TGA Consultation – Alignment with European medical device regulatory framework

MTAA Submission - August 2017

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Contents

1 Executive Summary

On 28th July 2017, the TGA opened the consultation *Alignment with European medical device regulatory framework – Up-classification of surgical mesh, Patient implant cards*. The consultation proposes implementing the following measures to align Australian and European regulatory requirements:

- Reclassification of all implantable surgical mesh medical devices from Class IIb (moderate to high risk) to Class III (high risk); and
- Introduction of formal requirements for medical device manufacturers to provide patient implant cards and product information directed at consumers for all implantable medical devices.

The recently adopted European Medical Device Regulation (MDR) 2017/745 of 5 April 2017 has introduced significant changes compared to the old Medical Devices Directive (MDD) 93/42/EEC, among them the up-classification of implantable surgical meshes and requirements for patient implant cards. According to the TGA, these two measures are being introduced first because of their ability to positively impact on patient safety. Other measures to further align with the new European MDR will continue to be progressed, with additional consultations next year.

MTAA appreciates the opportunity to comment on this consultation. MTAA supports alignment with European medical device regulatory framework, in line with recommendation 20 of the 2015 Medicines and Medical Devices Review (MMDR) by the independent expert panel lead by Emeritus Professor Lloyd Sansom AO.

In the next sections, we provide detailed feedback to each of the proposed implementation measures.

2 Reclassification of all implantable surgical mesh medical devices

Currently in Australia implantable surgical mesh medical devices are classified as Class IIb (moderate to high risk), using classification Rule 3.4 *Surgically invasive – long-term use (more than 30 days)*[1].

According to the EU MDR, surgical meshes are classified as Class III (high risk), as per Annex VIII Rule 8 for all implantable devices and long-term surgically invasive devices[2]. This represents an up-classification from Class IIb under the old MDD.

When the transitional period for implementing the EU MDR ends in May 2020, all implantable surgical meshes will be assessed using conformity assessment procedures for Class III medical devices. This involves an additional design examination certification, which is not required for Class IIb devices.

[1] https://www.tga.gov.au/sites/default/files/devices-argmd-p1-01.pdf
[2] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.117.01.0001.01.ENG&toc=OJ:L:2017:117:TOC

The TGA consultation paper mentions that full fees will be charged for normal application, assessment and audit fees (page 7). Given that for the previous up-classification of hip, knees and shoulder replacements no additional fees and charges were applied[3], we would like to propose that a similar arrangement be made for this up-classification as well.

MTAA has long held the view that the Australian regulatory framework should continue to be closely aligned with that of the EU. Most medical device inclusions in the ARTG, including for implantable surgical meshes, rely on CE Marking approvals hence it is sensible to have Australian transitional arrangements that mirror those of the EU.

An end of the Australian transitional period taking effect around 6 months after the end of the EU MDR transitional period seems appropriate as it will allow sponsors to finalise European certification prior to lodging applications for inclusion in the ARTG.

Article 120(2) of the EU MDR mentions that:

a) Certificates issued in accordance with AIMDD and MDD *prior to 25 May 2017* will remain valid until the end of the period indicated on the certificate, which shall become void at the latest on 27 May 2022.

b) Certificates issued in accordance with AIMDD and MDD *after 25 May 2017* will remain valid until the end of the period indicated on the certificate, which does not exceed five years from its issuance, but they will however become void at the latest on 27 May 2024. This gives manufacturers up to 7 years to complete re-certification of their entire portfolio to EU MDR.

MTAA agrees with the proposed arrangements for the transitional period outlined in the consultation paper and summarised in Figure 1. We understand that implementation timelines for Australia will mirror the European implementation timelines with a time lag of approximately 6 months.

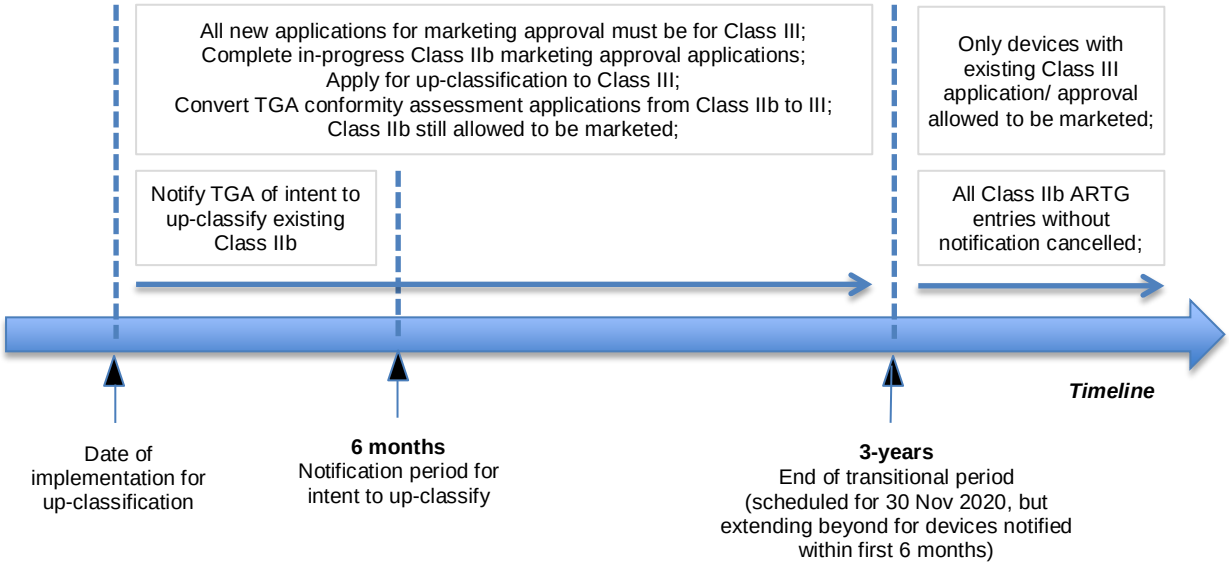

Figure 1: Implementation arrangements for the 3-year transitional period

[3] https://www.tga.gov.au/joint-reclassification-advice-transition-timeframe-extended-june-2015

3 Patient implant cards

The MTAA welcomes the clarity of proposed requirements for patient implant cards. We expect that their consistent implementation will improve predictability of applications outcomes.

As stated previously, the MTAA supports continued alignment with EU regulations and avoiding national-only requirements wherever possible. Hence, we agree with TGA's proposal to amend Essential Principle 13 of Australian regulation by aligning the scope of patient implant cards requirements with Article 18 of the EU regulations:

- Patient implant cards to be required for all implantable medical devices and long term surgically invasive implants, classified as Class IIb, Class III and AIMD;
- Exempt from patient implant card requirements: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;

MTAA agrees with the proposed transitional period for implementing the requirements for the patient implant cards, i.e. *after* the manufacturers of all relevant medical devices will have been re-certified under the new MDR. The transition period for the MDR will end early-mid 2020, with a deadline of May 2022 for EC certificates issued prior to 25 May 2017 and a deadline of May 2024 for EC certificates issued after 25 May 2017, as per Article 120(2) of the EU MDR. Implementation of requirements for patient implant cards should not be mandatory before the new effective date has been reached, including for imported "very high risk" devices (containing medicines or tissues of animal, biological or microbial origin) requiring a mandatory TGA conformity assessment, as has been experienced by many members of late.

As manufacturers and sponsors do not have direct access to patients receiving implants, it is incumbent upon medical practitioners to ensure that:

- patient implant cards are provided to patients *after surgery* upon being discharged from hospital; and
- patients are educated on the importance of keeping the card safe and secure in case information about the implant is required for subsequent medical procedures such as MRI scans;

As stated in the consultation document, implantable devices are not un-packaged by the patient receiving the implant, but rather by the surgeon or theatre staff implanting the device. Therefore, the TGA will need to engage the relevant medical colleges and provide necessary education through face-to-face workshops, news and targeted notifications, as well as permanent, easy-to-find information on the TGA website, in the section dedicated to health professionals. MTAA is pleased that our suggestion regarding the prerequisite of surgeon and hospital education regarding the future presence of the implant card has been put forward for implementation and we would be keen to assist in working with TGA on possible logistics.

The regulations and/or guidelines introducing the requirements on patient implant cards should allow some flexibility with regards to the actual method of implementation. For example, it may be more efficient and effective for manufacturers to provide a set of indelible, non-peel stickers that the theatre staff can affix on a card after the surgery, rather than provide pre-printed cards. This would accommodate situations where the selection of the size and shape of the implant is decided during surgery, and also to allow the manufacturer to supply one card per family of implants rather than one card per implant box, or combine a number of system parts onto one card, as needed.

Regarding publication of patient information, we have the following questions:

1. If the sponsor does not have a patient manual or does not wish to make public the entire patient manual (due to IP protection reasons), does the TGA require that the sponsor generate a patient information 'leaflet' (in electronic format) similar to the CMI for medicines and submit it for approval together with the application?

2. Will the requirement to have the patient information 'leaflet' (in electronic format) for publication on TGA's website be applied retrospectively including devices already included in the ARTG?

3. Will changes to the patient information 'leaflet' (in electronic format) require TGA approval or just notification to maintain currency? Will there be any costs associated with this?

We acknowledge that information on implantable medical devices would eventually be entered in a patient's MyHealth record in the future, and that mandating this is out of scope of the currently proposed regulatory change. Ideally, to avoid duplicative data entry and information management in both MyHealth *and* registries, e-health records should capture all necessary information in a centralised manner so that it can be used in clinical quality registries.

In conclusion, the MTAA is thankful for the opportunity to provide comments to the consultation. We look forward to working together with the TGA in achieving best possible outcomes for patient safety, effective regulatory requirements and minimising red tape for the MedTech industry.