Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Cosmetic injectables: Import and supply in Australia

The Therapeutic Goods Administration (TGA) continues to see unlawful imports of cosmetic injectable products and associated medical devices into Australia by registered health practitioners. For this document we refer to these collectively as 'cosmetic injectables' and they commonly include:

- lidocaine and hyaluronic acid pre-filled syringes
- botulinum toxin (botox) vials
- glutathione for parenteral administration
- medical devices including polydioxanone (PDO) threads and IV infusion kits.

Who can import cosmetic injectables to supply in Australia?

Only the approved supplier (sponsor), as entered on the Australia Register of Therapeutic Goods (ARTG), or their agent, can lawfully import cosmetic injectables into Australia for commercial supply. Supply includes sale of, administration to, or application in, the treatment of a person.

Cosmetic injectables imported for commercial supply must be the version manufactured and approved for the Australian market and not a parallel import. The products must be entered on the ARTG, under the name of the supplier, prior to importation unless an exception applies, like lawful access via an unapproved product pathway like the Special Access Scheme.

Do not import cosmetic injectables unless:

- you are the Australian approved supplier (sponsor), or their agent
- an exception applies.

What is a parallel import?

Many therapeutic goods, including cosmetic injectables, are available both in Australia and overseas.

Parallel import occurs when a legitimate version of an overseas product is imported with the intention of being sold in the Australian marketplace.

While these goods may be authentic and manufactured by the company indicated on the packaging, they are not the version of the product assessed for the Australian market and entered in the ARTG.

Parallel imports should not be imported into Australia for commercial supply unless an exception applies.

Risks of parallel imports?

All prescription only medicines, and medical devices on the ARTG undergo assessment by the TGA prior to inclusion to ensure they meet quality standards, including that they are sterile, contain only the labelled ingredients, and were manufactured in a suitable facility.

Parallel imports:

- are unapproved goods and have not been assessed by the TGA
- do not necessarily meet the same quality and safety standards as the Australian versions.

Patients seeking cosmetic injectables are at increased risk of adverse events when injected with products that have not been approved for supply in Australia.

One of the known issues with parallel imports is that they may not be delivered using appropriate cold chain storage protocols or other acceptable conditions that affect or maintain product viability. Internationally, this has been associated with acquired botulism infection as a severe adverse event following a cosmetic injection procedure.

How do I know if my product is a parallel import?

If your business intends to import and supply a therapeutic good, such as cosmetic injectables, to consumers or other businesses in Australia, you should obtain those products via formal manufacturer distribution channels.

Where you obtain genuine products without authorisation from the manufacturer, you may be purchasing a parallel import.

If any of the following apply to your product, it may be a parallel import.

- It has been purchased from an international online supplier, or direct from the international manufacturer.
- It has been purchased from a supplier other than the Australian Sponsor, or its authorised distributor.
- It has not been assessed by the TGA for the Australian market.
- The price is cheaper than is ordinarily expected to purchase the product in Australia.
- It has a pack or label that is different compared to the version of the product approved for supply in Australia, e.g. packaging and instructions for use are not in English.
- It is not delivered in appropriate cold chain storage.
- There are no Australian sponsor details on the package.

Responsibilities of health practitioners when importing cosmetic injectables

You must always ensure that any cosmetic injectables you import comply with Australian therapeutic goods legislation including:

- the *Therapeutic Goods Act 1989*
- the packaging and labelling requirements
- the *Therapeutic Goods Regulations 1990*
- the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*.

Health practitioners need to be aware of the regulatory requirements and lawful access pathways for unregistered goods.

Lawful access pathways include the Special Access Scheme (SAS) or Authorised Prescriber (AP) pathway.

The safest way to obtain cosmetic injectables for supply in the Australian market is to obtain them via formal domestic manufacturer distribution channels.

What are the consequences of importing unapproved cosmetic injectables?

Recent civil court outcomes reflect that any person undertaking business relating to therapeutic goods must be familiar with the regulations prior to undertaking that business. Ignorance of the applicable laws is not a defence.[1]

Additional consequences include:

Loss of product

Under instruction from the TGA, the Australian Border Force can seize and destroy unlawful imports of therapeutic goods, including cosmetic injectables. This means that the cost of the purchase of the product is also likely lost.

Fines or court action

The TGA investigates unlawful import, supply and advertising of cosmetic injectables in Australia and encourages compliance with Australian laws by providing education and guidance in the first instance. Failing to adhere to the Australian rules can attract significant penalties.

For repeated and deliberate non-compliance, the TGA takes escalated regulatory action which can include injunctions, infringement notices, civil court proceedings and criminal prosecution.

The TGA has issued infringement notices to several companies and individual medical practitioners for the alleged importation of unregistered medicines for clinical use when equivalent products could be obtained lawfully in Australia.

Referral to Ahpra

The TGA may also refer registered health practitioners to Ahpra and the relevant National Board.

Further information

- Find out more about being a sponsor on our website.
- Compliance actions and outcomes
- Media releases & statements
- Buying parallel imports | ACCC
- Selling parallel imports | ACCC.

1 Secretary, Department of Health v Enviro Tech Holdings Pty Ltd [2022] FCA 865