Conformity assessment certificates, changes to requirements for certain medical devices

Repeal of Regulation 4.1 of the Medical Devices Regulations

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On 23 July 2021 the Government repealed Regulation 4.1 and amended Regulation 5.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (https://www.legislation.gov.au/Series/F2002B00237).

This means that from 28 July 2021, medical devices that contain medicines or materials of animal, microbial, recombinant or human origin; and Class 4 in vitro diagnostic (IVD) medical devices no longer require mandatory TGA conformity assessment certification.

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). This ensures that safety and performance is demonstrated 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.

Changes to application audit requirements for medical devices

The application audit requirements for devices that contain medicines or materials of animal, microbial, recombinant or human origin and Class 4 in vitro diagnostic (IVD) medical devices have changed.

The amendment to Regulation 5.3 means that for devices that contain medicines or materials of animal, microbial, recombinant or human origin, and Class 4 in vitro diagnostic (IVD) the TGA can audit/review the documents issued under the following EU Regulations:

- Medical Devices Regulation (2017/745) (https://eumdr.com/)
- In Vitro Diagnostics Regulation (2017/746) (https://euivdr.com/)

Selecting applications for audit allows the TGA to review compliance with Australian-specific regulatory requirements, including ensuring safety and performance can be demonstrated, while also recognising the enhanced standards contained in these EU regulations.

For devices supported by older certificates issued under several earlier EU Directives, the TGA will conduct in-depth audits for all those applications that rely on conformity assessment documents issued under the following EU Directives:

- 93/42/EC (Medical devices) (https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en)
- 90/385/EEC (Active implantable medical devices) (https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/implantable-medical-devices_en)
- 98/79/EC (In vitro diagnostic medical devices) (https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/implantable-medical-devices_en)

This is in line with the way the TGA undertakes a risk-based assessments of applications for other high-risk medical devices.

For devices that were previously described under regulation 4.1 (those that contain medicines or materials of animal, microbial, recombinant or human origin, and Class 4 IVDs), we will accept conformity assessment evidence issued by the TGA, EU notified bodies and by Australian conformity assessment bodies. More information is available on the web page, 'Comparable overseas regulators for medical device applications (https://www.tga.gov.au/node/289428)'.

Review of application audit assessment fees

As the application audit requirements for devices that contain medicines or materials of animal, microbial, recombinant or human origin and Class 4 in vitro diagnostic (IVD) medical devices have changed, the TGA will be undertaking a review of applicant assessment audit fees. The application audit assessment fees can be found under fees and charges on the TGA website (https://www.tga.gov.au/node/282893).

Currently, a Level 1 audit focuses on the device's classification, the application of appropriate conformity assessment procedures and compliance with the Essential Principles (EP) such as EP13 relating to information provided with the device. A Level 2 audit further includes the review of clinical efficacy and performance data, risk management and supporting audit reports from notified bodies.

The TGA may need to expand Level 2 audits (and respective fees) for devices that contain medicines or materials of animal, microbial, recombinant or human origin and Class 4 in vitro diagnostic (IVD) medical devices to include an Engineering, Biomaterials, Sterility or Quality Management System audit component.

A review is underway to determine if changes are necessary to the current audit process and respective fees, with consultation to occur with industry on any subsequent proposed changes.

FAQ for manufacturers and sponsors

Do these changes mean the TGA is reducing its regulatory oversight?

No. These changes aim to avoid duplication and reduce regulatory burden on the medical device industry. They also recognise changes to the European Union's (EU) medical devices regulations (https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices) and Australia's harmonisation with these regulations. The TGA remains responsible for ARTG inclusion.

I paid an application and assessment fee for my TGA conformity assessment (CA) application, but I already have EC certification from a notified body that I can use to support an application to include my device in the Australian Register of Therapeutic Goods (ARTG). Can I get a refund?

If you paid your fee prior to 28 July 2021, there is currently no provision in the legislation for the TGA to refund application or assessment fees for devices undergoing TGA CA.

You may choose to withdraw your TGA CA application and use the EC certification issued by a notified body. Alternatively, you may choose to proceed with your CA application.

Any change to the fee arrangements (including the ability to refund fees already paid) will require Government approval. The TGA has commenced a process for Government consideration of changes to allow refunds.

If a TGA CA certificate is issued for your device and you apply for inclusion in the ARTG, your application will not be subject to an audit that has an associated assessment fee.

My application for ARTG inclusion is being audited by the TGA and I have paid an associated assessment fee. I also hold a European Union (EU) CA certificate issued under the EU Medical Devices Regulation (2017/745). Will this audit now cease, and can I get my audit fee refunded?

No the audit will not cease and there is currently no provision for a refund (see above). Your application was selected for audit consistent with the regulatory requirements in force at the time of application.

Do I need to tell the TGA if the conformity assessment documents (manufacturers evidence) supporting my ARTG inclusion change?

Sponsors are not necessarily required to update their manufacturer evidence when a change between sources of evidence has occurred. However, you must hold valid evidence at all times and provide it to us if we ask.

In some circumstances, however, you will need to update your manufacturer evidence with us. More information is available on the web page, 'Manufacturer evidence for medical devices and IVD medical devices (https://www.tga.gov.au/node/287913)'.

What evidence from comparable overseas regulators does the TGA accept?

We accept a range of conformity assessment documents issued by comparable overseas regulators for medical devices; sponsors can choose which to provide when submitting their applications for inclusion in the ARTG.

For devices that were previously described under regulation 4.1 (those that contain medicines or materials of animal, microbial, recombinant or human origin, and Class 4 IVDs), we will only accept conformity assessment evidence issued by the TGA, EU notified bodies and by Australian conformity assessment. More information is available on the web page, 'Comparable overseas regulators for medical device applications (https://www.tga.gov.au/node/289428)'.

I am a sponsor of an existing medical device supported by TGA CA, and I hold other evidence from a comparable overseas regulator as well. What are my options?

If you previously held TGA CA due to the mandatory requirements of Regulation 4.1, you still need to ensure you hold and maintain conformity assessment evidence or comparable overseas approval at all times.

For any new inclusion in the ARTG, you may now apply directly for inclusion in the ARTG using CA documents issued by a European notified body under:

- EU Regulation 2017/745 (MDR) (https://eumdr.com/) or 2017/746 (IVDR) (https://euivdr.com/)
- EU Directive 93/42/EC (Medical devices), 90/385/EC (Active implantable medical devices) or 98/79/EEC (In vitro diagnostic medical devices).

Your application may be subject to an audit to ensure the evidence demonstrates compliance with the Australian essential principles for the safety and performance of medical devices.

I am a sponsor of an existing medical device supported by TGA CA and I do not hold any other evidence from a comparable overseas regulator. What are my options?

If you previously held TGA CA, you may continue to do so. We will continue undertaking conformity assessments that can be used for inclusion in the ARTG.

Why is an application audit still required if I have MDR or IVDR certification?

Application audits are required for most high-risk devices relying on CA documents from comparable overseas regulators. This allows the TGA to review the evidence supporting the overseas approvals and exercise its responsibility to ensure medical devices comply with Australian regulatory requirements.

Applications relying on CA documents issued under EU Regulation 2017/745 (MDR) or 2017/746 (IVDR) may be selected for audit. However, audit assessment fees do not currently apply for applications supported by EU MDR or IVDR certification. Refer to Review of application audit assessment fees above.

What are the fees for the mandatory audit process?

Combined, the application and audit assessment fees are currently up to approximately $8,800. The annual charge for a Class III medical device is $1,210. More information is available under Fees and charges: summary from 1 July 2021 (https://www.tga.gov.au/node/282893).

What are the timeframes for application audits and the TGA CA certification process?

There is no legislated timeframe for audits. The time an audit takes depends on whether all requisite information was provided to the TGA and the quality of the data submitted.

The legislated timeframe for completing TGA design certification is 255 working days. Based on financial year 2019-20, median processing timeframes for initial and variation CA is 158 and 144 working days respectively. More information on TGA CA timeframes is available in the TGA performance statistic report July 2019-June 2020 (1.14Mb) (https://www.tga.gov.au/sites/default/files/annual-performance-statistics-report-july-2019-june-2020.pdf).

Topics:

Medical devices (https://www.tga.gov.au/products/medical-devices)