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Summary of the Regulatory Framework of Higher Risk Non-Surgical Cosmetic Procedures using S4 *(prescription only)* Cosmetic Injectables

04/06/2025

A patient safety initiative supported by:

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Australasian Society of Cosmetic and Procedural Dermatologists

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The complexity surrounding cosmetic injectables regulations is due to interplay of various regulatory bodies. Each of these regulatory bodies govern specific components in the clinical care-delivery of cosmetic injectables, from the eligibility, consultations, the facilities, the products, to the procedure, and aftercare.

It is important to remember that there are legislations or laws that dictates the legal requirements which we are legally obligated to comply with; and then there are professional standards and guidelines, providing health practitioners with the best practice standards of which we should adhere to. Compliance with both is paramount for patient safety, and it is not about fulfilling the bare minimum requirement, but about providing the best clinical care in the patient's best interest.

We have prepared a summary of the regulations grouped into:

1. What component of clinical practice they may apply to

2. Under the jurisdiction of which relevant regulatory body

This summary will help you apply the regulations into these relevant areas of clinical practice:

- **ADVERTISING OF COSMETIC INJECTABLES**
  – under the jurisdiction of TGA, AHPRA, ACCC.
- **'HANDLING' OF SCHEDULE 4 PHARMACEUTICALS (Prescription, Storage & Administration)**
  – under the jurisdiction of the Poisons Standards, state and territory laws.
- **PROFESSIONAL CONDUCT & CLINICAL STANDARDS IN NON-SURGICAL COSMETIC PROCEDURES**
  – under the jurisdiction of AHPRA and various professional boards (Nursing and Midwifery Board of Australia, Medical Board of Australia and Dental of Australia), and the state and territory laws can also come into play in the prescription of pharmaceuticals.

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1. Advertising and Marketing

Higher non-surgical cosmetic procedures are regulated health services that involves prescription only S4 medicines. Hence, advertising higher risk non-surgical cosmetic procedures falls under two regulatory jurisdictions:

1. AHPRA – Regulates health service provisions and advertisement of these services
2. TGA – Regulation of S4 medicines used in higher risk non-surgical cosmetic procedures and advertising of these prescription only S4 medicines.

Within AHPRA and TGA, there are also regulations surrounding the advertising of health services or prescription medicines in general, and then those specific to cosmetic practices and injectable products.

KEY POINTS

- Only use a protected title if you hold registration.
- Use of the term 'specialist' is restricted.
- Avoid using misleading claims about qualifications, experience or expertise.
- You must inform people of your registration details, registration type.
- Advertising material including practice and practitioner website and social media must comply with:
    a. *National Law Section 117-119*
    b. *National Boards' Guidelines for advertising of regulated health services*
    c. *National Boards' Guidelines for advertising higher risk non-surgical cosmetic procedures*
    d. *The current Therapeutic Goods Advertising Code*
    e. *Any TGA guidance on advertising non-surgical cosmetic procedures and the advertising requirements of section 133 of the National Law.*
    f. *Where the prescriber is a Registered Medical Practitioner, they must comply with the Medical Board of Australia's Guidelines for Registered Medical Practitioners who perform Cosmetic Surgery and Procedures.*

Area	Regulatory Body	Reference
General Advertising Laws	ACCC	Advertising and promotions | ACCC
Advertisement of Prescription Medicines in General	TGA	Advertising a health service | Therapeutic Goods Administration (TGA)
Advertisement of cosmetic *injectable medicines* (Schedule 4):		
The Updated Guidelines	TGA	Cosmetic injection services | Advertising a health service | Therapeutic Goods Administration (TGA)
FAQ on the Guidelines: (a detailed description of the practical application of TGA advertising regulations)	TGA	Advertising health services and cosmetic injections: frequently asked questions and answers | Therapeutic Goods Administration (TGA)
Reasons behind Guidelines	TGA	Referring to cosmetic injectables in advertising | Therapeutic Goods Administration (TGA)
'Advertising' to other health professionals: (e.g. conferences, training etc.)	TGA	Advertising to health professionals so that consumer rules do not apply | Therapeutic Goods Administration (TGA)
Advertisement of cosmetic *health service*		
Applicable to all registered practitioners	AHPRA	Ahpra-Guidelines-for-advertising-a-regulated-health-service-December-2020(5).PDF
Applicable to medical practitioners	AHPRA	Medical-Board-Guidelines-for-registered-medical-practitioners-who-advertise-cosmetic-surgery(4).PDF
Applicable to medical practitioners who advertise cosmetic surgery & procedures	AHPRA	Medical Board of Australia – Guidelines for registered medical practitioners who perform cosmetic surgery and procedures
Applicable to medical practitioners who perform cosmetic surgery (specific section on non-surgical procedures)	AHPRA	Medical Board of Australia – Guidelines for registered medical practitioners who perform cosmetic surgery and procedures
Applicable to all health practitioners/ businesses/groups who advertise 'higher-risk' non-surgical procedures	AHPRA	APRRA-Advertising higher risk non-surgical cosmetic procedures and APRRA-Performing non-surgical cosmetic procedures (section 11.1-11.2)

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2. ‘Handling’ of Schedule 4 Pharmaceuticals *(Prescription & Storage & Administration)*

Registered health practitioners MUST know and comply with the requirements of their state or territory drugs and poisons (or equivalent) legislation for Schedule 4 (prescription only) cosmetic injectables. These include requirements relation to permits, prescribing, records, supply, storage and transport.

In Australia, there is no national legislation or regulation that govern the supply, possession, prescription, storage or use of medicines, poisons or controlled substances. There is also no national legislation that govern the *authority* of health professionals to undertake certain actions in relation to these poisons (e.g. prescribing, storage, dispensing).

These are regulated by individual state and territory legislations. There is a relatively uniform regulatory approach throughout Australia because each state and territory refer to the national *Standard for the Uniform Scheduling of Drugs and Poisons* (also known as the Poisons Standard) to establish their legislations and regulations surrounding these substances. However, there are still some noticeable variations between individual states and territories.

For prescription of S4 pharmaceuticals in Australia, they must be prescribed by a doctor, dentist, or nurse practitioner. Nurses cannot administer these without a valid prescription and delegation.

Variations between state and territories are noted in the hold, storage and dispensing of these drugs. Most recently, Queensland Health released further ‘guidance’ on the current legislation (in place since 2021) on schedule 4 drugs as it applies cosmetic injectables:

> *‘Each State and Territory has its own laws that govern how medicines must be handled in that State or Territory. Queensland’s MPA and MPMR detail the authorities and limitations relevant to regulated substances placed on different health professionals in Queensland. In Queensland, RNs cannot possess a stock of S4 medicines for use in their clinics. However, RNs may hold individually dispensed medicines for individual clients.’*

Currently, only NSW and Queensland Health Departments have publicly engaged in making statements about the application of legislations to schedule 4 cosmetic injectables.

Area	Regulatory Body	Regulation
Prescription, Supply, Hold, Storage, Dispensing and Administration of S4 Injectable drugs in QLD	QH	*Medicines in beauty treatment and cosmetic injectable businesses | Queensland Health*
New regulations introduced in September 2021 specific to cosmetic injectables	NSW Health	*New laws that apply to administering cosmetic medicines*

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The State and Territory Legislations

The Poisons Standard: *The Poisons Standard (the SUSMP) | Therapeutic Goods Administration (TGA)*: is a legal instrument used for classification and scheduling of medicines and poisons, including containers and labeling. It is a national reference document for state and territory legislations associated with handling of medicines, poisons and controlled substances.

State	Legislation	Regulation
Australian Capital Territory	*Medicines, Poisons and Therapeutic Goods Act 2008*	*Medicines, Poisons and Therapeutic Goods Regulation 2008*
New South Wales	*Poisons and Therapeutic Goods Act 1996*	*Poisons and Therapeutic Goods Regulation 2008*
Northern Territory	*Poisons and Dangerous Drugs Act*	*Poisons and Dangerous Drugs Regulations*
Queensland	*Medicines and Poisons Act 2019 (MPA)*	*Medicines and poisons (Medicines) Regulation 2019 (MPMR)*
South Australia	*Controlled Substances Act 1984*	*Controlled Substances (Poisons) Regulations 1996*
Tasmania	*Poisons Act 1971*	*Poisons Regulations 2002*
Victoria	*Drugs, Poisons and Controlled Substances Act 1981*	*Drugs, Poisons and Controlled Substances Regulations 2006*
Western Australia	*Medicines and Poisons Act 2014*	*Medicines and Poisons Regulations 2014*

AHPRA defers to state and territory legislations for the handling of S4 Drugs.

> *'Registered health practitioners must know and comply with the requirements of their state or territory drugs and poisons (or equivalent) legislation for Schedule 4 (prescription-only) cosmetic injectables. For example, requirements relating to permits, prescribing, records, supply, storage and transport.'*

From:
Australian Health Practitioner Regulation Agency – Performing non-surgical cosmetic procedures
(section 6)

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3. Professional Conduct & Clinical Standards in Non-Surgical Cosmetic Procedures

The regulation of the practitioners, scope of practice and professional conduct in clinical practice are mainly regulated by AHPRA and its professional boards. There is some cross-over from Department of Health policies which set specific requirements in our clinical environment/facilities (e.g. infection prevention and control policies), as well as govern how we facilitate treatment, such as prescription of medicines.

In addition, our professional bodies such as the specialist colleges and societies may also publish professional guidelines that establish a peer-reviewed standard of care (SOC). Although these are not strictly 'legal' requirements, these standard of care documents may be referred to when profession misconduct is being considered during disciplinary actions taken by regulatory bodies. For example, RACGP's published professional standards for Telehealth: ***Principles for conducting telehealth consultations*** establishes the standard of care expected of a medical practitioner when engaging in the provision of telehealth.

Area of Clinical Practice	Regulatory Body or Guideline Resource	Regulation
Telehealth		
Telehealth consultation standards	AHPRA	*Medical Board of Australia – Telehealth consultations with patients*
Ability to prescribe cosmetic injectable via telehealth	AHPRA	*Medical Board of Australia – Guidelines for registered medical practitioners who perform cosmetic surgery and procedures*
Ability to prescribe cosmetic injectable via telehealth (Medical & Nurse Practitioners)	NSW Health	*New laws that apply to administering cosmetic medicines*
Frequency of Consultation & Prescription		
'Medical practitioners must have a consultation with the patient, either in person or by video, each time they prescribe them schedule 4 (prescription only) cosmetic injectables.	AHPRA	*Medical Board of Australia – Guidelines for registered medical practitioners who perform cosmetic surgery and procedures*
'must have either an in-person or video consultation with the person, each time they prescribe them a cosmetic injectable. Asynchronous prescribing of cosmetic injectables by text, email or online (or equivalent) is not acceptable practice'	AHPRA	*Australian Health Practitioner Regulation Agency – Performing non-surgical cosmetic procedures* (Section 3)
'(4) A direction has effect – for a written direction – for the period specified in the direction, not exceeding 6 months from the date on which the medical practitioner or nurse practitioner personally reviewed the patient under subclause (1),'	NSW Health	*Poisons and Therapeutic Goods Regulation 2008 – NSW Legislation* Section 68(C)
'(2) The prescriber must state the following information on the standing order – (a) (c) the date, no later than 2 years after the standing order is made, on which the standing order expires;'	QH	*Standing orders – Medicines and Poisons Act 2019* (Section 106)

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Area of Clinical Practice	Regulatory Body or Guideline Resource	Regulation
General Regulations on Non-surgical Services:		
Guidelines for **Registered Health Practitioners** who perform non-surgical cosmetic procedures	AHPRA	*Australian Health Practitioner Regulation Agency – Performing non-surgical cosmetic procedures*
Guidelines for **Medical Practitioners** who perform cosmetic surgery and procedures	AHPRA	*Medical Board of Australia – Guidelines for registered medical practitioners who perform cosmetic surgery and procedures*
The Use of Botulinum Toxin and Dermal Fillers by **Dentists**	Dental Board	*https://www.dentalboard.gov.au/News/2025-06-03-New-cosmetic-procedure-guidelines.aspx* and *Dental Board of Australia – Fact sheet: The use of botulinum toxin and dermal fillers by dentists*
Nurses & Cosmetic Procedures: Supervision & Scope of Practice	Nursing & Midwifery Board	~~*Nursing and Midwifery Board of Australia - Position statement on nurses and cosmetic medical procedures*~~ This document will be replaced on 2nd September 2025 by the AHPRA document below.
	AHPRA	*Australian Health Practitioner Regulation Agency – Performing non-surgical cosmetic procedures* (Appendix A)
Infection Control	NHMRC (National)	*Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019) | NHMRC*
	QH	*Infection control management plans | Queensland Health* and *Beauty therapy services | Health and wellbeing | Queensland Government* and *Queensland Health's position on cosmetic injectables and skin penetration procedures*
Infection Control **Infection Control & Facility Standards**	AHPRA	*Australian Health Practitioner Regulation Agency – Performing non-surgical cosmetic procedures* (Section 12 & 13)

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3a. Clinical Consultation for higher risk non-surgical cosmetic procedures

The clinical consultation forms the basis of all cosmetic treatments. A consultation could be either an in-person or a video consult.

The assessment during consultation should consider

- Person's history, relevant psychological, social and cultural aspects, and assessment for body dysmorphic disorder (BDD).
- Person's reasons (for example, a perceived need to please others) and internal reasons (for example, strong feelings about appearance).
- Person's expectations of the procedure must be discussed to check they are realistic.
- There are additional responsibilities if providing cosmetic procedures to persons under 18.

Prescriptions for cosmetic injectables

1. A consult must occur each time a cosmetic injectable is prescribed.
2. The consultation could be either an in-person or a video consult.
3. Each person must have an individual prescription
4. The following are not acceptable practices
    - ***Bulk or batch prescribing*** *(one prescription for multiple people)*
    - ***Asynchronous prescribing*** *(Asynchronous prescribing is prescribing that does not take place in the context of a real-time continuous consultation and is usually based on the patient completing a health questionnaire when the practitioner has never spoken with the patient).*

Resources

Australian Health Practitioner Regulation Agency – Performing non-surgical cosmetic procedures

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3b. Informed Consent

Prior to the undergoing the cosmetic procedure the health practitioner must ensure the patient has been provided enough information to make an informed decision about the cosmetic procedure and its costs. A copy of the signed consent to the cosmetic procedure and financial consent must be obtained and a copy of the signed consent must be given to the patient.

This information must be provided as a verbal consent discussion as well as written information.

Information provided must include

- Risk and benefits associated with the cosmetic procedure
- What alternatives are available
- Details of the registered health practitioner providing the cosmetic treatment
- Costs of the procedure

Resources

Australian Health Practitioner Regulation Agency – Performing non-surgical cosmetic procedures

Informed Consent info on the Australian Commission on Safety and Quality in Healthcare's website.

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4. Facility standards

Appropriate and adequate Infection prevention and control systems must be in place.

Facilities must be appropriately staffed and equipped to manage complications and emergencies.

Facilities where the higher risk non-surgical cosmetic procedure is performed must comply with relevant legislation, regulations and standards of the jurisdiction where the facility is located.

Health practitioners are encouraged to provide procedures in a facility accredited by ACSQHC approved agency.

Resources

Australian Commission on Safety and Quality in Health Care (ACSQHC)

5. Enforcement & Penalties

Notification of a regulatory breach may be received from the relevant regulatory body if non-compliance with either advertising or professional conduct has been found. An opportunity is given to the practitioner or entity to respond and/or rectify non-compliance. If deemed necessary, the relevant regulatory body may proceed with disciplinary actions, prosecutions, and/or penalties.

Regulatory Body	Information on Enforcement & Penalties
TGA	*Compliance management | Therapeutic Goods Administration (TGA)*
AHPRA	*Australian Health Practitioner Regulation Agency – Possible outcomes* and *Australian Health Practitioner Regulation Agency – How we manage advertising complaints* and *Ahpra-Guidelines-Guidelines-for-advertising-a-regulated-health-service-December-2020 (5).PDF*
QH	*Regulatory approach to medicines offences | Queensland Health*
NSW Health	*New laws that apply to administering cosmetic medicines*

6. Professional Indemnity

It is important to consult with your professional indemnity whether your current cosmetic practice, and the clinical model within which it operates are covered by your professional indemnity policy. In general, most indemnity providers will not cover practices that are non-compliant with regulatory guidelines.

It is a requirement of your AHPRA registration that all aspects of your practice must be covered by indemnity insurance.

'All health practitioners who undertake any form of practice in their respective profession(s) must have professional indemnity insurance (PII) arrangements that comply with the relevant registration standard, for all aspects of their practice.'

From:
Australian Health Practitioner Regulation Agency – Professional indemnity insurance arrangements

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Checklist

For Authorised Practitioners considering Higher Risk Non-Surgical Cosmetic Procedures using S4 Cosmetic Injectables and advertising a regulated health service.

1 ESSENTIAL CRITERIA

1. Practitioner must be an AHPRA Registered Health Practitioner

2. Practitioner must fulfill conditions of Registration annually

a) Renew AHPRA Registration annually	***ahpra.gov.au***
b) Have appropriate and adequate Indemnity cover	**Contact your Indemnity Provider** (Avant, MIGA, MDA National) **or Insurance broker.**
c) Documented participation in non-surgical cosmetic procedure specific CPD with each CPD cycle that includes • *Assessment and anatomy based* • *Theoretical AND hands on* • *Complication management* *(mandated by AHPRA Sec 9.5 AHPRA guidelines 2025)*	**CPD providers:** • *Non-surgical Symposium (NSS) Anatomy for Injectors (AFI)* ***nonsurgical.org.au*** • *ASCPD conference* ***ascpd.org.au***

2 ADVERTISING AND MARKETING

Only use a protected title if you hold registration.

Use of the term 'specialist' is restricted.

Avoid using misleading claims about qualifications, experience or expertise.

You must inform people of your registration details, registration type.

Advertising material including practice and practitioner website and social media must comply with the list below.

Refer to the June 2025 AHPRA Guidelines on higher risk non-surgical cosmetic procedures
Australian Health Practitioner Regulation Agency – Performing non-surgical cosmetic procedures
(section 11.1-11.2)

General Advertising Laws (ACCC):
Advertising and promotions | ACCC

Advertising of prescription medicines in general (TGA):
Advertising a health service | Therapeutic Goods Administration (TGA)

MANDATORY COMPLIANCE
a. National Law Section 117-119
b. National Boards' Guidelines for advertising of regulated health services
c. National Boards' Guidelines for advertising higher risk non-surgical cosmetic procedures
d. The current Therapeutic Goods Advertising Code
e. Any TGA guidance on advertising non-surgical cosmetic procedures and the advertising requirements of section 133 of the National Law.
f. Where the prescriber is a Registered Medical Practitioner, they must comply with the Medical Board of Australia's Guidelines for Registered Medical Practitioners who perform Cosmetic Surgery and Procedures.

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3 FACILITY STANDARDS

- Appropriate and adequate Infection prevention and control systems **must** be in place.
- Facilities must be appropriately staffed and equipped to manage complications and emergencies.
- Every facility must have an emergency kit and an emergency protocol.

Facilities where the higher risk non-surgical cosmetic procedure is performed **must** comply with relevant legislation, regulations and standards of the jurisdiction where the facility is located.

Health Practitioners are **encouraged** to provide procedures in a facility accredited by ACSQHC approved agency.

Recommended Compliance:
Australian Commission on Safety and Quality in Health Care (ACSQHC)

4 PRESCRIBING S4 COSMETIC INJECTABLES

MODEL 1:	MODEL 2:
In Person consult-On Site Prescribing	**Video consult – Remote Prescribing**
In Person patient consultation followed by onsite prescribing by an Authorised health practitioner.	Video consult and remote prescribing by *an Authorised health practitioner.*
A consult must take place each time a cosmetic injectable is prescribed.	A consult must take place each time a cosmetic injectable is prescribed.
Asynchronous Prescribing or bulk or batch prescribing of Cosmetic Injectables is not acceptable practice.	Asynchronous Prescribing or bulk or batch prescribing of Cosmetic Injectables is not acceptable practice.

MANDATORY COMPLIANCE
Authorised health practitioner must comply with the professional standards set by AHPRA with regards to consultation, assessment of patient suitability, examination, informed consent, informed financial consent, consent for use of images, Infection control standards.
Authorised health practitioner must comply with the professional standards set by AHPRA with regards to providing cosmetic procedures to persons under the age of 18.
Authorised health practitioners who prescribe prescription only medicines have responsibilities to care for the person for whom they are prescribed, regardless of whether or not the prescriber performs the procedure. AHPRA GUIDELINES 2025.
Authorised health practitioner must know and comply with relevant drugs and poisons legislation for Schedule 4 (prescription only) cosmetic injectables of the jurisdiction in which they are practising.
Authorised health practitioner must assess each patient for suitability, including psychological issues that may make them unsuitable. In addition, the motivation for requesting the procedure must be assessed.

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

The Poisons Standard (the SUSMP) | Therapeutic Goods Administration (TGA)

Ahpra & National Boards

Australian Health Practitioner Regulation Agency – Performing non-surgical cosmetic procedures

Queensland Government
Queensland Health

Medicines in beauty treatment and cosmetic injectable businesses | Queensland Health

NSW Government Health

New laws that apply to administering cosmetic medicines (NSW Health)

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Appendix

Glossary of Acronyms:

ACCC	Australian Competition & Consumer Commission
AHPRA	Australian Health Practitioners Regulation Agency
NHMRC	National Health and Medical Research Council
NMBA	Nursing & Midwifery Board of Australia
NSW Health	New South Wales Department of Health
QH	Queensland Department of Health
RACGP	The Royal Australian College of General Practitioners
SOC	Standard of Care
SUSMP	Standard for the Uniform Scheduling of Drugs and Poisons (also known as the Poisons Standards)
TGA	Therapeutic Goods Administration

Disclaimer

This document should not be considered legal advice or a legal interpretation of the legislations and regulations. This document was prepared to provide a summary of materials for reference.

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