Medical Devices: how to stay included
Annual Reports

Catherine Looram
Post-Market Investigator
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
Learning outcomes

At the end of this session it is envisaged that you will be able to:

• Understand the requirements and importance of why annual reports need to be provided to the TGA
• Identify the information that is required, by the TGA, in the annual report
• Recognise avoidable errors in annual reporting to the TGA
Overview

• Who
• When
• Why
• What
• How
• Specific to orthopaedic implants that have transitioned
• Important points to remember
• Key messages
• Learning outcomes
• Further information
Who

- **Sponsors** will be required to submit three annual reports to the TGA following inclusion for higher risk medical devices
- **TGA** reviews the information provided for any safety signals
When to provide annual reports and timelines

- Annual reports are due on 1 October each year
- Reports should be for the period 1 July of the previous year to 30 June of the current year
- Reports should be submitted for devices that were included in the ARTG within the last 3 years prior to the current reporting year
- The first report following the date of inclusion in the ARTG must be for a period of at least 6 months but no longer than 18 months
  - If the device is included in the ARTG 6 months before 1 January, the annual report is due in October of that year for information from 1 July of the preceding year to 30 June
  - If the device is included in the ARTG after the 1 January, the annual report will not be required until October the following year
Why do we conduct annual reporting?

To ensure that high risk devices new to the Australian market are continuing to meet the essential principles for safety and performance.

To ensure that the sponsor and manufacturer’s post-market surveillance system is functioning sufficiently to detect any issues as early as possible.
What is annual reporting?

• The TGA requests information about high risk devices every year for the first 3 years after inclusion in the ARTG

• The devices subject to annual reporting are as follows:
  – AIMD
  – Class III
  – Implantable Class IIb
  – Class 4 IVDs

• The sponsor will be required to provide, number of devices supplied, complaint and adverse event data
What information is required for annual reporting

- The information that the sponsor/manufacturer should include in the annual report for each applicable ARTG entry is as follows:
  - Product name
  - Model no(s) for each respective ARTG entry
  - Number supplied in Australia (Note - if Australian distribution is 0, data must still be provided regarding overseas distribution, complaints and adverse events)
  - Number supplied worldwide
  - Number of complaints in Australia and worldwide
  - Number of adverse events in Australia and worldwide
  - The rate of complaints and adverse events in Australia and worldwide
  - Device Incident Report (DIR) number of any adverse events reported to the TGA
  - Details of any regulatory/corrective action/notification by the manufacturer
What happens to annual reports?

- Reports are treated as confidential
- The annual reports are reviewed by the TGA
- Any issues arising will be discussed with the sponsor
  - The TGA investigator contacts the sponsor and the reporter and works with them to resolve any issues
- All reports are entered into the TGA’s record keeping system and referred to during the review if the current report is the second or third report for that device
How to provide the information for annual reporting

• Present the information in a clear and logical manner
• Present the information in a table format
• Provide the information electronically
  – Send medical device annual reports to postmarketdevices@tga.gov.au
An example of how information for annual reporting might be presented

<table>
<thead>
<tr>
<th>ARTG #</th>
<th>Product name</th>
<th>Model #</th>
<th># Supplied Australia</th>
<th># Supplied world wide</th>
<th># of Complaints Australia/ww</th>
<th># of Adverse events Australia/ww</th>
</tr>
</thead>
<tbody>
<tr>
<td>123456</td>
<td>Knee prosthesis – femoral component</td>
<td>ABC 123</td>
<td>200</td>
<td>8000</td>
<td>32/235</td>
<td>2/58</td>
</tr>
</tbody>
</table>
An example of how information for annual reporting might be presented

<table>
<thead>
<tr>
<th>Type of adverse event and/or complaints</th>
<th>Number</th>
<th>Percentage in Australia</th>
<th>Percentage worldwide</th>
<th>TGA DIR #</th>
<th>Regulatory action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Events</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>loosening</td>
<td>2</td>
<td>0.025%</td>
<td>0.058%</td>
<td>DIR 12345</td>
<td>Nil</td>
</tr>
</tbody>
</table>
Specific to orthopaedic implant prosthesis that have transitioned

• For orthopaedic implant prostheses that have been re-classified from Class IIb to Class III medical devices, information will be required on an annual basis for a minimum of 3 years if:
  – The device was subject to a TGA application audit based on the revision rate when the device transitioned from Class IIb to Class III; and/or
  – No devices were supplied to the Australian marketplace before 30 June 2012; and/or
  – The reporting period has not ended

• Information is NOT required if the prescribed reporting period has ended
• If the prescribing reporting period has ended the sponsor needs to indicate this and, in the report, reference the old Class IIb ARTG entry which relates to the new Class III ARTG entry
Orthopaedic implant transition from Class IIb to Class III

Did you have a Class IIb ARTG entry?
- Yes

Was a reclassification application submitted between 1 July 2012 – 30 June 2015?
- Yes

Was the application selected for audit based on revision rate and/or no devices supplied in Australia prior to 30 June 2012?
- Yes

Has the device been included in the ARTG as a Class III?
- Yes

A minimum of 3 annual reports are required as a Class III ARTG entry
- Yes

Device is not included in ARTG
Orthopaedic implant transition from Class IIb to Class III

Did you have a Class IIb ARTG entry?  
Yes

Was a reclassification application submitted between 1 July 2012 – 30 June 2015?  
Yes

Was the application selected for audit based on revision rate and/or no devices supplied in Australia prior to 30 June 2012?  
No

Has the device been included in the ARTG as a Class III?  
Yes

Has the prescribed reporting period ended for the old Class IIb ARTG entry?  
No

Provide a combined total of 3 annual reports between the old Class IIb and the new Class III ARTG entries

Advise TGA of old Class IIb ARTG number and related new Class III ARTG number
Orthopaedic implant transition from Class IIb to Class III

Did you have a Class IIb ARTG entry?

- Yes

Was a reclassification application submitted between 1 July 2012 – 30 June 2015?

- Yes

Was the application selected for audit based on revision rate and/or no devices supplied in Australia prior to 30 June 2012?

- No

Has the device been included in the ARTG as a Class III?

- Yes

Has the prescribed reporting period ended for the old Class IIb ARTG entry?

- Yes

Annual reporting information is not required

Advise TGA of old Class IIb ARTG number and related new Class III ARTG number

- Yes
Did you have a Class IIb ARTG entry?

Yes

Was a reclassification application submitted between 1 July 2012 – 30 June 2015?

Yes

Was the application selected for audit based on revision rate and/or no devices supplied in Australia prior to 30 June 2012?

No

Has the device been included in the ARTG as a Class III?

No

Device is not included in ARTG
Did you have a Class IIb ARTG entry?

Yes

Was a reclassification application submitted between 1 July 2012 – 30 June 2015?

Yes

Was the application selected for audit based on revision rate and/or no devices supplied in Australia prior to 30 June 2012?

No

Has the device been included in the ARTG as a Class III?

No

Has the prescribed reporting period ended for the old Class IIb ARTG entry?

Yes

Has the device been included in the ARTG as a Class III?

No

Annual reporting information is not required

Yes

Advise TGA of old Class IIb ARTG number and related new Class III ARTG number

A minimum of 3 annual reports are required as a Class III ARTG entry

Has the prescribed reporting period ended for the old Class IIb ARTG entry?

No

Provide a combined total of 3 annual reports between the old Class IIb and the new Class III ARTG entries

Device is not included in ARTG

Device is not included in ARTG

Yes

Yes

Yes

No

No

No

No
Example – Orthopaedic implant that has transitioned
TGA application audit based on the revision rate

• Annual report information will be required annually for a period of 3 years for the Class III device for the following:
  – An Orthopaedic Hip Stem used in a total conventional hip replacement was subject to a TGA application audit based on the revision rate of 2 Revisions/100 OBS Years when the device was transitioned from Class IIb to Class III (the NJRR acceptable revision rate 0.8 Revisions/100 OBS Years)
Example – Orthopaedic implant that has transitioned
No devices were supplied to the Australian marketplace before 30 June 2012

• Annual report information will be required annually for a period of 3 years for the Class III device for the following:
  – A shoulder joint implant where no devices were supplied to the Australian marketplace before 30 June 2012

https://en.wikipedia.org/wiki/Shoulder_replacement
Example – Orthopaedic implant that has transitioned

The reporting period has not ended

- Annual report information will be required for a combined total of 3 annual reports between the old Class IIb ARTG entry and the related new Class III ARTG entry for the following:
  - A knee joint implant that has transitioned from Class IIb to Class III, it has not been selected for audit based on revision rate and devices have been supplied to the Australian market place before 30 June 2012
  - Two annual reports have previously been provided for the old Class IIb ARTG entry
  - One further annual report is required for the new Class III ARTG entry
Important points to remember

- Provide all the information requested (and just the information requested) within the required timeframes
- Ensure the correct ARTG entry number corresponds to the device
- Proof reading – check accuracy, be careful of cut and paste
- Lack of information or relevancy – ensure all the information is made available, accurate and relevant to the request and device
- If the requested annual reports are not provided the TGA can take further regulatory action, such as cancelling the ARTG entries from the register
Key messages

• Be prepared:
  – Collect feedback
  – Analyse trends
  – Regularly review
  – Know what devices you supply and their corresponding ARTG number

• Be timely - the reports are all due on 1 October of each year. Don’t rely on TGA reminders

• Provide an argument for the notion that the figures demonstrate acceptable safety and performance

• Learn from the information that you are submitting
Learning outcomes

At the end of this session it is envisaged that you will be able to:

• Understand the requirements and importance of why annual reports need to be provided to the TGA
• Identify the information that is required, by the TGA, in the annual report
• Recognise avoidable errors in annual reporting to the TGA
Further Information

- **Therapeutic Goods Act 1989**, Chapter 4

- **Therapeutic Goods (Medical Devices) Regulations 2002**, Essential principles; Classification rules; Conformity assessment procedures

- **Australian regulatory guidelines for medical devices** (ARGMD)
  - Section 3 – The essential principles
  - Section 22 – Post-market vigilance and monitoring requirements

- postmarketdevices@tgano.gov.au