

## Medicines and Poisons – Industry Fact Sheet

### Schedule 4 Medical Cosmetic Injectables (Restricted Drugs)

The purpose of this communicate is to clarify your legal obligations that apply in the cosmetic settings around the purchasing/obtaining, possession, storage and administration of Schedule 4 cosmetic injectables (e.g. muscle relaxants and fillers) to ensure compliance with the Health (Drugs and Poisons) Regulation 1996 (The Regulation), Health Act 1937 and the Public Health Act 2005.

#### Schedule 4 cosmetic injectables

Cosmetic injectables contain Schedule 4 medicines or “restricted drugs” and can only be supplied and administered on written prescription. Medical professionals that are endorsed to prescribe Schedule 4 (S4) medicines must ensure they are acting within the scope and extent necessary for their practice. Queensland Health currently regulates activity on various restricted drugs under the provisions of the Regulation.

#### Industry compliance – what’s going on in this space?

Queensland Health Environmental Health Officers recently conducted a survey of operators across the Gold Coast area and found issues of non-compliance around obtaining, storage and administration of Schedule 4 medical cosmetic injectables.

The majority of compliance issues related to the following:-

- **Prescription** – S4 cosmetic injectables can only be prescribed by a doctor (or authorised prescriber). Ensure prescription of these restricted drugs is within your endorsement under the Regulation and within the scope of your practice.
- **Obtaining and purchase orders** – S4 cosmetic injectables are often obtained direct from suppliers rather than via a pharmacy. All orders for S4 cosmetic injectables should be placed and receipted by the endorsement holder (e.g. doctor). Only certain medical professionals are endorsed to obtain S4 medicines under the Regulation. Nurses are not endorsed to obtain an S4 and should only be obtaining via a doctor for the purposes of administering within the constraints of their endorsement under the Regulation.
- **Reconstitution** - Cosmetic injectables should be reconstituted in a hygienic, sterile dispensing area and stored in strict adherence to manufacturer guidelines and timeframes.
- **Cold chain (2-8°C)** - Muscle relaxants are extremely temperature sensitive and must be kept within 2-8°C. Most manufacturers recommend that reconstituted muscle relaxants should be used within 24 hours. For safety and efficacy, this time is further reduced if the reconstituted product is kept in aspirated form (refer to your specific manufacturers guidelines for further information).
- **Endorsement to administer** - Registered nurses are only permitted to administer S4 substances as a dispensed medicine or under the oral or written instruction of a doctor. Enrolled nurses are additionally required to be supervised during administration by a doctor or registered nurse.
- **Mobile operators/Dr & RN operating independently** – Particular challenges exists with regard to ensuring a hygienic dispensing area and appropriate maintenance of cold chain for temperature sensitive medicines (e.g. muscle relaxants). Doctors and nurses who work in independent clinics must ensure compliance with their endorsements around obtaining, possessing and administration of S4 cosmetic injectables.

The requirements of the Health (Drugs & Poisons) Regulation 1996 (The Regulation) and The Health Act 1937 (the Act) can be accessed via – [https://www.legislation.qld.gov.au/Acts\\_SLs/Acts\\_SL\\_H.htm](https://www.legislation.qld.gov.au/Acts_SLs/Acts_SL_H.htm)

Infection Control requirements under Chapter 4 of the Public Health Act (2005) may also apply. The Public Health Act 2005 can be accessed via

[https://www.legislation.qld.gov.au/Acts\\_SLs/Acts\\_SL\\_P.htm](https://www.legislation.qld.gov.au/Acts_SLs/Acts_SL_P.htm)

It is recommended that you thoroughly familiarise yourself and staff at your business with the legislative requirements and keep abreast of any national or state legislative amendments in future.

Doctors and nurses associated with your business are strongly encouraged to follow any mandatory registration conditions, codes of conduct or guidance/minimum standards provided by the Medical Board of Australia, Australian Health Practitioners Regulation Agency (AHPRA) and The Nursing and Midwifery Board of Australia with regards to assessing patients prior to prescribing restricted drugs (including those for technology-based consultation).

#### *Doctors*

Where a doctor does not conduct a physical assessment of a patient and yet issues a verbal or written instruction to an endorsement holder (e.g. to a Registered Nurse or under standing order), advice from Queensland Health Medicines Regulation and Quality Unit is that the prescribing doctor remains ultimately responsible for the patient and any injury or misdemeanours that may occur. Failure of a Doctor to see a patient prior to issuing a written or oral instruction to an RN, or obtaining S4s for an RN may prove difficult to defend from a professional practice standpoint.

#### *Registered and Enrolled Nurses*

Cosmetic nursing is not currently a recognised qualification in Queensland by the *Act* or the Regulation and cannot be utilised as a quality standard or a benchmark for compliance. Unless the S4 is a dispensed medicine, the Regulation requires RNs to be under the implicit oral or written instruction of a Doctor/authorised prescriber when administering a prescription medicine. In addition to the above, enrolled nurses must also be under supervision of a doctor, dentist, midwife or registered nurse.

Registered and enrolled nurses cannot independently purchase, administer, store or prescribe S4 cosmetic injectables. Registered and enrolled nurses involved with the administration of S4 cosmetic injectables in Queensland must act within their endorsement under the Regulation or face potential legal action.

To ensure your compliance going forward, further consultation with AHPRA or relevant industry bodies is recommended regarding what is considered appropriate and acceptable methods of prescription and patient assessment for S4 cosmetic injectables.

#### **Notify of any unauthorised administration**

Matters of non-compliance relating to Professional Practice Standards can now be directed to the Queensland Office of the Health Ombudsman via [www.oho.qld.gov.au](http://www.oho.qld.gov.au)

Your assistance in notifying the Office of Health Ombudsman and/or your local public health unit of any unauthorised operators or non-compliance with professional practice standards is appreciated.

#### **Further Information**

Should you require further information or advice, please contact the Gold Coast Public Health Unit on (07) 5687 9000 or email [EH\\_GoldCoast@health.qld.gov.au](mailto:EH_GoldCoast@health.qld.gov.au)

For queries in relation to professional practice/compliance with your requirements as a medical professional, please contact AHPRA on telephone **1300 419 495**.

For requirements around prescribing and administering for medical conditions under the Pharmaceutical Benefits Scheme Section 100 Botulinum Toxin Program, refer to [www.pbs.gov.au](http://www.pbs.gov.au)