Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Comparable overseas regulators for medical device applications

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On 23 July 2021, the Australian Government made a decision to repeal Regulation 4.1 and amend Regulation 5.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

This means that from 28 July 2021, the range of applications for inclusion in the Australian Register of Therapeutic Goods (ARTG) that can rely on conformity assessment documents issued by European notified bodies was expanded. These amendments have changed the conformity assessment certification and audit requirements for medical devices that contain medicines or materials of animal, microbial, recombinant or human origin; and Class 4 in vitro diagnostic (IVD) medical devices.

Before the change, under regulation 4.1, sponsors of such devices could only rely on conformity assessment certification by the Therapeutic Goods Administration (TGA) for inclusion in the Australian Register of Therapeutic Goods (ARTG) for these types of devices.

Now sponsors can provide conformity assessment documents issued by notified bodies designated by a member state of the European Union to support an application for inclusion in the ARTG. These changes recognise the significantly enhanced standards, processes and clinical evaluation requirements contained in the European Union's (EU) Regulations for Medical Devices and In Vitro Diagnostics (https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices). It is important to note that Australia has some different regulatory requirements to Europe (e.g.: biologicals) and therefore, the amendment to Regulation 5.3 provides for the TGA to audit applications to ensure the information provided meets the Australian regulatory requirements (see below for further information) prior to approving the device for supply in Australia.

The TGA remains responsible for including all medical devices in the ARTG. The TGA will continue to provide product assessments and quality management assessment when required by legislation or at the request of a manufacturer.

For more information, see Changes to medical device regulations affecting when conformity assessment certificates are required (https://immunisationhandbook.health.gov.au/node/289667).

The TGA recognises a range of international assessments and approvals from comparable overseas regulators that sponsors can choose to provide when submitting their applications for inclusion of medical devices in the Australian Register of Therapeutic Goods (ARTG). The TGA is also increasing the use of assessment reports as the basis for abridgement of the assessment of an application for a TGA conformity assessment certificate.

The Expert Review of Medicines and Medical Devices Regulation (MMDR) (http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation) made recommendations aimed at streamlining the TGA's processes for including medical devices in the ARTG in order to improve access by Australian consumers to new medical devices. The Government decided that the TGA should make greater use of marketing approvals for devices in overseas markets when the device has been approved by a third party that has been designated by an authority that is similar to the TGA, or by a comparable overseas regulator (in line with MMDR Recommendation 15, Pathways 2A & 2B). The Government also agreed (under Recommendation 17) that, in consultation with stakeholders, criteria to assess comparability of overseas regulators be developed.

The TGA has long accepted certification from European notified bodies as evidence of compliance with the conformity assessment procedures, in addition to the conformity assessment certificates issued by the TGA.

Since October 2018, comparable overseas regulators and assessment bodies include:

- Notified bodies designated by the medical device regulators of European member states, under the medical device regulatory frameworks of the European Union
- the Food and Drug Administration of the United States
- Health Canada
- Medical Device Single Audit Program (MDSAP) Auditing Organisation
- the Ministry of Health, Labour and Welfare and Pharmaceutical and Medical Devices Agency of Japan.
- Singapore's Health Sciences Authority (HSA)

Criteria for comparable overseas regulators

The following five criteria are used when considering overseas regulator assessments and approvals for Australian regulatory purposes:

1. **Comparability of the regulatory framework**

   Scope

   - Does the overseas regulator take into account the same or similar regulatory objectives and other factors that are prescribed in the TGA's legislation and regulations (e.g. is the definition of a medical device substantially the same)?
   - Does it take into account objectives that are excluded in the Australian legislation, for example additional policy objectives such as industry development or environmental protection?
   - Does the overseas regulator provide complete (un-redacted) reports and is supporting scientific data used in assessments available if necessary?

   Operational alignment

   - Is there a clearly defined framework within which assessment reports are prepared by an overseas regulator?
   - Does the overseas regulator require or allow for compliance with international standards in assessing medical devices?
   - Does the overseas regulator routinely provide its assessment reports in English and are these available to the relevant sponsor?

2. **IMDRF membership**
   - Is the overseas regulator a participating member of the IMDRF (i.e. a member of the IMDRF management committee)?
3. **Life cycle approach and post-market vigilance**
   - Does the overseas regulatory framework apply across the life cycle of medical devices?
   - Does the overseas regulator have a robust approach to post-market vigilance?
4. **Communication and cooperation with overseas regulators**
   - Do the overseas regulator and TGA have communication and/or cooperative arrangements in place?
   - Is there a framework within which assessment reports prepared by overseas regulators, as well as surveillance signals, regulatory actions etc., can be shared with the TGA (and vice versa)?
5. **Expertise of the overseas regulator**
   - Does the overseas regulator have experience in conducting product evaluations and QMS assessments, by competent resources, which would satisfy the expectations for

internationally agreed best practice, both generally and for particular types of medical devices?

These are considered in developing advice for the Secretary on whether to add an overseas regulator to the Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018 (https://www.legislation.gov.au/Series/F2018L01410). Further discussion on these criteria is included in the consultation on this issue in 2017 (https://immunisationhandbook.health.gov.au/node/283514).

Using overseas market authorisation evidence

In consultation with the medical devices industry, the TGA has developed guidance which provides an overview on the use of specific overseas assessments and approvals by sponsors in their applications for ARTG inclusion and when they request the abridgement of applications for TGA conformity assessment certification:

- Use of market authorisation evidence from comparable overseas regulatory bodies for medical devices (https://immunisationhandbook.health.gov.au/node/285179)

We have also developed a number of questions and answers to provide applicants with examples of when TGA will conduct an application audit, and at what level.

- Use of market authorisation evidence from comparable overseas regulatory bodies for medical devices - questions and answers (https://immunisationhandbook.health.gov.au/node/289426)

Topics:

Medical devices (https://immunisationhandbook.health.gov.au/products/medical-devices)

What went wrong? (mandatory)

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