

Legal supply of cosmetic injectables in Tasmania

Fact sheet and frequently asked questions for people working in the cosmetic injectables industry

This fact sheet provides information for registered health practitioners and people working in the cosmetic injectables industry on their legal obligations when supplying Prescription Only cosmetic injectables in Tasmania.

What are cosmetic injectables?

Cosmetic injectables are often referred to as either anti-wrinkle treatments or dermal fillers.

Anti-wrinkle treatments involve the injection of botulinum toxin to relax muscles, preventing the skin from creasing and causing wrinkles. Anti-wrinkle treatments are often used to prevent lines around the eyes and mouth, forehead lines, and throat lines.

Dermal fillers involve injection of a filler material (collagen, hyaluronic acid or similar polymers) under the skin to fill deep folds (such as lines running from the corner of the nose to the corner of the mouth), create fuller lips and pad out hollow cheeks and eyes.

Deoxycholic acid acts to destroy fat cells and is marketed in Australia for injection under the chin to reduce 'double chin'.

Are cosmetic injectables Prescription Only medicines in Australia?

Botulinum toxin and deoxycholic acid are both listed in Schedule 4 of the Commonwealth's *Poisons Standard* classifying them as Prescription Only medicines. Common brand names include Botox®, Dysport® and Belkyra®.

The following substances are used in dermal filler products in Australia and are also Prescription Only when included in preparations for injection or implantation, for tissue augmentation or for cosmetic use:

- Collagen (e.g. Zyderm®, Zyplast®, CosmoPlast® and Cosmoderm®)
- Hyaluronic acid and its polymers (Restylane®, Perlane®, Dermalive®, Juvéderm®, Emervel®, Sub Q®, Esthelis®, Hylaform® and Belotero®)
- Calcium hydroxyapatite
- Polyacrylamide (Aquamid®)

- Polycaprolactone
- Polylactic acid (Newfill®, Nufill® and Sculptra®)

Some cosmetic injectables also contain Prescription Only local anaesthetics.

Who can legally obtain, possess and administer Prescription Only medicines in Tasmania?

A **medical practitioner** may obtain, possess, prescribe and administer a Prescription Only medicine in the lawful practice of their profession – in the course of medical treatment.

A **dentist** may obtain, possess, prescribe and administer a Prescription Only medicine in the lawful practice of their profession – in the course of dental treatment.

An **authorised nurse practitioner** may obtain, possess, prescribe and administer a Prescription Only medicine in accordance with an authorisation (and associated conditions) issued to them under Section 25B of the *Poisons Act 1971*.

A **registered nurse** is not authorised to obtain (including purchase) Prescription Only medicine unless they are an *authorised officer of a medical institution**.

Consulting rooms, clinics and day procedure centres do not meet the definition of a medical institution.

A **registered nurse** (outside of a *medical institution* or *residential care service*) may only possess and administer a Prescription Only medicine when:

- In the scope of their professional practice when a Prescription Only medicine has been dispensed to a patient by a pharmacist; or
- When the registered nurse is acting under the direct supervision, and in accordance with the instructions, of a prescriber. These instructions must be recorded on the patient's medical record. Direct supervision requires the prescriber to be physically present at the premises during administration and available to respond in a timely manner if required.

An **enrolled nurse** (outside of a *medical institution* or *residential care service*) whose registration with the Nursing and Midwifery Board of Australia includes medication administration, may only administer a Prescription Only medicine when there is a valid written order for administration from a prescriber, and under supervision by an appropriately qualified person.

An instruction (whether verbal, written, or electronic) from a prescriber to a nurse to administer a Prescription Only medicine after conducting a remote tele-health consultation does not constitute a valid order for administration.

Premises must not hold Prescription Only medicines unless they are in the possession and under the control of a person authorised to obtain such substances as detailed above.

Persons who are not registered health practitioners are not authorised to obtain, possess or administer any Prescription Only medicines for cosmetic use (unless the substance has been legally prescribed and dispensed to them for their own medical treatment).

* A *medical institution* is defined in the *Poisons Regulations 2018* as an institution the sole or main object, or one of the main objects, of which is, or is held out to be, the provision of accommodation (whether with or without medical or other treatment) for –

- (a) persons suffering from any illness, injury, infirmity or mental disorder; or
- (b) pregnant women or women immediately after childbirth; or
- (c) persons who are substantially and permanently handicapped by illness, injury or congenital deformity, or by any other disability; or
- (d) persons who are aged;

Is advertising of Prescription Only medicines legal?

Advertising of Prescription Only medicines throughout Australia must comply with the Commonwealth Therapeutic Goods Administration's *Therapeutic Goods Act 1989*, the *Poisons Standard*, and the TGA's *Therapeutic Goods Advertising Code (No.2) 2018*.

A person must not include any reference to a Prescription Only medicine in any advertisement except in professional publications intended for circulation only within the medical, nursing, veterinary, dental or pharmaceutical professions or the wholesale drug industry.

The Tasmanian poisons legislation restricts the advertising of Prescription Only medicines and offence penalties apply for non-compliance.

Advertising of cosmetic injectables to the public which refer to 'botox', 'hyaluronic acid' or any other Prescription Only medicines or brand names is a breach of legislation.

Do any professional practice standards apply?

The Australian Health Practitioner Regulation Agency (AHPRA) is responsible for the implementation of the National Registration and Accreditation Scheme by working with 15 National Health Practitioner Boards across Australia.

It is a registered health practitioner's individual responsibility to ensure they are familiar with and practice in accordance with all registration standards, codes, guidelines, position statements, and policies issued by the regulating National Board (e.g. Nursing and Midwifery Board of Australia, Medical Board of Australia, Dental Board of Australia).

Can I import cosmetic injectables from outside Australia?

It would be a breach of the *Therapeutic Goods Act 1989* to import and/or supply therapeutic goods for cosmetic injection purposes that are not included in the *Australian Register of Therapeutic Goods*.

Can I operate a cosmetic injectables business from my own home or in a patient's own home?

The environment in which a cosmetic injection is administered must satisfy the appropriate standards of hygiene and accepted standard of conduct by a registered health practitioner. Appropriate medical treatment should be readily available in the event of a serious adverse reaction. Administering a Prescription Only injection in a residential setting may not meet these requirements. It would be recommended to discuss this matter with your National Board, Professional Indemnity Insurer, and any relevant professional organisation responsible for developing evidence-based practice standards.

Contact

For queries relating to Tasmanian poisons legislation please contact:

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