

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.

The information in this fact sheet is of a general nature only and should not be taken as legal advice. It is incumbent on individual registered health practitioners and people working in the cosmetic injectables industry to ensure that they understand and operate in accordance with their obligations under the *Tasmanian Poisons Act 1971*, *Poisons Regulations 2018* and other relevant laws.

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.

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
- Hyaluronic acid and its polymers

- Calcium hydroxyapatite
- Polyacrylamide
- Polycaprolactone
- Polylactic acid

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 only possess, sell, offer or agree to supply, prescribe, dispense and administer a Prescription Only medicine in the lawful practice of their profession.

A **dentist** may only possess, sell, offer or agree to supply, prescribe, dispense and administer a Prescription Only medicine in the lawful practice of their profession.

A **nurse practitioner** may possess, sell, offer or agree to supply, prescribe, dispense and administer a Prescription Only medicine if he or she is authorised to do so in writing by the Secretary, Department of Health under section 25B of the *Poisons Act*.

A **registered nurse** may possess, offer or agree to supply, dispense and administer a Prescription Only medicine if he or she is authorised to do so in writing by the Minister for Health under section 25A of the *Poisons Act*.

Regulation 68 of the *Poisons Regulations* restricts the circumstances in which the Minister may issue an authorisation under section 25A of the *Poisons Act*. The circumstances described in regulation 68 include circumstances where the registered nurse is in charge of a day-treatment centre approved by the Secretary, Department of Health and is administering or supplying the medicine in accordance with the instructions of a medical practitioner.

A day-treatment centre is a centre, which is not private residential premises, at which a person is admitted and discharged on the same day for medical treatments, surgical treatments or treatments that are in the same or similar vein to medical treatments or surgical treatments.

It is incumbent on any registered nurse seeking authorisation from the Minister under section 25A of the *Poisons Act* to demonstrate how the circumstances described in regulation 68 are met.

A **registered nurse** working in a medical institution may administer restricted substances in accordance with an authorisation or oral instructions issued in accordance with regulation 65 of the *Poisons Regulations*. A medical institution is an institution concerned with providing accommodation to people who are unwell, pregnant or who have just given birth, disabled or aged.

A **registered nurse** may also administer a restricted substance to a person who is not in a medical institution or a residential care service if the registered nurse is acting under the direct supervision, and in accordance with the instructions, of a medical practitioner or nurse practitioner under regulation 67 of the *Poisons Regulations*.

The requirement for direct supervision in regulation 67 cannot be satisfied through video consultation.

An **enrolled nurse** whose registration with the Nursing and Midwifery Board of Australia includes medication administration, may administer a Prescription Only medicine in accordance with the written authority of a prescriber and under the supervision of an appropriately qualified person.

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

People 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.

Is advertising of Prescription Only medicines legal?

Advertising of Prescription Only medicines throughout Australia must comply with the legislation including the Australian Government's *Therapeutic Goods Act 1989*, *Therapeutic Goods Regulations 1990* and the Therapeutic Goods Advertising Code. In addition, in Tasmania such advertising must comply with the *Poisons Act* and *Poisons Regulations*.

Under the *Poisons Regulations*, it is an offence for a person to advertise a Prescription Only medicine except in publications that generally circulate only to people who are lawfully engaged in medical, dental, nurse practitioner veterinary, optometrical, podiatric, midwifery or pharmaceutical practice, or in the manufacture of supply of such medicines.

Advertising cosmetic injectables to the public by reference to particular substances is a breach of legislation.

Do any professional practice standards apply?

The Australian Health Practitioner Regulation Agency (Ahpra) supports 15 National Health Practitioner Board to implement the National Registration and Accreditation Scheme for health professions.

Registered nurses are required to practice in accordance with the National Law as in force in Tasmania and within the standards, codes, guidelines and other frameworks developed by the National Health Practitioner Board which applies to them. For registered nurses, this is the Nursing and Midwifery Board of Australia.

It is a registered health practitioner's individual responsibility to ensure they are familiar with and practice in accordance with all those standards, codes, guidelines and other frameworks.

Can I import cosmetic injectables from outside Australia?

It may be an offence to import therapeutic goods that are not included in the Australian Register of Therapeutic Goods (ARTG). This is because, under the Australian Government's *Therapeutic Goods Act*, therapeutic goods must be entered in the ARTG before they can lawfully be imported into Australia, unless a specific exemption, approval or authority applies.

Contact

Pharmaceutical Services Branch
Public Health Services
Department of Health
GPO Box 125, Hobart, Tasmania 7001
Phone: (03) 6166 0400
E-mail: pharmserv@health.tas.gov.au

Office of the Chief Nurse and Midwife
Clinical Quality, Regulation and Accreditation
Department of Health
GPO Box 125, Hobart, Tasmania 7001
Phone: (03) 6166 1570
E-mail: ocnm@health.tas.gov.au