MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

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Dear Managing Director

Regulatory action in New Zealand regarding surgical mesh following the recent Australian decision

You will be aware that, on 28 November 2017, the TGA (Therapeutic Goods Administration) in Australia announced regulatory action in relation to certain surgical mesh products following a review of published international studies and the clinical evidence supplied for surgical mesh devices used in urogynaecological surgery. This review concluded that there is a lack of available evidence to establish that the benefits of using the affected products outweigh the risks.

The TGA has decided to remove transvaginal surgical mesh products whose sole use is in the treatment of pelvic organ prolapse (POP) via transvaginal implantation from general approval. The TGA has also required that, for certain other products, their scope of approval be reduced to exclude use in POP. The action also affects some products used for stress urinary incontinence (SUI). Medsafe is not aware of any similar action having been taken by other trusted regulators, to date. The TGA decision is available at: http://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants.

Medsafe has taken the view that the Australian outcome has given sufficient reason to consider that the products involved in the Australian action may not be safe. As a consequence, continued use of these products is considered inadvisable.

I have, under delegation from the Director-General, issued a notice under section 38 of the Medicines Act, to the relevant companies in New Zealand requesting evidence to demonstrate the safety of the devices involved. These notices were issued today.

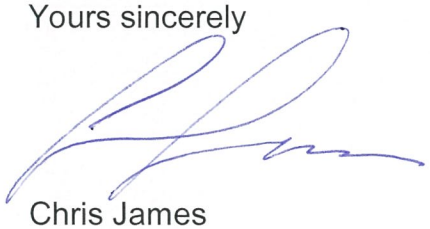
The text of section 38 is provided as Appendix 1, for your information. The Medicines Act 1981 can be accessed at: http://legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html?src=qs. The names of the companies involved and products are presented as Appendix 2.

Through discussions with the companies involved, Medsafe understands that most intend complying with the Australian requirements in the New Zealand market and will be either ceasing supply of their devices or altering the indications for which they are recommended, by 4 January 2018.

Assuming no evidence is provided by the companies, or should evidence be provided for assessment that is subsequently not acceptable, the effect of section 38 will be to prohibit a company from selling its device in New Zealand. This will not necessarily prohibit the use of those products by medical practitioners who have a particular need, however, Medsafe signals that the justification for that use should be robust and professionally defensible. While the company in New Zealand would not be able to supply an affected device, it could be obtained from overseas and used for individual cases.

I will keep you updated on progress with this action. Medsafe requests that you inform your members of this update.

Yours sincerely



Chris James
Group Manager
Medsafe

Appendix 1

Copy of section 38 of the Medicines Act 1981

38 Restrictions on sale of medical devices

(1)

For the purposes of this section,—

(a)

the term **medical device** includes an irradiating apparatus within the meaning of section 5(1) of the Radiation Safety Act 2016:

(b)

a medical device is unsafe if the use of that device may be injurious to the health of the person using it or the person in respect of whom it is used:

(c)

2 or more medical devices shall be deemed to be of the same kind, notwithstanding any minor differences or any difference in any name, if they are—

(i)

substantially similar to one another; and

(ii)

designed to be used in the same way; and

(iii)

sold for the same therapeutic purpose.

(2)

If the Director-General has reason to believe that any medical device may be unsafe, he may, by notice in writing to the importer or manufacturer in New Zealand, state the reasons for his belief, and require the importer or manufacturer to satisfy him of the safety of that medical device.

(3)

The importer or manufacturer shall supply to the Director-General, within 45 days after receiving the notice under subsection (2), or such further time as the Director-General may allow, evidence of the safety of the medical device.

(4)

If the Director-General is not satisfied, by evidence supplied to him pursuant to a notice under subsection (3) or otherwise of the safety of the medical device, he may at any time, within the period of 45 days following the receipt of that evidence, by a further notice under subsection (2) require the manufacturer or importer to supply him with further evidence of the safety of the medical device.

(5)

The fact that the Director-General does not exercise the powers conferred on him by this section in respect of a medical device shall not be deemed to warrant the safety of the medical device.

(6)

The Director-General may exercise the powers conferred on him by this section from time to time with respect to different importers or manufacturers of the same kind of medical devices, and the fact that he has not exercised any of those powers in respect of a particular kind of medical device, or that he has informed any person that he is satisfied of the safety of a particular kind of medical device, shall not prevent him from exercising any such power in respect of that kind of medical device where new information comes to his attention.

(7)

In any proceedings for an offence against this section in which it is alleged that 2 or more medical devices are of the same kind, it shall be presumed that those medical devices are of the same kind until the contrary is proved.

(8)

Every person commits an offence and is liable on conviction to imprisonment for a term not exceeding 6 months or a fine not exceeding $5,000 who,—

(a)

having received a notice under subsection (2) and failed to comply with subsection (3), sells the medical device; or

(b)

having received a notice under subsection (4), sells the medical device before he has been notified by the Director-General that he is satisfied of the safety of the medical device.

Section 38(1)(a): amended, on 7 March 2017, by section 99 of the Radiation Safety Act 2016 (2016 No 6).

Section 38(8): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).