Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Understanding your regulatory obligations for exempt medical devices

Guidance for sponsors and manufacturers about regulatory requirements for exempt therapeutic goods.

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On this page

Purpose

Some medical devices are exempt from needing to be included in the ARTG before import, export or supply.

Exempt therapeutic goods do not need to be included in the ARTG. They do still need to comply with other regulatory requirements.

A list of exempt medical devices is in Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Legislation

Therapeutic Goods (Medical Devices) Regulations 2002

Ongoing responsibilities

Despite being exempt, these products are still regulated by us. Sponsors and manufacturers still need to comply with ongoing responsibilities. These include:

Adverse-event reporting

Sponsors and manufacturers of exempt medical devices should report adverse events or near adverse events. You can do this through our Incident Reporting and Investigation Scheme (IRIS).

Sponsors or manufacturers who have an account with us can submit these reports through the TGA eBusiness Portal. If you do not have an account you can use this medical device incident report form.

Reporting a problem doesn't make the manufacturer, sponsor, user, or patient liable. We ask that all adverse events are reported for exempt devices supplied in Australia.

Recall of medical devices

The Uniform Recall Procedure for Therapeutic Goods (URPTG) provides a consistent approach for undertaking recall and non-recall actions for therapeutic goods supplied, imported into or exported from Australia.

This guide helps sponsors conduct recalls and non-recalls using a standardised process.

The URPTG is also applicable when we order an appropriate responsible entity to conduct a mandatory recall.

It's important that sponsors do not determine what action to take (recall or not). They must:

1. Go through the URPTG
2. Notify us and
3. Get our agreement to proceed.

Any overseas regulatory actions should be reported to us if the product involved is from the same batch or production run.

Compliance with the Therapeutic Goods Advertising Code

Advertisements for medical devices must follow the Therapeutic Goods Advertising Code.

This applies for advertising of any format including print, online and social media.

Our Advertising Code should be communicated to sponsors' suppliers and retailers. In particular about unauthorised claims of a therapeutic good.

Ads can't use the claim 'TGA approved' unless it's specifically authorised by the TGA.

Certain therapeutic claims are classified as ‘restricted representations’. You must seek approval from us before being able to advertise such claims to the general public.

Compliance with conformity assessment procedures (CAP)

A manufacturer must hold appropriate evidence to demonstrate the application of the:

- appropriate conformity assessment procedures, or
- requirements comparable to conformity assessment procedures.

Depending on the device classification, a manufacturer's minimum requirements will vary. These are specified in Part 3, Division 3.2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

For some Class I devices, this requires holding an Australian Declaration of Conformity. The Australian Declaration of Conformity states which conformity assessment procedures the manufacturer has chosen to use to demonstrate that their medical device meets the Essential Principles. The ongoing obligations of a manufacturer vary depending on which conformity assessment procedures they have used.

In some instances, evidence of conformity from comparable overseas regulators can be used to demonstrate that Australian requirements are met. These are assessed at the time of inclusion.

Evidence of conformity must be maintained and kept up to date. Any changes, suspensions, revocations or lapses of conformity certificates must be notified to the Australian sponsor for notification to the TGA.

Manufacturers should have the following evidence:

- Technical documentation that demonstrates the conformity of their devices with the Essential Principles.
- A quality manual or similar document to detail the manufacturer's quality management system and procedures.
- Evidence that an appropriate conformity assessment procedure has been applied.
- Any notice, report, certificate or other documents in relation to the quality management system issued to the manufacturer by us.
- Details of any post-market activities undertaken after the device was supplied in Australia.
- Details of any changes or variations to the device and/or quality management system. See Varying entries in the ARTG - medical devices and IVDs.
- The design, production process and intended performance of the medical device.
- These records must be kept for a minimum of 5 years after the manufacture of the last medical device. On our request, the manufacturer must make the records available to us.

If you only manufacture Class I devices you may not be subject to all the above. An example is manufacturers of Personal Protective Equipment (PPE).

Compliance with the Essential Principles (EP)

It is the manufacturer's responsibility to show compliance with the Essential Principles.

If you meet essential requirements under the European MDR, you need to do a gap analysis to make sure Australian EPs are covered.

When circumstances prevent compliance, you must notify the sponsor. The sponsor will then notify us.

If there aren't any major safety issues, a consent process can be arranged.

Not complying

There are criminal and civil penalties for not complying with ongoing responsibilities.

Topics: Regulatory compliance

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