Safer Care Victoria

18 August 2017

Therapeutic Goods and Administration
136 Narrabundah Lane
Symonston ACT 2609

To whom it may concern,

## Re: TGA Submission. Up classification of surgical mesh and patient implant cards

Safer Care Victoria (SCV) is pleased to respond to the invitation to comment on the proposed up-classification of surgical mesh and patient implant cards. SCV agrees with the alignment of Australian and European regulatory requirements to;

a) Reclassify all implantable surgical mesh medical devices from Class IIb (medium to high risk) to Class III (high risk)
b) The introduction of formal requirements for medical device manufacturers to provide patient implant cards and product information for consumers for all implantable medical devices.

## Surgical Mesh

We endorse the need for the TGA to clearly define what constitutes a mesh product for the benefit of the public, clinical care providers, product manufacturers and regulatory authorities.

### Approval of surgical mesh by the TGA

Surgical mesh, for the purpose of this response, includes synthetic or biological mesh used for incontinence and pelvic organ prolapse procedures, implanted by the vaginal or abdominal route. Prior to TGA approval for surgical mesh to be used for non-trial clinical practice, the product should go through formal clinical trial evaluation and independent peer review, requiring level 1 and 2 evidence of both efficacy and safety. All mesh products should include a product identifier sufficient for tracking that can also be appended to clinical notes. Patient information leaflets should list possible complications and include national contact information of the company and details of the TGA's adverse events reporting service to be contacted in the event of post-implant complications.

### Registry of surgical mesh

It is the view of SCV that there needs to be greater accountability of mesh products in relation to post-operative tracking. This would include;

- a compulsory clinical quality registry of patients implanted with mesh that comprises a minimum of;
  - the manufacturer, product name and serial number of the mesh
  - when it was inserted
  - who inserted the mesh
  - hospital where the procedure took place
  - indication for mesh insertion
- such a registry should be developed in accordance with the Australian Commission on Safety and Quality in Health Care Framework for Australian clinical quality registries
- the responsibility for submitting data to such a registry would lie with the clinician implanting the mesh

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- defined adverse events involving surgical mesh should be reported through the TGA's adverse events reporting system.

**Restriction of surgical mesh**
Until more is known about the surgical mesh products available, SCV recommends that the use to registered mesh products is restricted to those indications for which there is proven effectiveness and safety, supported by level 1 and 2 evidence. Any surgical mesh product without such evidence should only be used within an Australian Clinical Trials Registry-registered and HREC approved clinical trial.

**Impact of the re-classification on the availability of proven mesh products**
Re-classification of mesh products may have an impact on the continued availability of mesh medical products with proven benefit. As such, the TGA should discuss the implications of the re-classification with product manufacturers, local distributors and professional bodies to ensure the public have access to surgical mesh products with a favourable efficacy and safety profile.

## Patient information

SCV agrees with providing patients with a card detailing product information, national contact details and for this to be available in multiple languages to meet the needs of the local population. In addition, patients should be provided with contact details for reporting adverse events to the TGA.

Yours faithfully

**Professor Euan Wallace AM**
Chief Executive Officer
Safer Care Victoria

VICTORIA State Government