetic services, and Table 2 adds to this by showing those complaints in related service areas that involved a cosmetic purpose to the service.

Table 1: Complaints where cosmetic service is primary categorisation

	2012-13		2013-14		2014-15		2015-16		2016-17	
Complaints classified as Cosmetic Services	**No.**	% of complaints	**No.**	% of complaints	**No.**	% of complaints	**No.**	% of complaints	**No.**	% of complaints
	30	0.7%	88	1.8%	43	0.8%	94	1.5%	94	1.5%

Table 2: Cosmetic matters across related service areas

	2012-13		2013-14		2014-15		2015-16		2016-17	
Service area	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Cosmetic Services	30	93.8%	88	97.8%	43	87.8%	94	57.3%	94	64.4%
Alternative health		0.0%		0.0%		0.0%	40	24.4%	26	17.8%
Surgery	2	6.3%	2	2.2%	6	12.2%	25	15.2%	25	17.1%
Anaesthesia		0.0%		0.0%		0.0%	4	2.4%	1	0.7%
General medicine		0.0%		0.0%		0.0%	1	0.6%		0.0%
Grand Total	**32**	**100.0%**	**90**	**100.0%**	**49**	**100.0%**	**164**	**100.0%**	**146**	**100.0%**

The Commission has observed a number of other features of cosmetic service complaints that are important to highlight:

- Often complaints are anonymous or complainants wish to withhold their identity. While we cannot be certain of the reason for this, it seems likely that complainants have a degree of self-consciousness about the treatment they sought and /or a desire not to compromise the ability to get corrective treatment or a refund for ineffective treatment.
- A proportion of complaints are made by other cosmetic service providers.

The Commission has used its own motion complaint power in relation to cosmetic services on a number of occasions, including following the tragic death of a woman in a beauty clinic in Sydney about several individual health practitioners, as well as about an unrelated cosmetic clinic following receipt of complaints about individual practitioners who worked there.

2.2.2 Who is complained about?

As seen in Chart 1, approximately 70% of complaints refer to individual practitioners (registered and non-registered) with the remaining 30% referring to health organisations. Across both categories, almost all of the complaints related to private health service delivery.

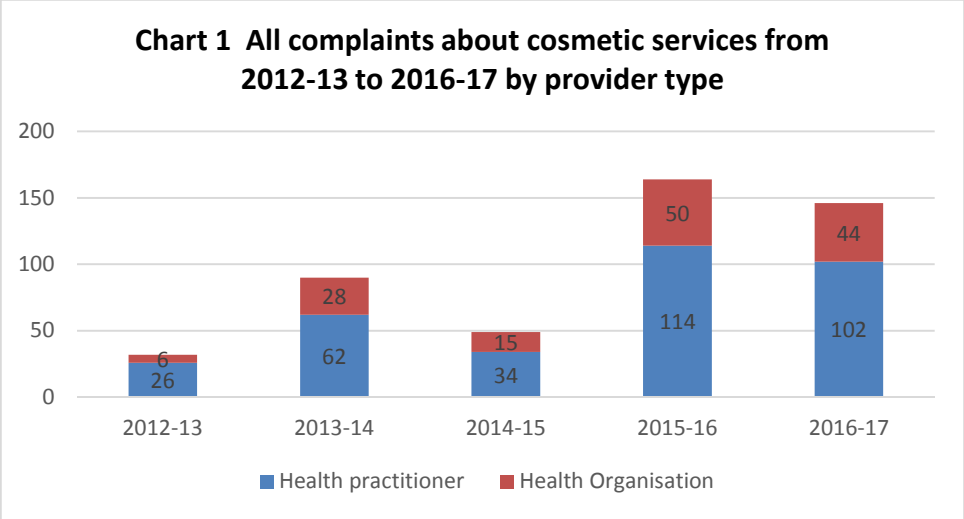


Table 3 shows provides a further breakdown of complaints about individual practitioners between registered and non-registered practitioners, showing a general increase in the percentage of complaints relating to non-registered practitioners.

Provider Type	2012-13		2013-14		2014-15		2015-16		2016-17	
	No.	%	No.	%	No.	%	No.	%	No.	%
Registered practitioner	24	92.3%	56	90.3%	33	97.1%	80	70.2%	81	79.4%
Non-registered practitioner	2	7.7%	6	9.7%	1	2.9%	34	29.8%	21	20.6%
Health practitioner total	**26**	**100.0%**	**62**	**100.0%**	**34**	**100.0%**	**114**	**100.0%**	**102**	**100.0%**

Chart 2 presents the breakdown of cosmetic service complaints about non-registered practitioners for the period 2015-16 to 2016-17 by profession, which shows that cosmetic therapists and alternative health providers are predominant.

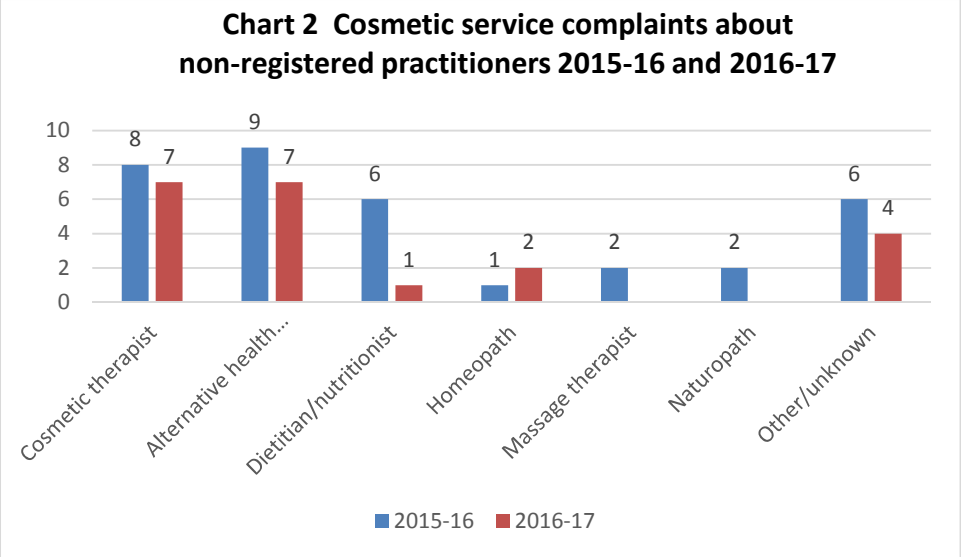
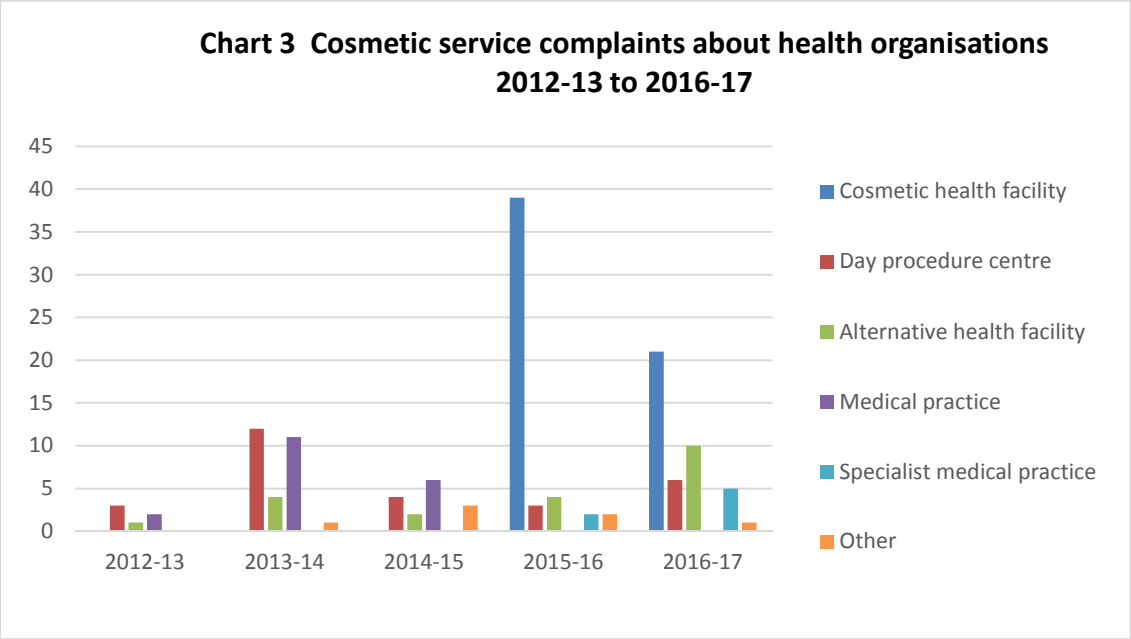


Chart 3 presents the breakdown of cosmetic service complaints about health organisations, which shows that cosmetic health facilities, day procedure centres and alternative health facilities are the most complained about.

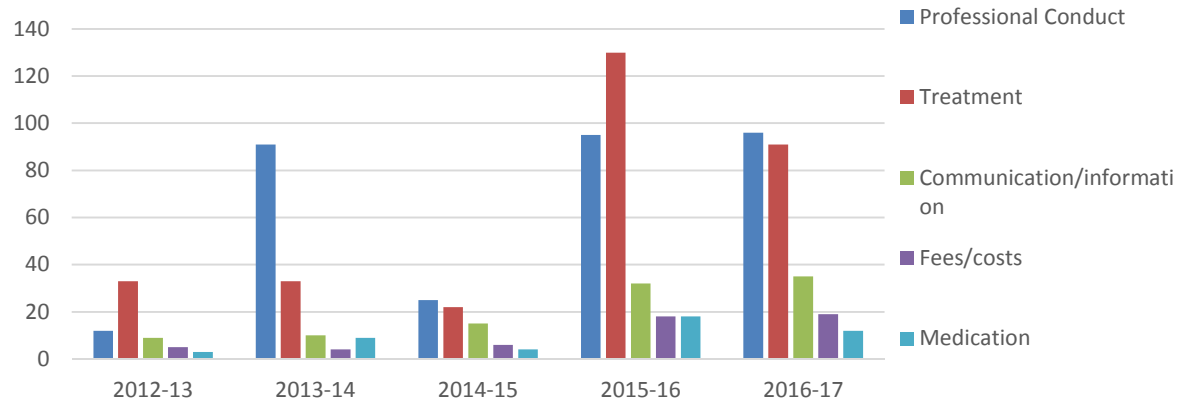


2.2.3 What is complained about?

Chart 6 below shows that the predominant issues raised in complaints about cosmetic services have consistently been professional conduct and treatment.

- Within the professional conduct category, “illegal practice” and “breach of guideline/law” account for approximately two thirds of this issue category.
- Within the treatment category, “unexpected treatment outcome/complications” and “inadequate treatment” accounted for 75% of all treatment issues raised in complaints over the past five years.

Chart 4: Top 5 issues raised in complaints about cosmetic services 2012-13 to 2016-17



2.3 How has the Commission managed these complaints

In 2016-17, 99 complaints relating to cosmetic services were assessed and the outcomes of these assessments are set out in Table 4 below.

TABLE 4: Outcomes of Cosmetic Services Complaints- 2016-17

Complaint outcome	Number	%
Discontinue	18	18.2%
Discontinue with comments	11	11.1%
Investigation	9	9.1%
Refer to another body	28	28.3%
Refer to Professional Council	13	13.1%
Resolved during Assessment	5	5.1%
Withdrawn	2	2.0%
Ongoing at close of reporting period	13	13.1%
Total	**99**	**100.0%**

It shows that:

- Over a quarter (28.3%) were referred to another body. Of the 28 complaints referred, 17 were referred to AHPRA and five to the Pharmaceutical Regulatory Unit.
- 13.1% were referred to the relevant Professional Council.
- Over 9 % were referred for investigation, and this is almost twice the proportion of all complaints referred for investigation – which is typically around 5%.
- 18.2% were discontinued, with a further 11.1% discontinued with comments.

Over the past couple of years and into 2017-18 the regulatory actions taken to date on beauty clinics and cosmetic services within NSW have included:

- The Commission commenced and/or completed over 50 investigations - 35 investigations into individual registered and non-registered practitioners and 17 into health organisations delivering cosmetic procedures.
- Making recommendations to a private health facility which changed its policies, procedures and business practices relating to breast surgery and influenced changes in the regulations relating to cosmetic procedures. This is the approach that the Commission adopted in

relation to complaints received in 2015 regarding the sedation procedures of a private health facility delivering breast augmentation services. The case is summarised at attachment A.

- Issuing two public warnings about cosmetic services. (See attachments B and C). One was issued on 28 September 2017 following an escalation in complaints regarding cosmetic procedures being undertaken in cosmetic clinics and the risks to the health and safety of people attending those clinics. The other had been issued on 30 June 2016 and warned of cosmetic surgical and medical procedures being performed by non-registered health practitioners in residential premises and hotel rooms in the Sydney area.
- Consideration of prosecution of private premises detected as performing procedures while not correctly licensed.
- Referral of a number of complaints relating to the supply and administration of medicines to the Pharmaceutical Regulation Unit of NSW Health.
- Referral of complaints that raise issues relating to the qualifications of registered practitioners or a person holding out to be a registered practitioner and misleading advertising matters to AHPRA.

3. The roles and responsibilities of other Commonwealth and state regulators

3.1 NSW Professional Councils

Unique to NSW, and a strong feature of the complaints management system is its co-regulatory design. There are 14 Professional Councils for each of the registered practice areas and these Councils work alongside the Commission to address complaints relating to registered practitioners. There are shared and distinctive roles played by the Councils.

In terms of shared roles, the Commission is the assessment, investigation and prosecution entity for all complaints relating to NSW practitioners. Councils may nevertheless receive complaints directly or via AHPRA and they must then they notify the Commission of the complaints (under s11). The Commission then assesses the complaint.

Furthermore, whenever a complaint about a registered practitioner is received, the Commission must notify the relevant Council as soon as practicable after the complaint is received (under section 10 of the Act). When Councils receive complaints directly or via AHPRA, they must then they notify the Commission of the complaints (under s11). The Commission then assesses the complaint.

Once a complaint about a registered practitioner is assessed by the Commission and before a determination is made, the Commission is obliged to consult with the relevant Council on the proposed outcome (section 12). In the consultation process the highest call wins – so if any party seeks investigation, then investigation must occur (section 13).

Robust, knowledge-driven decision making occurs through the consultation process and as a result, outcomes are informed by the experience of subject experts. A previous Parliamentary Inquiry into the Queensland Health Ombudsman recommended that the NSW joint consultation system be adopted in Queensland, in recognition of its benefits.

The distinctive role for the Professional Councils, and one in which the Commission has no role or powers, is the ability to suspend or place conditions on a registered practitioner to protect public

health and safety and to protect the public interest under section 150 of the Health Practitioner Regulation National Law (NSW).

The Councils also manage practitioners who are considered to be suffering from an impairment or whose performance is deficient in a way that requires active remediation.

3.2 NSW Ministry of Health

The Ministry is the policy body for the development of the health regulation framework. Within the NSW Ministry of Health, there are also a number of operational areas which have regulatory responsibilities which may be relevant to the delivery of cosmetic services.

- **Regulation and Compliance**

The Regulation and Compliance Unit monitors private health facilities to ensure compliance with the NSW licensing standards set by the *Private Health Facilities Act 2007* and the Private Health Facilities Regulation 2017. The aim is to ensure:

  - the maintenance of appropriate and consistent standards of health care and professional practice in private health facilities, and
  - safe practice in the delivery of health care in private health facilities.

- **Pharmaceutical Regulatory Unit**

The Unit is responsible for the administration of the *Poisons and Therapeutic Goods Act 1966* and the Poisons and Therapeutic Goods Regulation 2008, and the development of policies and guidelines to complement the legislation. It aims to ensure that medicines are appropriately available to the public and are stored, distributed, prescribed and supplied in accordance with legislative requirements. In the cosmetic services space, it is responsible for:

  - investigating the alleged illegal, inappropriate or unprofessional supply, administration or prescribing of medicines and poisons
  - investigating the alleged self-administration of drugs for non-medical reasons by health professionals
  - inspecting to ensure compliance with Poisons and Therapeutic Goods legislation and for the purpose of assessing license applications to supply poisons and/or restricted substances and licenses to manufacture or supply drugs of addiction by wholesale.

- **Health Protection**

Health Protection NSW is responsible for surveillance and public health response in NSW including monitoring the incidence of notifiable infectious diseases and taking appropriate action to control the spread of diseases.

The Public Health Units fall within its jurisdiction and it is also administers the *Public Health 2010* and Public Health Regulation 2012.

3.3 NSW Fair Trading

NSW Fair Trading safeguards the rights of all consumers and advises business and traders on fair and ethical practice. It provides services directly to individuals and businesses to create a fair, safe and equitable marketplace. The agency investigates unfair practices and ensure that the products sold in NSW are safe and meet their regulations and safety standards. It administers consumer protection legislation including the *Fair Trading Act 1987* and Australian Consumer Law.

Its main involvement in the cosmetic services domain relates to false or misleading advertising about beauty products and services. The Department is also in a position to provide information to the Commission about businesses that may be involved in complaints that are under investigation.

3.4 The Australian Health Practitioner Regulation Agency (AHPRA) and National Boards.

AHPRA is the national registration body and oversees the operation of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law), which came into effect on 1 July 2010. 14 health professions are currently regulated by nationally consistent legislation under the National Registration and Accreditation Scheme.

AHPRA also supports the National Boards that are responsible for regulating these health professions. The primary role of the National Boards is to protect the public and they set standards and policies that all registered health practitioners must meet.

Of note in relation to the regulation of registered practitioners, including in the cosmetic services space, is the Medical Board Code of Conduct which requires the practitioners work within their areas of competence and scope of practice and maintain the knowledge and skills to deliver safe care.

The Medical Board has also developed and issued guidelines which tackle key issues is relation to cosmetic treatments such as fuller assessment and consideration of alternative solutions or treatments for patients seeking cosmetic treatments and the need for a cooling off period to provide space for a patient to consider proposed surgery and any associated risks prior to undergoing the procedure.

In relation to cosmetic services, AHPRA has a role in managing complaints about 'holding out' (health practitioners who claim to be one of the registered professions but are not) as well as investigating and prosecuting offences relating to false and misleading advertising.

The National Law protects the public by ensuring that only registered health practitioners who are suitably trained and qualified are able to use protected titles. The law allows for penalties to be issued by a court for using protected titles or holding out as a registered practitioner when not entitled to. The maximum penalty which a court may impose per charge is $30,000 (in the case of an individual) or $60,000 (in the case of a body corporate).

AHPRA can also investigate and prosecute a person or entity who advertises a regulated health service, in a way that is or is likely to be false, misleading, or deceptive under section 133 of the National Law. A registered health practitioner, or a business providing a regulated health service, whose advertising breaches the National Law, may be prosecuted and ordered by a court to pay a $5,000 penalty per offence (for an individual) or a $10,000 penalty per offence (for a body corporate).

3.5 Commonwealth role in regulating supply of medicines: Therapeutic Goods Administration (TGA) and Australian Border Force

The TGA is responsible for ensuring that therapeutic goods and devices available for supply in Australia are safe and fit for their intended purpose. The TGA regulates the supply of:

- medicines prescribed by a doctor or dentist
- medicines available from behind the pharmacy counter
- medicines available in the general pharmacy
- medicines available from supermarkets

- complementary medicines, including vitamins
- medical devices, from simple devices like bandages to complex technologies like heart pacemakers
- products used to test for various diseases or conditions, and
- vaccines, blood products, and other biologics.

It also regulates the manufacturing and advertising of these products.

In terms of the issues associated with cosmetic clinics, medicines and devices that are marketed, supplied and administered must be registered of the Australian Register of Therapeutic Goods (ARTG) and furthermore, the importation of medicines is controlled under the *Customs Act 1901* by the Australian Border Force. The *Therapeutic Goods Act 1989* and the *Poisons and Therapeutic Goods* legislation work together.

By way of example, injectable dermal fillers and Botox are Schedule 4 medicines and the legislation requires these medicines:

- be prescribed by an authorised and registered medical practitioners/ dentist
- be supplied only to an authorised practitioner or other authorised person
- be administered only in accordance with a prescription, and a prescribing medical practitioner is responsible for ensuring that the medicine is administered by a competent person
- safe storage of these products is required.

4. Opportunities for Collaboration

4.1 Policy Development

The Commission continues to take opportunities influence policy development through issues identified in its complaints and investigations. As noted above, this issues raised in complaints and investigations during 2015 assisted to inform the development of the Private Health Facilities Amendment (Cosmetic Surgery) Regulation 2016 , through which the private health facilities regulation was extended to specified cosmetic procedures, whether or not those procedures involved anaesthesia and this extended protection relating to procedures such as breast implants, reductions and lifts, significant liposuction, 'tummy tucks' and the like.

4.2 Joint Operations with NSW Health

During 2017 and 2018 there has been a planned and coordinated response to the inspection and investigation of health clinics.

The Commission and the NSW Ministry of Health (Pharmaceutical Regulation Unit) have joined forces to undertake proactive raids on multiple premises in precincts where these facilities are clustered, with the intention of understanding more fully the business models of these entities; identifying more clearly the nature and extent of the risks posed; and determining the most appropriate regulatory responses to these risks.

These proactive raids have enabled each organisation to gather the evidence necessary to take relevant regulatory action. One example is described at attachment D.

4.3 Improved co-ordination within NSW

The NSW Regulators Forum was established in early 2017. It meets quarterly and is chaired by the NSW Ministry of Health. Its initial focus has been on strengthening policy and operational linkages between the various elements of health regulation –including the Commission; various arms of the Ministry of Health such as Pharmaceutical Regulatory Unit, Health Protection, Regulation and Compliance; Health Professional Councils Authority; and Medical Council of NSW and Dental Council of NSW.

The Forum takes a data and evidence driven approach to identifying emerging risks to public health and safety and strategic consideration of the respective roles and responsibilities and powers, as a framework for operational collaboration.

The next development that is now occurring is inclusion of NSW Fair Trading operational planning and implementation.

4.4 Working alongside AHPRA

In many instances, effective management of complaints relating to cosmetic services will require referral of certain aspects for action by AHPRA, whose powers will be relevant in a number of respects as outlined in section 3.4.

The Commission regularly refers such matters to AHPRA and has also commenced a regime of joint inspection and investigation visits when both organisations are involved in responding to a complaint.

The Commission also supports and benefits from developments in the National Law. In August 2017, Health Ministers agreed to proceed with amendments to the National Law to strengthen penalties for offences committed by people who hold themselves out to be a registered health practitioner, including those who use reserved professional titles or carry out restricted practices when not registered. Drafting of the amendment Bill has commenced and will be brought forward to Ministers for approval.

4.5 Broader National Collaboration

It has also become increasingly apparent that success in addressing the problems requires a strategy that brings the powers and actions of state and national regulators together in a coordinated fashion.

Furthermore, because the services involved are more in the nature of commercial businesses than health service providers and because the business model operated on national and international scales, the response must work across the boundaries of health, business and consumer regulation. It is only through judicious and effective use of powers across these areas that there will be the ability to disrupt the activities of disreputable and risky individuals and clinics.

At the planning and strategy level, NSW has become a member of the national Consumer Health Regulators Group. This Group was formed in April 2017 and consists of regulators from across Australia with an interest in consumer health. The Group is currently chaired by the Australian Competition and Consumer Commission and other members include AHPRA, the Therapeutic Goods Administration and the Private Health Insurance Ombudsman and the NSW Health Care Complaints Commission. The focus of the group is on sharing information that will enable earlier identification of risks to health consumers and clearer and more coordinated arrangements for addressing those risks.

Building on the connections made through the Consumer Health Regulators Group, the Commission and the Ministry have therefore commenced a regime of closer collaboration with Commonwealth regulators in operations relating to beauty clinics. The focus for the Commission has been on linking with the Therapeutic Goods Administration (TGA), Border Force (and potentially a broader suite of Commonwealth regulators) in addition to strengthening collaboration on matters referred to AHPRA.

5. Adequacy of Powers and Functions

The Commission does not have policy development or legislative reform functions and therefore issues regarding to the nature and adequacy of the regulatory framework are a matter for the NSW Ministry of Health and ultimately the government. The observations in this section may assist in informing policy and practice in the important area of regulating cosmetic services.

5.1 Differences in complaints management powers

The Commission's powers differ in some relevant respects from those that apply to the independent regulators in other states. In some respects they are wider, and in others more narrow.

- **Entry and search powers**

NSW provisions relating to powers of entry, search and seizure are outlined in sections 33 and 34 in the *Health Care Complaints Act 1993*. These powers are only able to be exercised when a complaint is in investigation and only with consent or under the authority of a search warrant.

The Commission currently benefits from the broader search and seize powers of the inspectors of the Pharmaceutical Regulation Unit. The PRU is able to search premises and seize goods under powers conferred to it in section 43 of the NSW *Poison and Therapeutic Goods Act 1966*. When conducting joint inspections of beauty and cosmetic clinics with the PRU, Commission staff carry out investigative actions jointly under the authority of the PRU's. This allows the Commission to participate in fact finding inspections which would otherwise not be possible as its own powers of entry require a matter to already be in investigation.

In Queensland the entry and search powers are outlined in Division 2 of the *Health Ombudsman Act 2013*. They are broader and have a general power of entry which apart from consent and search warrant, also allows authorised persons to enter a premises if "*it is a public place and the entry is made when the place is open to the public*". In addition, unlike NSW and Victoria, its powers apply to all complaints and are not confined to those only in investigation.

- **Public health warnings**

Under section 94A of the *Health Care Complaints Act 1993*, the Commission may issue a public warning if following or during an investigation, it is of the view that a particular *treatment or health service* poses a risk to public health or safety. A public warning may not be issued about a specific named health facility or individual registered provider.

In Victoria, public warnings are able to name a health service provider. Under section 84 of the Victorian *Health Complaints Act 2016*, the Commissioner may publish a statement setting out the *name* of a health service provider if they reasonably believe there has been a contravention

of a code of conduct applying to the general health service provided and is satisfied that it is necessary to make the order to avoid a serious risk to the health, safety or welfare of the public.

- **Interim and permanent prohibition orders**

Sections 41AA to 41D of the *Health Care Complaints Act 1993* outline the powers of the Commission in regard to interim and permanent prohibition orders. These extend only to individual non-registered practitioners – they are not able to be issued in regard to a health facility. This is also the case with the Queensland Office of the Health Ombudsman.

In Victoria, sections 90 to 102 in its legislation cover prohibition orders. The difference to NSW is that prohibition orders there may be made about either an individual non-registered practitioner or a health facility. For example, there is a current interim prohibition order for 'Sparadise Medical and Cosmetic Clinic' triggered by a serious complaint from a consumer who visited the health service for a cosmetic procedure and had a very poor outcome: https://hcc.vic.gov.au/statements-orders/prohibition-orders/131

5.2 Working with private facilities following investigations

Under section 42(1)(b) of the Act, the Commission may make recommendations to a health organisation at the end of an investigation. This applies to both public and private health organisations.

The Commission has strong practices in place for monitoring and auditing the implementation of recommendations for public health facilities. The Commission receives notification of action taken or proposed in response to these recommendations from the Secretary of Health, and it also has the co-operation of public health facilities to conduct an audit program that allows to visit a public health facility to examine compliance with the recommendations.

The Commission can also require in recommendations that a private health facility that it notify it of action taken to implement recommendations, but there is no power to enter the facility after an investigation to conduct an inspection to determine compliance.

5.3 The health regulation framework

As noted above, a difficult feature of the cosmetic sector is that the services provided do not easily fit within the usual definitions of health services and may often not be provided in a clinical setting. The types of procedures provided in this sector are also rapidly evolving and unpredictable.

Some issues and questions that arise in the context of complaints management and investigations include:

- What responsibility should medical practitioners have for ensuring that any facility in which they are conducting surgical procedures is appropriately licensed and equipped?
- Is there a need for further guidelines or standards in relation to day surgery where there lower levels of sedation and anaesthesia are being used?
- Are there opportunities to review and, if necessary, add procedures to the list of procedures that must be carried out in a licensed facility and to also ensure appropriate penalties for breaches?
- Would there be benefit in establishing a protected title of "cosmetic surgeon" under the National Law?
- What is the expected nature of the consultation that must occur with patients who are being prescribed schedule 4 medicines in a cosmetic clinic context?

- What training and experience should a person administering schedule 4 drugs in a beauty or cosmetic clinic environment have?

5.4 Further strengthening national collaboration

Initial operational collaboration with national bodies reinforces that continued development of this collaboration will be central to effective regulation of the cosmetic services sector.

While the relative roles and responsibilities of key entities seem relatively clear, there is benefit from further consideration on aspects such as:

- whether additional Commonwealth agencies (such as Border Force and Australian Taxation Office) can be more involved;
- how and when cross jurisdictional action can be mobilised to ensure a rapid response capability;
- arrangements for settling the nature and sequence of actions that may be required and the arrangements for co-ordinating and leading those; and
- ensuring that there is smooth and timely data and information exchange.

Attachments

Attachment A : Case study – Recommendations to a health organisation

In 2015, the Commission received a number of complaints about a non-registered health facility that was delivering breast augmentation services. Medical complications had occurred following these procedures.

Specifically, this facility was allowing deep sedation during breast augmentation surgery, which posed risks to the health and safety of members of the public.

The Commission's investigation involved close cooperation with the NSW Ministry of Health's Private Health Care Unit (PHCU) and the collection of the anaesthetic records of a large sample of patients. The Commission also secured expert advice on the technical issues and use of local anaesthetic agents and vasoconstrictors, such as adrenaline.

Noting also that many patients were unhappy with the outcome of the surgery even where there were not complications arising from the techniques of sedation, the investigation also examined the consent processes that the facility had in place.

During the investigation, the facility elected to change its business model to ensure that breast augmentations would be conducted only at its licensed operation, so that deeper sedation or general anaesthetic could be used as necessary and with appropriate protection for patients.

The facility also agreed to a change to its consent procedures. Patients now benefit from a more thorough consent process, which specifically addresses in detail their acknowledgment and awareness of undergoing a breast augmentation where a breast lift is clinically indicated, and the associated risks and outcomes. The facility specifically recommends that patients in these circumstances consult with a plastic surgeon (and they provide a referral) before undergoing breast augmentation.

These improvements were formally acknowledged and captured in recommendations to the facility as the outcome of the investigation.

New legislation has now been passed by the NSW Government to define certain types of cosmetic procedures that must be conducted in licensed premises – this includes all breast augmentation surgery. This regulation took effect from March 2017.

Attachment B:

Public Warning under s94A (1) of the Health Care Complaints Act 1993: Cosmetic surgical and medical procedures performed by non-registered health practitioners: 30 June 2016

The NSW Health Care Complaints Commission is receiving an increasing number of complaints about cosmetic procedures being performed in residential premises and hotel rooms, by non-registered practitioners in NSW, particularly in the Sydney area.

The cosmetic services being offered by non-registered practitioners are being advertised through various social media platforms, in particular "Wechat". The procedures involve a range of skin penetration procedures and administration of Schedule 4 prescription-only medication to 'improve' appearance. This includes double eyelid suturing, nose bridge lifts, protein suture facelifts, the administration of Botox, Dermal fillers and Glutathione skin whitening injections.

It is illegal for a non-registered practitioner to undertake these procedures and because there is no validation of their qualifications and experience, there is a real risk to public health and safety. Furthermore, the procedures are being performed in facilities that have little, if any, infection control measures as per the Public Health Act 2010 and the Public Health Regulation 2012 (the Regulations).

The medications used by the non-registered practitioners are imported and not on the Australian Register of Therapeutic Goods (ARTG). The import and supply of medication that is not on the ARTG is unlawful and dangerous since there is no way of determining the efficacy and safety of the medicines.

The Commission is currently conducting an investigation into a complaint made by a female who underwent a double eyelid suture procedure in a residential apartment in the Sydney area. The treatment caused bruising and scarring to the patient and damage to her eyelids. The Commission's investigation has so far determined that the practitioner who carried out the surgery is not registered as a medical practitioner in Australia and was not qualified to conduct the surgery. Upon executing a search warrant at the premises, Commission staff located a number of prescription-only medications that had been illegally imported into Australia. This included Botulinum toxin (Botox) and hyaluronic acid injection preparations (Dermal fillers).

The Commission urges those individuals seeking cosmetic surgical and medical procedures to be vigilant in their research prior to proceeding.

The following factors should be considered before committing to a cosmetic surgical or medical procedure:

1. Is the practitioner appropriately qualified, experienced and accredited?

Cosmetic surgical procedures – these procedures are required to be performed by a medical practitioner and the consumer should be assessed by that medical practitioner before scheduling the procedure.

Administration of Schedule 4 drugs for cosmetic use – the consumer is required to have a consultation with a registered medical practitioner (in person or by video), for a management plan to be created and for that medical practitioner to prescribe the restricted substance. The consumer is required to be under the direct care of the medical practitioner, but the substance can be administered by a registered nurse who has been appropriately trained.

Consumers are encouraged to ask a practitioner about their qualifications, training and experience. They can also check to see if a practitioner is registered in Australia through the Australian Health Practitioner Regulation Agency (AHPRA) website on www.ahpra.gov.au. If the practitioner is not registered in Australia, you should not proceed.

2. Is the facility appropriately equipped?

Cosmetic surgical and medical procedures are wide ranging and as such, there is no one piece of legislation regarding the licensing and registration requirements of these facilities. Consumers considering skin penetration procedures should be mindful of the following:

- Premises where skin penetration procedures are performed need to be registered with the local government which enables random inspections to be conducted to monitor compliance with the Regulations;
- The premises needs to be clean and hygienic, have a waste disposal bin, have a hand basin that has a clean supply of water and have liquid soap and single use towels or a hand dryer for drying hands;
- Protective equipment needs to be worn by the person carrying out the procedure, including the use of gloves that have never been worn and a clean gown or apron;
- Needles used must not have been previously used and need to be disposed of using an appropriate sharps container.

3. Am I appropriately informed?

The practitioner performing the procedure should provide the consumer with enough information to make an informed decision about whether to have the procedure. Consumers should be provided with at least the following information:

- What does the procedure involve?
- Is the procedure new or experimental?
- What are the range of possible outcomes of the procedure?
- What are the risks and possible complications associated with the procedure?

ATTACHMENT C:

Public Warning under s94A of the Health Care Complaints Act - Unsafe and Illegal Practices at Beauty and Cosmetic Clinics: 28 Sep 2017

The NSW Health Care Complaints Commission is concerned about complaints regarding cosmetic procedures undertaken in cosmetic clinics and the risks to the health and safety of people attending those clinics.

What should consumers do to protect themselves?

The Commission strongly urges those individuals seeking cosmetic procedures or cosmetic surgery to be vigilant in their research prior to proceeding. In all cases the following factors should be considered before committing to the procedure or surgery:

1. Is the procedure supported by a practitioner who is appropriately qualified, experienced and accredited?

Cosmetic procedures typically involve the use of Schedule 4 drugs which include, but are not limited to, Botulinum toxin type A (Botox) and hyaluronic acid injection preparations (Dermal fillers)and medications designed to numb tissue such as Lidocaine in injectable and cream form. For these medications, the consumer is required to have a consultation with a registered medical practitioner (in person or by video), for a management plan to be created and for that medical practitioner to prescribe the restricted substance. The consumer is required to be under the direct care or supervision of the medical practitioner.

2. Is the facility appropriately registered, infection controlled and equipped?

Cosmetic procedures are wide ranging and there are a number of relevant requirements in legislation regarding the licensing and registration requirements of these facilities.

Consumers considering skin penetration procedures should be mindful that if there is no registered practitioner working at premises where skin penetration procedures are performed, the facility must be notified to the relevant local council. This enables random inspections to be conducted to monitor compliance with the Regulations. Consumers should also satisfy themselves of the following:

The premises needs to be clean and hygienic, have a waste disposal bin, have a hand basin that has a clean supply of water and have liquid soap and single use towels or a hand dryer for drying hands;

Protective equipment needs to be worn by the person carrying out the procedure, including the use of gloves that have never been worn and a clean gown or apron;

Needles used must not have been previously used and need to be disposed of using an appropriate sharps container.

Medication ampoules must only be used once and the consumer is entitled to ask that the single use ampules are shown to them before and / or during the procedure.

3. Are you having cosmetic surgery?

There are extra protections in place for consumers who are undergoing cosmetic surgery (which includes procedures such as significant liposuction, fat transfer, facial implants that are on the bone or involve deep tissue surgery, breast augmentation or reduction, and "tummy tuck").

These procedures are the subject of new legislative requirements that came into operation in March 2017. The full list of cosmetic surgical procedures which need to be conducted at licensed premises is at http://www.legislation.nsw.gov.au/regulations/2016-288.pdf.Consumers should assure themselves that any facility that involves the administration of anesthetic (including a general, epidural or major regional anesthetic to achieve more than conscious sedation) or that involves cosmetic surgery of the kind listed in the regulation is in fact licensed.

Cosmetic surgical procedures are also required to be performed by a medical practitioner and the consumer should be assessed by that medical practitioner before scheduling the procedure. Consumers are encouraged to ask a medical practitioner about their qualifications, training and experience. They can also check to see if a practitioner is registered in Australia through the Australian Health Practitioner Regulation Agency (AHPRA) website on www.ahpra.gov.au. If the practitioner is not registered in Australia, you should not proceed.

4. Are you appropriately informed?

The practitioner performing the procedure should provide the consumer with enough information to make an informed decision about whether to have the procedure. Consumers should be provided with at least the following information:

- What does the procedure involve?
- Is the procedure new or experimental?
- What products are being used in the procedure and are these products registered?
- What are the range of possible outcomes of the procedure?
- What are the risks and possible complications associated with the procedure?

5. Why is this warning being issued?

In NSW consumers are increasingly spending money on a range of cosmetic services. These services include a range of skin penetration procedures including micro-needling and Platelet Rich Plasma treatment, non-surgical breast and hip enhancements, nose bridge lifts, double eyelid suturing and anti-ageing facial treatments. The procedures often include the administration of Schedule 4 prescription-only medication including Botulinum toxin type A (Botox) and hyaluronic acid injection preparations (Dermal fillers), in addition to medications designed to numb tissue such as Lidocaine in injectable and cream form.

The issues raised in the complaints received include:

- Whether the products being used in these treatments are registered or unregistered products. Use of unregistered products which may be of inferior quality and untested pose a health risk. The import and supply of medication that is not on the Australian Register of Therapeutic Goods (ARTG) is unlawful and dangerous since there is no way of determining the efficacy and safety of the medicines.

- Whether the person prescribing the medication is registered under the Health Practitioner Regulation National Law. The Schedule 4 medications typically used in cosmetic treatments must be prescribed to the individual by a registered medical practitioner. The administration of medications by non-registered and unqualified persons without a prescription is dangerous because there is no informed assessment of the clinical risks associated with the treatment and no validation of their qualifications and experience. Consumers who receive treatment in these circumstances are taking unnecessary risks that could ultimately lead to life changing injuries or indeed death.

In response to these complaints the Commission has completed and is conducting a range of investigations. One key element of this work is the active investigation of complaints concerning the care and treatment of a woman who died following a cosmetic procedure at the Medi Beauty Laser and Contour Clinic in Chippendale, NSW.

The Commission is also involved in joint operations with the NSW Department of Health's Pharmaceutical Regulatory Unit to inspect beauty/cosmetic clinics in a number of areas across Sydney to examine their operations and identify and address any areas of non-compliance.

The Commission has serious concerns that persons are carrying out medical-related procedures to 'improve' aesthetic appearance whilst not appropriately registered as a medical practitioner. No registered medical practitioners were present during the inspections of any of these clinics. The inspections also provided evidence that medicines that are not on the ARTG continue to be unlawfully imported into Australia and used in beauty/cosmetic clinics.

A number of non ARTG medications were seized during the joint operation. These included Lidocaine cream with significant strength (ranging from 10.5 to 19.8 %), Erythromycin Ointment, (an antibiotic) and Schedule 4 medication unlawfully imported in bulk from China, and non ARTG Botulinum toxin type A imported from South Korea. In addition, Hyaluronidase, A (an injectable enzyme solution that speeds the natural breakdown of hyaluronic acid) was seized. This medication is used to counteract the effects of hyaluronic acid based fillers for patients whose original dermal filler treatments did not turn out as they expected. Non ARTG approved Iodine and Vitamin B and C injections were also seized together with anesthetic lip and eyebrow paste.

A significant amount of non- ARTG medical devices imported from China were also found. These included Cannulas, needles, sutures, gauze, masks and gloves. These devices must be sterile and such imported devices cannot be guaranteed to have been sterilized to Australian standards therefore potentially increasing the risk of infection to consumers.

<u>Attachment D:</u> Coordinated Investigation of a Health Facility in NSW

The NSW Health Care Complaints Commission received multiple complaints concerning a doctor not registered in Australia performing cosmetic procedures at a beauty clinic and that the clinic was using foreign injectable products that were not on the Australian Register of Therapeutic Goods (ARTG).

An investigation was commenced and this was conducted in collaboration with the Pharmaceutical Regulatory Unit (PRU) of the NSW Ministry of Health and Public Health Unit (PHU). Inspections of the clinic found numerous non-ARTG products such as hyaluronic acid injections.

The Commission's investigation found that the clinic was carrying out skin penetration practices, but was not registered as a skin penetration premises as required under the *Public Health Act 2010*. The PHU also discovered that the clinic had very unsatisfactory infection control. For instance:

- No autoclave for sterilising reusable skin penetration implements.
- Equipment (tattoo pen) used in connection with skin penetration procedures was not cleaned and dried after use and not kept in a clean condition.
- Reusable articles that may be used to penetrate a person's skin were not sterilised.
- Articles used in skin penetration procedures and manufactured for single use were not disposed of immediately after the procedures in an appropriate sharps container.
- Single use of ink/pigment containers used in cosmetic tattooing were stored with non-sterile products.

The investigation concluded that the clinic lacked management and had poor arrangements for operational accountability. The clinic had failed to understand its regulatory responsibilities and at a risk to the public, it operated without relevant registration and without adequate infection control. The numerous non-ARTG products found on the premises were reportedly there without the knowledge of the owner.

The Commission made numerous recommendations to the clinic under section 42 of the *Health Care Complaints Act 1993,* with the aim of ensuring full compliance with relevant legislative requirements. The clinic was required to provide the Commission with evidence of existing protocols in use that ensured only ARTG approved products are used and only appropriately Australian registered medical practitioners are responsible for the ordering and prescribing of scheduled medications to clients. Further, the Commission stated that if no such protocols exist, the clinic was to establish these.

The Commission also required the clinic to provide all staff with training in infection control protocols and standards and ensuring their awareness that only ARTG products can be used when providing health services and the health risks associated with using non-ARTG products. Evidence of the content of the training and evidence of the training having been delivered was also required.

The clinic provided the Commission with all relevant documentation to confirm that these recommendations have been fully implemented. The Commission will continue to work with PRU and the PHU to monitor compliance.