Australian Government
Department of Health
Therapeutic Goods Administration

Post-market reviews

Version 1.1, October 2020

TGA Health Safety Regulation

Contents

Post-market reviews

Changes are coming to the way in which you can view and respond to post-market reviews of medical devices. More information can be found at: New compliance dashboard for post-market medical device reviews.

Post-market reviews are conducted by us in order to ensure your product continues to meet its legislative obligations. If you have a product included in the Australian Register of Therapeutic Goods (ARTG), it may be selected by the Therapeutic Goods Administration (TGA) for post-market review at any time.

There are a number of reasons a product may be selected for post-market review including, but not limited to, the following:

- Detection of a trend or signal amongst post-market data held by TGA or other regulators. This data can include, but is not limited to, adverse event reports, annual reporting, clinical publications and device tracking registers.
- Information received from, or action taken by, other medical device regulators.
- Identification of a safety or performance issue for a similar device currently included in the ARTG.
- Unresolved or repeated recalls.
- Literature review of available clinical evidence.

Note

All classes of medical devices, including Class I (non-sterile, non-measuring), are able to be selected for post-market review.

Who or what is reviewed?

When undertaking a post-market review we may choose to review any aspect of a medical device throughout its lifecycle including, but not limited to:

- The sponsor.
- The manufacturer.
- Ingredients or materials used in the device.
- The product itself.
- The Instructions For Use.
- Packaging and labelling.
- Clinical data relevant to conditions or the physical application of the device.

How will I know my product is under review?

The TGA will notify you when your product is being reviewed with a written notice and a request for information contained within a letter issued under section 41JA of the *Therapeutic Goods Act 1989*. This letter will contain a request for specific information we require in order to conduct the review. The letter will also be visible in your TGA Business Services (TBS) account in the Medical Devices Post Market Compliance Dashboard.

Note

If you receive a request for information under the Therapeutic Goods Act, the time frames for responding will be clearly stated in the letter. Failure to comply with the request as set out in this communication will result in further regulatory action including cancellation of your inclusion from the ARTG. If you cannot meet the deadline you have been given, please contact the TGA staff member identified in the request as soon as practicable to negotiate an extension. Requests for extensions received close to the deadline are unlikely to be granted.

There are civil and criminal penalties associated with supplying false or misleading information to a Federal Government agency.

How do I respond to requests for information and other notifications?

The letter you receive will specify how you need to respond to the TGA and the information, documents, or samples required. Letters sent by the TGA relating to a post-market review will require you to provide information and documents through the compliance dashboard.

The dashboard is designed to allow sponsors to view any requests or notifications from the TGA, and to respond to them. Requests and notifications may include:

- requirement to provide information and documents;
- requirement to provide samples; and
- proposal to suspend or cancel entries from the Australian Register of Therapeutic Goods (ARTG).

Instructions on how to navigate the compliance dashboard can be found at: Post market review compliance dashboard.

What happens next?

Once we have received the requested information we will review and determine one of the following outcomes:

- Further information is required.
- Action is required (Regulatory or non- regulatory).
- The review is complete.

Further information is required

If during the course of the review we determine that further information is required, we may request it through an additional section 41JA notice. For minor clarifications or supplementary information, you may be contacted by telephone or email.

Action is required

Where a review identifies issues with your inclusion or product, we will work with you to implement appropriate corrective actions to mitigate the identified risks associated with your product. Outcomes of the review may be regulatory or non-regulatory and may include, but are not limited to;

- Amendments to the Instructions For Use.
- Design changes.
- Product recall.
- Suspension or cancellation of the device from the ARTG.
- The imposition of conditions of inclusion such as;
  - further reporting requirements;
  - restriction of use to particular patient cohorts or medical conditions.

The review is complete

Once all information provided to us has been assessed and any outstanding actions completed, you will be notified of the completion of the post-market review in writing.

Note

The TGA can re-open a post market review or commence a new review at any time.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Post Market Reforms & Reviews Section	October 2019
V1.1	Inclusion of the new compliance dashboard and link to the guidance document	Devices Post Market Reforms & Reviews Section	October 2020

Therapeutic Goods Administration

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Reference/Publication #