Regulatory action on surgical mesh implants

31 January 2018

Medsafe has today announced the outcomes of recent regulatory action on surgical mesh products in New Zealand.

In December 2017, Medsafe used the provisions in the Medicines Act 1981 to request safety information from four suppliers of surgical mesh products in New Zealand.

Section 38 of the Medicines Act 1981 permits the Director-General of Health to request safety information from a supplier should there be reason to believe a medical device is unsafe.

This action followed the Australian TGA (Therapeutic Goods Administration) review of surgical mesh for urogynaecological use, and subsequent regulatory action.

"All four companies contacted have responded and have confirmed that all products removed from the Australian register are no longer supplied in New Zealand," says Chris James, Group Manager, Medsafe.

This means:

- All surgical mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation will no longer be supplied
- One product, a single incision mini-sling for the treatment of stress urinary incontinence, is also now no longer supplied in New Zealand.

This action only relates to use of surgical mesh in pelvic organ prolapse via transvaginal implantation and one single type of mesh for stress urinary incontinence. This action does not affect the ongoing supply of surgical mesh products for other uses such as hernia repair or stress urinary incontinence.

For those products where changes to warnings in the Instructions for Use were required to be made by the TGA, companies have advised Medsafe these changes have either been implemented or will be implemented once the wording has been agreed.

Medsafe will be continuing to work with these companies to ensure changes are implemented in New Zealand as soon as possible.

"The section 38 review and restrictions are the strongest action possible under current legislation," says Mr James.

"As with all medical devices, Medsafe continues to monitor the use of surgical mesh products. Information for surgeons and patients is published on the Medsafe website.

Patients who are considered for surgery, where there is potential for the implantation of surgical mesh products, should be fully informed about the benefits and risks of treatment and informed consent obtained."

FURTHER INFORMATION:

Medsafe has been informed that the following products are no longer supplied in New Zealand:

Boston Scientific NZ Ltd
Solyx
Uphold Life

(The other products are available with amended Instructions for Use)

Culpan Medical
Restorelle DirectFix Anterior mesh
Restorelle DirectFix Posterior mesh
ALTIS single incision sling

(The other products are available with amended Instructions for Use)

Endotherapeutics NZ Ltd
TOA Sling
TVA Sling
Multi Purpose Sling
BSC Mesh
EndoGYNious
Ophira Minisling