Australian Government
Department of Health
Therapeutic Goods Administration

Alignment with European medical device regulatory framework

Up-classification of surgical mesh
Patient implant cards

Version 1.0, July 2017

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

Introduction

This paper outlines the TGA's intention to implement two measures to align Australian and European regulatory requirements:

- Reclassification of all implantable surgical mesh medical devices from Class IIb (medium 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.

We are looking for views and feedback on the proposed approach for implementing these changes, and impacts on industry, healthcare professionals, and current and potential future recipients of the medical devices.

Comments on all the options are welcomed from individuals, industry, healthcare and patient representatives and individuals. This feedback will assist us to identify issues and address any unintended consequences to inform the proposal and the regulatory amendment process.

Background

Why change?

Implementation of these changes is in response to the Governments decision in September 2016 to accept Recommendation Twenty of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR).

Because the European regulations were not finalised until recently (published and adopted in May 2017) we have not be able to consult on this aspect of alignment with the European Regulations until this point in time.

> **Recommendation Twenty**
>
> The Panel recommends that:
>
> 1. The regulation of medical devices by (TGA) is, wherever possible, aligned with the European Union framework including in respect of the:
>
>   A. Classification of medical devices;
>
>   B. Essential Principles/Requirements;
>
>   C. Adoption of a risk-based approach to variations to medical devices.
>
> 2. Should the (TGA) seek to apply specific requirements, there must be a clear rationale to do so.

Revised European regulations on medical devices agreed on 5 April 2017[1] included significant changes to the previous regulatory arrangements. This included the up-classification of surgical

[1] Revisions of Medical Device Directives https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision_en
These changes were published in the Official Journal of the European Union on 5 May 2017 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC

meshes from Class IIb (medium to high risk) to Class III (high risk),[2] and the introduction of an 'implant card' containing information about implanted medical devices for a patient.[3] The new rules apply after a transitional period, which for surgical mesh is three years after the regulation came into force (25 May 2020).

The update of the European regulatory framework was extensive, and there are a number of other changes to be considered in alignment with the European framework in the context of MMDR Recommendation Twenty.

These two measures are being progressed first, given their ability to positively impact on patient safety around mesh devices. Other measures to further align with the new European regulatory framework will also be progressed, with planned consultation during 2018.

Up-classification of surgical meshes

What are surgical meshes?

Surgical mesh is used to provide temporary or permanent support for weakened structures and/or muscles in surgery. Repair of hernias, pelvic organ prolapse (POP) and stress urinary incontinence (SUI) conditions are common uses for surgical meshes.

A hernia is the abnormal exit of tissue or an organ, such as the bowel, through the wall of the cavity in which it normally resides. Hernias come in a number of different types, and most commonly involve the abdomen, specifically the groin. About 27% of males and 3% of females develop a groin hernia at some time in their life. Uncomplicated hernias are principally repaired by pushing back, or "reducing", the herniated tissue, and then mending the weakness in muscle tissue, which may include reinforcing the defect with surgical mesh.

POP is a common condition where there is a weakness in the pelvic floor such that pelvic organs including the bladder, rectum or uterus are able to descend or sag into the vagina. These conditions generally arise through childbirth, injury or surgery. Up to 50% of women will have some prolapse present. Not all POP are symptomatic. If the POP is symptomatic and pose problems, patients may be treated either surgically or non-surgically. Among the surgical methods, repair can be done by using the patient's own tissue; native tissue repair or using surgical mesh. Surgical mesh devices may be implanted through the abdominal or transvaginal approach to provide support to the pelvic floor muscles. The choice of surgical approach depends on the type of prolapse and individual patient characteristics.

SUI describes conditions where there is accidental urine leakage when the bladder is under pressure, for example through coughing, exercising or other strenuous activity. As with POP, symptoms can be mild, moderate or severe or it can significantly affect quality of life. SUI that has become bothersome, was reported in 15% of women aged 25-84 (Lukacz et al)[4]. When used in the treatment of SUI, the mesh is implanted as a 'mesh sling' procedure to support the urethra or bladder neck.

[2] Regulation (EU) 2017/745 of the European Parliament and of the Council, Annex VIII, Chapter III – Classification Rules, 5.4, Rule 8: All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: [...] are breast implants or surgical meshes, in which cases they are classified as class III

[3] Regulation (EU) 2017/745 of the European Parliament and of the Council, Article 18 - Implant card and information to be supplied to the patient with an implanted device

[4] Lukacz ES et al. *Evaluation of women with urinary incontinence.* UpToDate. Last updated Dec 2016. Accessed from: https://www.uptodate.com/contents/evaluation-of-women-with-urinary-incontinence (3/4/17).

Surgical mesh devices were first developed for the treatment of abdominal hernias. In the late 1990s, medical device manufacturers began to supply the meshes for use in urogynaecological surgery. A rapid uptake of urogynaecological meshes for surgical treatment of SUI and POP, followed in the next decade, both in Australia and overseas.

Surgical mesh can be made of synthetic or biological material. Polypropylene mesh is an example of the synthetic type. The mesh may be absorbable, non-absorbable or a combination of both. Absorbable mesh will degrade and lose strength over time but non-absorbable mesh will remain in the body permanently. Most urogynaecological mesh is permanent synthetic mesh.

What's changing?

In Australia synthetic surgical meshes are currently classified as Class IIb[5]. There are some surgical meshes which are already classified as Class III, such as meshes including medicines or materials of animal, microbial or recombinant origin; and there will be no change for those devices.

Under this proposal, all synthetic meshes would be require be up-classified to Class III. As a result, manufacturers of these surgical meshes will be required to seek additional conformity assessment certification. Manufacturers will already hold certification of full quality assurance procedures,[6] but will now also require design examination certification[7] for each mesh medical device.

To supply, import or export medical devices in Australia the device must be included in the Australian Register of Therapeutic Goods (ARTG). Once they have appropriate conformity assessment certification, applicants will need to apply to up-classify any existing Class IIb ARTG entries for surgical meshes. Applicants may seek TGA conformity assessment certification or have the option of using equivalent European conformity assessment certification when seeking marketing approval in Australia, as is already the case for existing ARTG entries.

How will this be implemented?

This change will be implemented by amendment of the Classification Rules in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Transitional arrangements

It is proposed that transitional arrangements in Australia will mirror those in Europe, with a period of around three years.

The transition arrangements in Europe for medical devices will end in May 2020. The Australian transition would be scheduled to end on 30 November 2020, around 6 months after the end of the European transition. This provides a window for applicants to finalise European certification prior to lodging applications to include the device in the ARTG in Australia.

[5] Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 2, Part 3, 3.4 Surgically invasive medical devices intended for long-term use and implantable medical devices.
[6] Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full quality assurance procedures (except Part 1.6)
[7] Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1.6 - Examination of design of Class 4 IVD medical device, Class 4 in-house IVD medical device, Class AIMD medical device or Class III medical device

Applications

As at the date that the proposed amendment comes into effect:

- All new applications for marketing approval of surgical meshes in Australia will need to be for a Class III medical device.
- Sponsors of existing surgical mesh devices already included in the ARTG as a Class IIb medical device will need to apply to have their device/s included as Class III medical devices, with applications to up-classify all surgical meshes to have been received by the end of the transition period. Where an application to up-classify the mesh has not been determined, the mesh can continue to be supplied under the existing ARTG entry until the Class III application is finalised (including applications not finalised at the end of the transition period) or another decision has been made.
- A notification period would operate for the first six months of the Australian transition period. All sponsors of existing Class IIb surgical meshes would need to notify the TGA within this period of all products they intend to up-classify. These products can continue to be supplied under the existing Class IIb entry for the duration of the transition. Any surgical mesh product not notified in this period would need to be covered by a Class III ARTG entry. Where an up-classification application is not received by the end of the transition period the related Class IIb ARTG entry will be cancelled.
- Any marketing approval Class IIb applications for surgical meshes in progress on the date the regulations come into effect may continue, and will be included as Class IIb if approved. The Class IIb entry will then need to seek up-classification as part of the transition arrangements for existing surgical meshes.
- Any TGA conformity assessment applications for Class IIb surgical mesh, in progress at the time of the change to the classification rules, will be amended to cover Class III requirements. This means the applications will be expanded to also undertake a design examination for each surgical mesh product. Normal fees will apply for the additional assessments, and will be invoiced once the scope of additional work is determined by the TGA.

Fees and charges

Normal application, assessment and audit fees will apply for applications. Normal annual charges will also apply for Class III surgical mesh ARTG entries following up-classification.

Questions

- Are there any unintended consequences that may arise out of this change?
- If there are issues, provide suggestions for mitigating them?

Patient implant cards

What are patient implant cards?

The Therapeutic Goods (Medical Devices) Essential Principles (EPs) currently require certain information be provided by manufacturers with medical devices including information:

- identifying the device
- identifying the manufacturer of the device
- explaining how to use the device safely, having regard to the training and knowledge of potential users of the device
- detailing any warnings, restrictions, precautions, side effects or residual risks in relation to the use of the device
- detailing risks arising, because of other equipment, for example magnetic field interference from magnetic resonance imaging devices

However, the Essential Principles do not make explicit the requirement for provision of the device information or any cautionary information to the patient.

The new European regulations (Article 18) require:

1. The manufacturers of implantable devices shall provide together with the device the following:

(a) information allowing the identification of the device, including the device name, serial number, lot number, the Unique Device Identifier (UDI), the device model, as well as the name, address and the website of the manufacturer

(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions

(c) any information about the expected lifetime of the device and any necessary follow-up

(d) any other information to ensure safe use of the device by the patient including (the overall qualitative and quantitative information on the materials and substances to which patients can be exposed).

The information referred to in subparagraph (a) shall be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by any means that allow rapid access to that information and shall be stated in the language(s) determined by the concerned Member State. The information is to be written in a way that is readily understood by a lay person and updated where appropriate. Updates of the information shall be made available to the patient via the website mentioned in point (a) of the first subparagraph.

In addition, the manufacturer shall provide the information referred to in point (a) of the first subparagraph on an implant card delivered with the device.

The proposed change to the Therapeutic Goods Regulations would parallel the new European requirements, making the requirement for patient cards and information explicit in the regulations, to improve information flow to patients and doctors, and to assist in improving patient-doctor discussions.

Patient implant cards and information are already being provided by some medical device manufacturers, and are required in other jurisdictions including the USA. These cards are

provided to recipients of certain implantable devices such as orthopaedics devices, and active implantable devices.

This proposal also complements work being progressed by the Australian Commission on Safety and Quality in Health Care to strengthen the informed consent process around procedures that may involve certain mesh products.

How will this be implemented?

The proposed medical devices patient implant card and patient information leaflet would not just apply to mesh devices. It is proposed to apply to all implantable medical devices and long term surgically invasive implants (i.e. all Class IIb, Class III and active implantable medical device (AIMD)), except certain articles such as sutures, staples, dental fillings etc. This is in alignment with the EU regulations.

This would be achieved by amendment to the Therapeutic Goods (Medical Devices) Regulations 2002. It is anticipated that patient implant cards and information be compulsory for all implantable medical devices in Australia by amending Essential Principle 13.

It is anticipated that information on implantable medical devices would increasingly be entered into a patient's Myhealth record in coming years. Mandating this is out of scope of the currently proposed regulatory change.

Transition

The European transition period for this change is also three years, and by early-mid 2020 the manufacturers of all relevant medical devices will have been re-certified under the new regulatory arrangements, including this requirement. At that stage, it is proposed that Australian sponsors relying on European certification for their relevant ARTG entries will be required to submit a manufacturers' evidence update to demonstrate compliance with this change.

From the time the regulatory amendments come into force, all relevant conformity assessment applications will be explicitly required to comply with this requirement.

Publication

Current TGA regulations require consumer medicines information to be made available to consumers either in the pack or in another manner that will enable the information to be given to the person to whom the medicines are administered or otherwise dispensed.

In line with this, for devices, the patient information will be published on TGA's website and function in a similar manner to the consumer medicines information, which is provided by sponsors to patients prior to their use of the therapeutic good. Patients and medical practitioners would be able to access up to date information about the implant, improving transparency and enabling informed decisions.

As in Europe, manufacturers would also be required to maintain this patient information on their website, as indicated on the patient implant card supplied with the device.

Education

In addition to making patient card and consumer-targeted information mandatory (as part of the conformity assessment process for potential inclusion of the medical device in the ARTG), this proposal will also be supported by:

- an education and awareness program to be conducted through liaison with respective clinical colleges and patient associations, industry peak bodies and by the TGA and device manufacturers.
- updated industry guidance on the TGA websites and in documents
- communications on the TGA website.

Typically, implantable devices are not un-packaged by the patient receiving the devices, but rather the surgeon or theatre staff implanting the device. These activities will seek to encourage and support the provision of the patient implant cards to patients.

Questions

- Do you have any suggestions about effective ways to ensure that the patient ID card reaches the patient?
- Do you have any comments or suggestions on alternative or additional strategies to promote the provision of the implant card to the patient?
- Are there any issues or unintended consequences that may arise out of this change?
- If there are issues, provide suggestions for mitigating them?

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #