Mon 4 December 2017

Joint Media Statement by Health Consumers Councils across Australia:

Health Issues Centre (Vic)
Health Consumers Queensland
Health Consumers' Council (WA)
Health Consumers Alliance of SA
Health Care Consumers Association (ACT)
Health Consumers New South Wales

TGA action on mesh welcomed but not enough:

Call for national TGA register and state/territory safety audit and services now

As the state/territory peak health consumer organisations we have added our voices to those of mesh-damaged women across Australia calling for the banning of mesh. We congratulate these women on the impact of their strong lobbying with the historic decision by the TGA to remove some mesh products (POP mesh and mini-slings) from their register of approved devices. This move has been celebrated by mesh-damaged women around the world.

Whilst we welcome this move by the TGA, we are disappointed doctors can still apply for these devices to be implanted in women under the Special Access Scheme. We hope surgeons are discouraged by the ban and are reticent to apply for special access to these devices, given the lack of evidence for use and the devastating impact of these devices on so many injured women. In the absence of a full ban, the TGA must commit to a strong regulatory framework and transparent public reporting on special access applications when the changes to register come into effect. Information must be made available to the community in a timely manner on who applies for these devices (e.g. which kinds of specialists, public/private), for what indications and how many women are still receiving them.

We also ask what the TGA's decision means for women for whom approved mesh products still on the register and designed to treat stress urinary incontinence are recommended in the future as a safe treatment. Given the complications experienced and legal action being taken by women affected by these mesh devices which remain on the register, and a dearth of accurate retrospective data of women-reported complications that would give us accurate data on the safety of these devices, how will women be able to make an informed decision?

We call on the TGA to immediately establish a Mesh User Registry along the lines of the Australian Orthopedic Association National Joint Replacement Registry (AONJRR), which would ensure there is a central database of device types implanted by women and a way to track complications.

We call the state and territory health departments to ensure national consistency of a range of responses, and expect that women and consumer groups are and will be deeply involved in their development:

- Develop informed decision making processes for women being recommended the SUI devices
- Commence a retrospective survey of women who have received all pelvic mesh devices. Health departments must sensitively and transparently advise women of potential complications, ascertain if women are currently experiencing complications and ensure these are lodged with the TGA.

- A specialised multidisciplinary service must be offered to these women including specialists, pain management, psychological support, physiotherapy and peer support.

We look to the recommendations from the Senate Inquiry due to be released in February next year to further strengthen safe provisions around mesh (see below for recommendations from our joint submission).

For media comment contact Danny Vadasz, Health Issues Centre Victoria (0419 531 468) and Melissa Fox, Health Consumers Queensland (0404 88 2716).

Recommendations

For the reasons outlined above we support the call to action by the APMSG and recommend:

1. The suspension of the use of mesh for prolapse and stress urinary incontinence, due to the severity of complications, with the suspension not to be lifted unless and until their safety and efficacy is established.
2. Free medical expertise and help being made to women already injured including access to experienced mesh removal surgeons sourced internationally if necessary.
3. Acknowledgement and ongoing support for adversely affected women. The host organization, format and language of information and promotional materials should be co-designed with affected women and consumer organisations. The support provided should include:
    i. A consumer help line.
    ii. Website for women with evidence based information around risks and benefits of treatment options.
    iii. Recognition and support for women with ongoing incontinence issues.
    iv. Recognition and support for women with ongoing disability issues and facilitate access to NDIS funding.
    v. Referral to specialist surgeon who can advise and treat the complications.
4. Explicit and clear warnings to clinicians, patients and families of potential adverse effects of mesh (Including appropriate information for women with hearing or sight impairment or from CALD backgrounds).
5. Full public disclosure of the clinical trials and other evidence used by the TGA in determining that the products were fit for market.
6. Full public disclosure of how the TGA has responded to adverse events reported by women injured through pelvic mesh devices.
7. A broader Senate inquiry into the operations of Therapeutic Goods Administration TGA in relation to its failure to ensure the safety and efficacy of pharmaceuticals and medical devices in Australia.

We call on the Commonwealth Government to:

8. Establish a Gynecological Mesh User Registry along the lines of the Australian Orthopedic Association National Joint Replacement Registry (AONJRR). The purpose of the AONJRR is to 'benefit patients by enhancing the outcome of joint replacement surgery through the provision of comprehensive, quality, validated information'.[1] A Gynecological Mesh User Registry would fulfill a similar purpose for women suffering from, or concerned about, potential adverse effects. The database should also have a consumer-friendly interface which facilitates women logging in and self-reporting their complications.
9. Consider having a Register for all mesh devices implanted in patients.

In line with previous Senate inquiry recommendations we also call on the Commonwealth Government to direct:

10. Commonwealth Government to legislate to introduce mandatory reporting for health practitioners

and pharmacists to the Therapeutic Goods Administration for a range of (yet to be specified) severe adverse events for medications and medical devices.[2]

11. Furthermore, we recommend that the TGA regularly publish full de-identified details (not just summaries) of adverse events associated with the use of medications and medical devices on a publicly accessible website.

12. The Department of Health to undertake further work to address the issue of inducements paid by pharmaceutical companies and medical device manufacturers to doctors and teaching hospitals, in line with the Physician Payment Sunshine provisions of the Patient Protection and Affordable Care Act of 2009 in the United States. The definition of inducements should include a commercial interest in a company or device; any cash payments or discounts offered to medical practitioners; and any other gifts provided to medical practitioners.[3]

We also recommend that:

13. There needs to be enhanced participation of consumers in all the TGA processes with a formal place in the assessment for input from consumers and consumer organisations which would form part of the data package used for that assessment in line with international best practice on consumer involvement in health technology assessment. There should be robust consumer participation on all TGA committees with a transparent process for nominating and publication of the results of any such process.

14. In our efforts to gather women's experiences of transvaginal mesh, we have heard of concerning complications experienced by men and women who have had mesh inserted for other conditions. We think this warrants the further investigation of use of all mesh devices.

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1 Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. Adelaide: AOA; 2016 https://aoanjrr.sahmri.com/documents/10180/275066/Hip%2C%20Knee%20%26%20Shoulder%20Arthroplasty

2 Australian Government Response to Senate Community Affairs References Committee Report on The Regulatory Standards for the Approval of Medical Devices in Australia August 2012 (recommendation 8) http://www.health.gov.au/internet/main/publishing.nsf/Content/3141B94933949C69CA257BF0001B750C/$File/Final%20Govt%20Response_approved%20310812.pdf

3 Australian Government Response to Senate Community Affairs References Committee Report on The Regulatory Standards for the Approval of Medical Devices in Australia August 2012 (see recomendation18) http://www.health.gov.au/internet/main/publishing.nsf/Content/3141B94933949C69CA257BF0001B750C/$File/Final%20Govt%20Response_approved%20310812.pdf