Australian Government
Department of Health
Therapeutic Goods Administration

The Poisons Standard and Medical Devices

Guidelines for labelling

Version 1.1, September 2018

TGA Health Safety Regulation

The purpose of this guidance is to help manufacturers and sponsors understand how the TGA interprets requirements, and thus indicate how manufacturers and sponsors can comply.

This is a guide only, and manufacturers and sponsors are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia, and if necessary, to seek professional advice. It is the responsibility of each manufacturer or sponsor to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

Contents

Introduction

This document intends to provide guidance for the requirements applicable to medical devices containing poisons.

The Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard or SUSMP)[1] classifies poisons, including medicines, into schedules in order to set the level of control on their availability. It includes provisions for labelling, containers, storage, disposal, record-keeping, sale, supply and possession of poisons[2]. The scheduling of poisons in Australia is implemented through the relevant State and Territory legislation[3].

The requirements in the Poisons Standard aim to assure the mitigation of the risks associated with the availability of these therapeutic goods and should be applied in conjunction with other existing legislation, including requirements set out in the *Therapeutic Goods Act 1989*.

Requirements for medical devices are provided in the Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations)[4].

For the purposes of this guidance, only labelling requirements are discussed in detail, as in general other requirements outlined in the Poisons Standard are controls imposed on the retail distribution and sale of the substances. All the requirements are outlined in full in Parts 2 and 3 of the current Poisons Standard.

Appendix A of Part 5 the Poisons Standard lists products that are exempt from the requirements of the standard. Generally, Class III medical devices are specified in Appendix A of Part 5 as being exempt from the requirements of the Poisons Standard:

> *MEDICAL DEVICES classified as Class III by the classification rules set out in Schedule 2 to the Therapeutic Goods (Medical Devices) Regulation 2002…*

However, the following types of devices are specified as exceptions to the Class III medical device exemption:

> *a) injectable tissue reconstructive, augmentation and restoration materials, including collagen;*
>
> *b) medical devices which include anticoagulants;*
>
> *c) artificial tears;*
>
> *d) urinary catheters; or*
>
> *e) intra-articular fluids.*

This means that all medical devices listed above that contain a scheduled poison are not covered by the general exemption for Class III medical devices and therefore are subject to the requirements of the Poisons Standard.

[1] https://www.legislation.gov.au/Details/F2018L00168 (current version dated 27 February 2018) – Poisons Standard March 2018

[2] The Poisons Standard is made under Part 6-3 of Chapter 6 of the *Therapeutic Goods Act 1989*

[3] The laws in each State and Territory give effect to the Poisons Standard

[4] https://www.legislation.gov.au/Series/F2002B00237/Compilations - Therapeutic Goods (Medical Devices) Regulations 2002

Specific poisons of interest for medical devices

Injectable tissue reconstructive, augmentation and restoration materials used in injectable implants such as dermal fillers and synovial fluid supplements are regulated as medical devices. These are a type of device that is included in the list of exceptions to the medical device exemption in the Poisons Standard.

The following substances are listed in Schedule 4 of the Poisons Standard when used in preparations for injection or implantation for the purpose of tissue augmentation or for cosmetic use:

- Collagen
- Hyaluronic acid and its polymers[5]
- Polyacrylamide
- Polycaprolactone
- Polylactic acid
- Calcium hydroxyapatite

Some of the above substances may also be found in other types of medical devices (for example, calcium hydroxyapatite is commonly used as a coating on orthopaedic implants), however these medical devices are not specified in the list of devices that are required to comply with the Standard (the list of exceptions to the exemption).

Examples of medical devices that should comply with the Poisons Standard

Product	Requirements
Syringes prefilled with a dermal filler containing Hyaluronic acid	These products fall under exception *a) injectable tissue augmentation materials.* Hyaluronic acid is Schedule 4 in preparations for injection or implantation for tissue augmentation or for cosmetic use. As such, these medical devices are **required to comply** with the Standard.

[5] Changes to the scheduling of Hyaluronic acid and its polymers are due to come into effect in June 2018 – this substance will be scheduled when present in any preparation for injection (the specific purposes for tissue augmentation or for cosmetic use will be removed)

Examples of medical devices that are exempt from the Poisons Standard

Product	Requirements
Lubricating eye drops or contact lens solutions containing sodium hyaluronate	These products fall under exception *c) artificial tears*. However, the listing for Hyaluronic acid in Schedule 4 does not include this purpose or preparation (these devices are not intended for implantation or injection). As such, these devices are **not required to comply** with the Standard.
Orthopaedic bone cement containing a Schedule 4 antibiotic	These products are covered by the general exemption for Class III medical devices. Although they are for tissue reconstruction and/or restoration, they are not injectable and consequently not captured by exception a). As such, these devices are **not required to comply** with the Standard.

Current medical device regulations

Any medical device supplied in Australia must comply with the requirements set out in the MD Regulations, including relevant provisions of the essential principles. The essential principles set out the requirements relating to the safety and performance of medical devices. There are six general principles that apply to all devices (use of medical devices not to compromise health and safety, design and construction of medical devices to conform with safety principles, medical devices to be suitable for intended purpose, long-term safety, medical devices not to be adversely affected by transport or storage, benefits of medical devices to outweigh any undesirable effects); and nine principles about design and construction that apply to devices on a case-by-case basis.

The MD Regulations do not explicitly refer to the Poisons Standard. However, in general, in order to demonstrate compliance with the essential principles, a manufacturer and/or supplier (the sponsor) of a medical device that contains a poison and is not exempt from the Poisons Standard, must be able to demonstrate that any risks associated with that poison, are acceptable risks when weighed against the intended benefit of the medical device to the patient.

The Regulations require[6] that the device labelling specifies:

- Any warnings, restrictions, or precautions that should be taken, in relation to use of the device
- Any particular handling or storage requirements applying to the device
- If applicable, that the device must only be used by persons with appropriate technical knowledge, experience, education or training

[6] See essential principles 1, 2 and 13: https://www.legislation.gov.au/Details/F2018C00049 - *Therapeutic Goods (Medical Devices) Regulations 2002*, Schedule 1.

This information must reflect and be consistent with the requirements of the Poisons Standard to minimise the risks of harm that can be caused by these products if they are used incorrectly and without appropriate precautions.

Section 1.1(1) of Part 2 of the Poisons Standard provides that a person 'must not sell or supply a poison unless it is labelled in accordance with Part 2 Section 1 of this Standard'. Section 1 of Part 2 (Section One Labels) sets out a number of specific labelling requirements such as letter height, colour contrast etc. It also provides that the primary pack and immediate container must contain the required signal heading.

Therefore in order to demonstrate compliance with the essential principles, the manufacturer/sponsor must be able to demonstrate compliance with these specific requirements for labelling set out in the Poisons Standard[7].

Please note

In order to provide clarity to manufacturers and sponsors, to promote the objects of the Act, and maintain a national system of controls, the Medical Device Regulations clarify that those medical devices that are not exempt from the Poisons Standard must comply with all relevant requirements for packaging, labelling and instruction for use.

How to comply with the Poisons Standard labelling requirements

Note that the below examples are for labelling requirements relating to the Poisons Standard only – for more detail on these specific requirements, please see the latest version of the Poisons Standard[8].

Nonetheless the information provided on and with medical devices, including labelling, packaging and instructions for use, must comply with all applicable requirements set out in Essential Principle 13[9] (Schedule 1 of the MD Regulations).

[7] This interpretation of the requirements is consistent with the intent of the law to provide a consistent framework for therapeutic goods across Australia and adopt a uniform approach to control the availability and accessibility, and safe handling of poisons in Australia. These requirements are in addition to, and not in substitution for, the provisions of any other legislation that relate to therapeutic goods.

[8] https://www.tga.gov.au/publication/poisons-standard-susmp

[9] https://www.legislation.gov.au/Details/F2018C00049 - Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1, Part 2.

Example 1: Synthetic dermal filler containing lidocaine and hydroxyapatite

The following information[10] must be first on the primary pack and immediate container label for a synthetic dermal filler containing lidocaine and hydroxyapatite in 1mL pre-filled syringes:

PRESCRIPTION ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

This medical device contains 0.3% lidocaine (lignocaine) hydrochloride and 30% calcium hydroxyapatite

Unless a specific requirement applies[11], these must be written:

a) on the outside face of the label or container; and

b) in the English language; and

c) in durable characters; and

d) in a colour or colours to provide a distinct contrast to the background colour; and

e) in letters at least 1.5 millimetres in height*

*approval may be sought for the use of smaller letters (at least 1 mm) on containers <20 millilitres.

As this device is supplied in a 1mL syringe, the exemption for 'Selected containers' would apply (container is less than 10mL): if the syringe is the 'immediate container', and it is further enclosed in a 'primary pack' then only the primary pack must meet all of the applicable requirements and the label on the syringe itself (i.e. the immediate container) must state 'This medical device contains 0.3% lidocaine (lignocaine) hydrochloride and 30% calcium hydroxyapatite' and the name of the manufacturer or distributor for the poison.

Example 2: Synovial fluid supplementation substance containing hyaluronic acid and gentamicin

The following information[10] must be first on the primary pack and immediate container label for a synovial fluid supplementation substance containing hyaluronic acid in 12mL pre-filled syringes:

PRESCRIPTION ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

This medical device contains 10mg/mL sodium hyaluronate and gentamicin sulphate (2%)

[10] The reference to 'prescription only medicine' is required under paragraph 1.3(1)(a) of Part 2 of the Poisons Standard to reflect States and Territories legislation, but the application of the Poisons Standard does not make the device a 'medicine' for the purposes of the *Therapeutic Goods Act 1989*.

[11] For example, Part 2, Sections 1.3(1)a and 1.3(1)c of the Poisons Standard.

Unless a specific requirement applies[12], these must be written:

a) on the outside face of the label or container; and

b) in the English language; and

c) in durable characters; and

d) in a colour or colours to provide a distinct contrast to the background colour; and

e) in letters at least 1.5 millimetres in height*

*approval may be sought for the use of smaller letters (at least 1 mm) on containers <20 millilitres.

[12] For example, Part 2, Sections 1.3(1)a and 1.3(1)c of the Poisons Standard.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch, Therapeutic Goods Administration	20/04/2018
V1.1	Minor amendment to align with changes to the Therapeutic Goods (Medical Devices) Regulations 2002 regarding conditions applying automatically.	Medical Devices Branch, Therapeutic Goods Administration	10/09/2018

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