Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

The TGA's approach to delays in medical device conformity assessment recertification

Due to COVID-19 pandemic and implementation of EU MDR/IVDR

Version 1.3, June 2023

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Background

Changes to the medical device directive (93/42/EEC) and the IVD Directive (98/79/EC) along with the current COVID-19 pandemic, limiting international travel, have resulted in the potential inability of medical device manufacturers to maintain the currency of their conformity assessment document supporting their Australian Register of Therapeutic Goods (ARTG) inclusions for medical devices supplied in Australia.

Under the Australian legislation, medical devices included in the ARTG must have the appropriate conformity assessment procedures applied to the medical device, and sponsors must ensure the manufacturer holds the appropriate conformity assessment document for their devices.

Purpose and scope of this guidance document

The Therapeutic Goods Administration (TGA) is issuing this guidance to inform sponsors (and, where relevant, manufacturers) about the general approach the TGA will take to the lapsing of conformity assessment documents due to delays in audits due to COVID-19 and the limitations on the current number of notified bodies designated under the European Medical Devices Regulation (MDR).

This guidance applies to both overseas and Australian conformity assessment documents. However, where there is a need to distinguish between the two, we use more specific terms – see below under Terminology.

How does this guidance relate to the legislative timeframe?

This document explains how sponsors' conduct, with regard to notifying the TGA about conformity assessment lapsing, will affect the TGA's consideration of **whether it is necessary to suspend or cancel the device to which the documentation relates from the ARTG.**

Separately, there are criminal and civil penalty sanctions if a sponsor fails to notify the TGA within 60 days of becoming aware that a conformity assessment certificate used to support the application for inclusion in the ARTG (other than a conformity assessment certificate issued by the TGA) has been restricted, suspended, revoked or is no longer in effect[1].

However, in terms of whether a device should remain in the ARTG, the TGA will take a risk-based approach. This document explains how sponsors giving proactive and early notice to the TGA of lapsing, as well as other relevant information, will reduce the risk of their devices being suspended or cancelled from the ARTG.

This guidance is not legislative in nature and is subject to the requirements of the therapeutic goods legislation. The exact approach taken by the TGA will depend on the facts of the case and the relevant legislative provisions.

[1] *Therapeutic Goods Act 1989*, sections 41MP(2)(d)(ii) and 41MPA(2)(d)(ii) and regulation 5.7(1)(d) of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Note

Given the circumstances that have led to the changes outlined in this document, the TGA will continue to monitor developments relating to COVID- 19 and its effect on the processes for conformity assessment in both Australia and internationally. As those circumstances change, the TGA will consider whether changes to the processes outlined in this guidance are necessary and will update this guidance accordingly.

Terminology

In this guidance, the following terms are used:

- **a conformity assessment document** (CAD): is a reference to a certificate issued by the TGA, an Australian conformity assessment body certificate, or an overseas comparable regulator conformity assessment document (see below);
- **a conformity assessment certificate** (CAC): is a reference to a certificate issued by the TGA under section 41EE of the *Therapeutic Goods Act 1989* (the Act);
- **an overseas regulator conformity assessment document** (ORCAD): certificate or other evidence of conformity assessment issued by an overseas regulator after that regulator is satisfied that requirements, comparable to the conformity assessment procedures, have been applied to a medical device by the manufacturer of that device;
- **an overseas regulator**: is a reference to an overseas regulator determined by the Secretary to be an overseas regulator under s 41BIB of the Act.

Lapsing of CADs

Where a CAD has **lapsed** (that is, has expired solely because of passage of time and not because of regulatory action[2]), this will not result in automatic cancellation of a device entry in the ARTG. The TGA will consider, in deciding whether suspension or cancellation of a device entry is warranted, whether the sponsor has taken reasonable steps to mitigate the problem. In doing so, the TGA will consider the following matters:

- **the steps which the sponsor has taken to mitigate the situation**: for example, approaching their manufacturer to ensure they are seeking an extension or renewal of a CAD, and organising inspections, or seeking permission from the relevant overseas regulator to continue to manufacture the devices pending renewal of the CAD;
- **the timeliness of the sponsor's actions**: for example, did the sponsor act in advance of the expiry of the CAD to ensure their manufacturer would seek an extension (in the case of a CAC), or to seek recertification/renewal/extension (in the case of an ORCAD) including scheduling of manufacturer inspections?;
- **the extent to which the sponsor has kept the TGA informed**, proactively, of actions the sponsor and/or its manufacturers are taking, for example, informing the TGA promptly of the pending expiry of CADs, and of the proposed actions by the manufacturer and/or the sponsor, together with relevant supporting evidence (e.g. correspondence between the manufacturer and the sponsor);
- where applicable[3], whether the sponsor in the absence of a CAD has provided information to the TGA to substantiate that the devices have had the conformity

assessment procedures, or requirements comparable to the conformity assessment procedures[4] to the satisfaction of an overseas regulator, applied to them; and

- **the presence or absence of other reasons for the lack of a current CAD**: that is, where the loss of the CAD was not due solely to the delays in audits because of COVID-19 but was due to some compliance issue on the part of the sponsor. Where the CAD was **suspended, cancelled, or revoked**, rather than lapsed, see below.

If a sponsor does not provide satisfactory evidence to the TGA that it has taken reasonable steps to mitigate the expiry of the CAD, the TGA may exercise its powers of suspension or cancellation of entries in the ARTG in accordance with the Act.

Suspension/cancellation/revocation of a CAD (rather than lapsing)

Where the CAD has been suspended, cancelled, revoked or otherwise terminated due to non- compliance issues on the part of the manufacturer, the TGA will apply the terms of the Act. That is, the TGA will consider suspension or cancellation of the relevant device entries in accordance with the Act. (But note that where a CAC is revoked, the TGA must cancel the entry in the ARTG – see s 41GK of the Act).

Supply of devices that have not had conformity assessment procedures, or comparable overseas ones, applied to them, is in breach of the conditions of inclusion of the device in the ARTG. Where the relevant conformity assessment document is a CAC, the TGA may revoke or suspend the CAC in accordance with the Act.

What the TGA expects from sponsors in relation to lapsing conformity assessment certification

Sponsors (and manufacturers, if the document is a CAC) are strongly advised to notify the TGA promptly:

- if their CADs are pending expiry and there may be issues with obtaining extensions or new CADs, outlining what steps they are taking to address the problem;
- in the case of CACs: submitting an extension application to the TGA at least 6 months prior to expiry of the current CAC;
- if their CADs have already lapsed, the reasons for the lapse, and what action they are taking to address this issue.

[3] Note that some devices must have a CAC: see regulation 4.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002.*

[4] Under s 41FN(3)(b)(i) of the Act, it is a condition of inclusion in the ARTG that the sponsor have available sufficient information to substantiate that the conformity assessment procedures have been applied to the kind of device or that requirements, comparable to those procedures, have been applied to the kind of device to the satisfaction of an overseas regulator

Sponsors (or if relevant, manufacturers) should notify the TGA of the above matters, together with relevant supporting documents, by completing the notification form hosted on the TGA Consultation Hub using the link below:

https://consultations.tga.gov.au/tga/notification-form-lapses-in-conformity-assessment/

There is no fee associated with notification and a guidance document is available to assist sponsors with completing and submitting the notification form. The guidance document is available on the TGA website and with the notification form on the TGA Consultation Hub.

If you have any questions regarding the notification form, please email the TGA at dvs@health.gov.au The TGA will take failure to inform it promptly of the above matters into account in deciding whether device entries should be suspended or cancelled.

Version history

V1.0	Original publication	Devices Post Market Reforms and Reviews Section/Medical Devices Branch	October 2020
V 1.1	Updating to refer to relevance of 60-day legislated timeframe for criminal and civil penalty sanctions (MD regulation 5.7 and s 41MP/MPA of the Therapeutic Goods Act) to subject matter of this document	Devices Post Market Reforms and Reviews Section/Medical Devices Branch	January 2021
V 1.2	Updating to include link to Conformity Assessment certification lapse notification form on TGA Consultation Hub	Devices Post Market Reforms and Reviews Section	September 2022
V.1.3	Minor update in text to clarify legislated requirements	Devices Post Market Reforms and Reviews Section	June 2023

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Reference/Publication #