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working to prevent and manage pain

25 August 2017

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Email: info@tga.gov.au

Re: Alignment with European medical device regulatory framework

I am writing to you on behalf of Painaustralia – Australia's leading pain advocacy body – in relation to the consultation regarding the up-classification of surgical mesh and patient implant cards.

The fact that extensive use of transvaginal mesh implants has created a significant number of new cases of chronic pain is of great concern to Painaustralia.

One in five Australians and as many as one in three older Australians live with chronic pain.[1,2] People with chronic pain have the greatest levels of disability in our community.[3] It is the leading cause of early retirement from the workforce[4] and the level of workforce participation in people with chronic pain could be as low as 19%.[5]

At a total cost to Australia of more than $34.3 billion, chronic pain places a major burden on our economy, third only to cardiovascular disease and musculoskeletal conditions among the National Health Priority Areas.[6] The economic burden of chronic pain increases with the level of pain disability, which suggests the need for, and potential benefits of, prevention of chronic pain and improving management through treatment plans targetting the impact of pain on daily functioning.[7]

Following are some key issues that we have identified in relation to the Therapeutic Goods Administration's (TGA) proposed changes to:

- up-classify surgical mesh from Class IIb to Class III; and
- require provision of patient medical device ID cards (patient implant cards) to patients.

Key Issues

1. Chronic pain a significant problem with transvaginal mesh implants

Painaustralia supports the TGA's intention to reclassify all implantable surgical mesh medical devices from Class IIb (medium to high risk) to Class III (high risk). This would bring Australian regulations into line with European regulations and require manufacturers of synthetic meshes to seek additional conformity assessment certification. It will also give greater protection to women in relation to the use of transvaginal mesh.

The more than 700 women who joined the class action against manufacturers of pelvic mesh implants Johnson & Johnson Medical Australia and subsidiary companies Ethicon Inc and Ethicon Sarl allege the implants have left them with catastrophic injuries as well as chronic pain.

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The alleged aggressive marketing of pelvic mesh implants to surgeons combined with an inadequate classification rating could have made transvaginal mesh an option of choice for the treatment of urogynaecological issues typically caused by childbirth.

Around 100,000 women have received the implant and as many as 30% of them are now suffering complications.[8] In a recent 2017 survey conducted by the Health Issues Centre, 65% of respondents indicated that they now live with severe, debilitating or unendurable chronic pain.[9]

While there is sound reasoning to allow more than three years for transitional arrangements (by 30 November 2020), Painaustralia asks the TGA to consider whether there is scope to fast-track up-classification of transvaginal mesh, given the high risk of ongoing damage to the health of Australian women and related impacts on families, the community and our economy.

Recommendations:

1. All surgical mesh should be up-classified from Class IIb to Class III.

2. The TGA should consider fast-tracking up-classification of transvaginal mesh.

2. Accessibility, quality and timeliness of consumer information

In order to empower consumers to make sound decisions about their health and welfare and deliver on a patient-centred model of care, there should be a requirement for full consumer disclosure about potential risks and benefits for all medical devices.

In the TGA's proposal, although it was not made absolutely clear, it appears that there will be two sources of information for consumers: consumer information provided pre-procedure and patient implant cards post-procedure. However, there is little detail about what should be included in each. This would be the most effective way to provide consumers with targetted information and help create an environment of full disclosure.

Painaustralia believes that, in line with the requirement for all medications, there should be a comprehensive list of potential side-effects including ongoing health problems (such as chronic pain) provided to consumers. Warnings should be specific to each surgical mesh device and where possible include statistics about numbers of people adversely affected.

The TGA states that the patient information will be published on TGA's website, however, this relies on patients making an effort to visit the site. Painaustralia believes it would be more effective to require the information be provided direct to consumers, for example, by requiring doctors to print the information for consumers to take home with them. It should also be provided to key groups who can disseminate the information and provide a central source of consumer contact, such as Painaustralia as the peak body for the pain sector.

Information about the potential risks and benefits should be provided to consumers during consultations with doctors or other health professionals, to ensure they are fully informed prior to agreeing to procedures being scheduled.

In relation to the transition period of three years (by early-mid 2020), Painaustralia also asks the TGA to consider whether there is scope to fast-track the requirement to provide patient information and patient implant cards in cases of transvaginal mesh, given the high risk of ongoing damage to the health of Australian women and related impacts on families, the community and our economy.

Recommendations:

3. There should be a requirement for the provision of patient information on two occasions: pre-procedure information sheets and post-procedure patient implant cards.

4. Information should be provided to consumers in a direct manner (in addition to the TGA website).

5. Information should be provided to key bodies that can act as a dissemination point including peak bodies such as Painaustralia.

6. There should be full disclosure about potential risks and benefits and this should be specific to each mesh device.

7. The TGA should consider fast-tracking requirements for provision of patient information in relation to transvaginal mesh.

2b. Chronic pain in relation to transvaginal mesh

Patient implant cards should also provide information about where to go for help should long-term complications arise in relation to their specific implant, in particular chronic pain. Given the high incidence of chronic pain in people with pelvic mesh implants, patient implant cards should include information about where to go for help should post-surgical pain persist.

Unfortunately there is still very limited understanding within the community and the medical profession about best-practice treatment and management of chronic pain and it is common for people who live with pain to take years to find the right help and support to learn to manage it effectively. The right information would avoid this problem.

While chronic pain and in particular post-surgical pain is unlikely to be cured, it can be effectively managed to reduce pain-related disability, improve function and quality of life, within ongoing access to multidisciplinary pain management.[10] Since chronic pain is not just a physical condition but rather an experience that affects people psychologically, emotionally and socially as well, management must be holistic in order to be effective.

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Multidisciplinary pain management involves a team of health professionals managing the one patient with a person-specific plan. It will involve ongoing and regular consultations with a range of health professionals in addition to the coordinating doctor, usually a psychologist and physiotherapist and possibly also a pharmacist and social worker or vocational counsellor trained in multidisciplinary pain management.[11] There are often group pain education sessions that teach people to understand pain and how they can self-manage their pain (self-management is an important part of pain management). Support groups are also encouraged. (For more information about multidisciplinary pain management please visit our website www.painaustralia.org.au)

Recommendations:

8. Where chronic pain is a significant potential ongoing side-effect, patient implant cards should provide information about where to find help and support for multidisciplinary pain management.

Conclusion

Painaustralia supports the TGA's proposal to up-classify surgical mesh from Class IIb to Class III, and require provision of patient medical device ID cards (patient implant cards) to patients.

We would like the TGA to consider fast-tracking these change in relation to transvaginal mesh, given the significant risk to public health.

We would also like to see clarification on the content requirements of information provided to consumers, the occasions of information exchange (we believe there should be two, pre and post procedure), and the mode of information exchange (to ensure all information is provided direct to consumers, rather than only on the TGA website).

We would be interested in working with the TGA to provide further information, resources and support. Should you wish to discuss any of the matters arising from this submission, please contact Painaustralia Chief Executive Officer Carol Bennett.

Yours sincerely

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