Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Submitting annual reports for medical devices

Guidance for sponsors of certain medical devices that are required to submit annual reports on safety and performance.

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Purpose

Sponsors of certain medical devices are required to submit annual reports for the first three years of inclusion in the Australian Register of Therapeutic Goods (ARTG). The submission of annual reports is part of the device lifecycle approach for the sponsor to demonstrate that:

- high risk devices that are new to the Australian market continue to meet the Essential Principles for safety and performance; and
- the manufacturer's post-market surveillance system can identify any safety or performance issues or signals associated with the device as early as possible.

If you are a sponsor of a medical device that is:

- an implantable Class IIb device; or
- a Class III device; or
- an Active Implantable Medical Device (AIMD) (now Class III devices); or
- a Class 4 in vitro diagnostic (IVD) device

then one of your automatic post-market obligations is to provide three consecutive annual reports to us after your device is included in the ARTG. The details are referenced in Regulation 5.11 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Legislation

Therapeutic Goods (Medical Devices) Regulations 2002

Due dates and reporting periods

Annual reports should cover the period from 1 July to 30 June and are due on 1 October each year. Your first report should be for a period of at least six months, but not longer than 18 months. If the information is limited to the time the device has been on the Australian market because it hasn't been supplied elsewhere, this should be stated in the report.

Subsequent reports are to be provided by 1 October for a further 2 years.

Timing of ARTG inclusion	Annual report is due	Annual report must include data
Between 1 July and 31 December	1 October of the following year	Data from 1 July of the preceding year to 30 June.
Example: XYZ Pty Ltd's medical device is included in the ARTG on 4 September 2016. Their first annual report will be due on 1 October 2017 as they will have over 6 months of data as of 30 June 2017. If XYZ's device is available in other countries, then their data must include global statistics from 1 July 2016. If XYZ's device is not available in other countries, then their first annual report must include information from 4 September 2016 through to 30 June 2017.		
Between 1 January and 30 June	1 October of the following year	Data from the date of inclusion in the Register through to date to 30 June.
Example: XYZ Pty Ltd's medical device is included in the ARTG on 20 January 2016. Their first annual report will be due on 1 October 2017 as they do not have 6 months of data available as of 30 June 2016.		

Things to include in your annual report

You should include the following in your annual report:

- ARTG number.
- Product name(s).
- Model number(s).
- Number of devices supplied in Australia by product/model.
- Number of devices supplied worldwide (numbers should include devices that are the same but supplied under a different name in another jurisdiction) by product/model.
- Number of complaints in Australia by product/model.
- Number of complaints by product/model.
- Number of adverse events and incident rates in Australia (Rate = No. of events/No. Supplied x 100 = Rate %).
- Number of adverse events and incident rates world-wide.
- A list of all complaints and adverse events identifying the jurisdiction where the complaint or adverse event originated.
- Device Incident Report (DIR) number of those adverse events reported to us.
- Details of any regulatory/corrective action/notification by the manufacturer.

Submit your annual report

Annual reports must be provided in electronic form and can be emailed to medicaldevicesurveillance@health.gov.au marked for the attention of the Annual Report Coordinator.

> The TGA does not provide a reminder that your annual report is due. Failure to submit your annual report on time could lead to your inclusion being revoked.

Your information needs to be in a clear and logical table format. The following is an example of how to present your annual report:

ARTG	Product name	Model number	Number supplied in Australia	Number supplied worldwide	Number of complaints Aus / WW	Number of adverse events Aus / WW
123456	Knee prosthesis - femoral component	ABC 123	200	8000	32/235	2/58

Type of complaints	Number	Percentage in Australia	Percentage worldwide	TGA DIR #	Regulatory action
Adverse events					
loosening	2	0.025%	0.058%	DIR 12234	Nil

Next steps

First, we will review your report.

You will only be contacted if additional information is required.

All annual reports that are submitted to us are treated as confidential. However, the information contained within the report is used for the ongoing monitoring of the safety and performance of the devices.

Supporting documents

Template: Annual report data collection [Excel, 15.28 KB]

Topics: Safety Therapeutic goods regulation

Page history

25 January 2024
Updated to include:

- "high risk devices that are new to the Australian market continue to meet the Essential Principles for safety and performance; and"
- "the manufacturer's post-market surveillance system can identify any safety or performance issues or signals associated with the device as early as possible."
- Clarification of Active Implantable Medical Device (AIMD) to Class III medical devices.
- References made to Regulation 5.11 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Other minor editorial changes.

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