MTAA Position Paper to the Senate Report: Number of women in Australia who have had transvaginal mesh implants and related matters (March 2018)

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1. Executive Summary

On 15 February 2017, the Senate referred the following matter to the Senate Community Affairs References Committee for inquiry and report:

The number of women in Australia who have had transvaginal mesh implants and related matters.

The inquiry terms of reference covered:

1. *The number of women in Australia:*
   a) *who have had transvaginal mesh implants;*
   b) *who have had transvaginal mesh implants who have experienced adverse side effects; and*
   c) *who have made attempts to have the mesh removed in Australia or elsewhere.*
2. *Information provided to women prior to surgery about possible complications and side effects.*
3. *Information provided to doctors regarding transvaginal mesh implants and possible complications and side effects.*
4. *Any financial or other incentives provided to medical practitioners to use or promote transvaginal mesh implants.*
5. *The types and incidence of health problems experienced by women with transvaginal mesh implants and the impact these health problems have had on women's lives.*
6. *The Therapeutic Goods Administration's:*
   a) *role in investigating the suitability of the implants for use in Australia;*
   b) *role in ongoing monitoring of the suitability of the implants; and*
   c) *knowledge of women suffering with health problems after having transvaginal mesh implants.*
7. *Options available to women to have transvaginal mesh removed.*

On 28 March 2018, the Senate Committee released its report *Number of women in Australia who have had transvaginal mesh implants and related matters*[1]. The report made 13 recommendations[2].

In a March 29th, 2018, media release MTAA broadly welcomed the report recommendations. CEO Ian Burgess said that "MTAA is committed to working with the Government to progress relevant recommendations as determined by the Government"[3].

In the next sections we provide specific feedback to the Senate Committee report recommendations.

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[1] Parliament of Australia – Report: Number of women in Australia who have had transvaginal mesh implants and related matters, 28 March 2018: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Report

[2] Parliament of Australia – Report: Number of women in Australia who have had transvaginal mesh implants and related matters, 28 March 2018 - List of recommendations: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Report/b01

[3] MTAA Media Release: Medical device industry call for My Health Record to include medical device data, 29 March 2018 - https://www.mtaa.org.au/news/medical-device-industry-calls-my-health-record-include-medical-device-data

2. MTAA position on the Senate Committee report recommendations

Recommendation 1

> *Noting the vital role of adverse reporting in post-market surveillance, the committee recommends that the Australian Government, in consultation with the states and territories and the Medical Board of Australia, review the current system of reporting adverse events to the Therapeutic Goods Administration to:*
>
> - *implement mandatory reporting of adverse events by medical practitioners;*
> - *provide guidance on what constitutes an adverse event for use by consumers, medical practitioners and device sponsors;*
> - *improve awareness of the reporting system; and*
> - *examine options to simplify the reporting process;*

Adverse event reporting is an essential part of post-market safety monitoring of therapeutic goods, because it provides important information on the nature and magnitude of the problem, and reassess, if necessary, the risk profile of the therapeutic good. Early signal detection enables minimising harm to patients.

While mandatory for sponsors of medical devices[4], adverse event reporting is optional for medical practitioners. Unless the obligation to report is extended to medical practitioners, some adverse events will always go unreported.

TGA noted: "Importantly, an adverse event is not always caused by the therapeutic good itself. An adverse event could be a result of incorrect user interaction or other circumstances such as two properly functioning devices that do not operate as intended when used in combination. The occurrence of an adverse event does not necessarily mean that there is something wrong with the therapeutic good."[5]

MTAA supports making adverse event reporting mandatory for medical practitioners. The definitions and guidelines for what constitutes an adverse event and the statutory timelines should be aligned with requirements applicable to industry.

[4] Therapeutic Goods (Medical Devices) Regulations 2002, Regulation 5.7 Conditions applying automatically—period for giving information about adverse events etc. (Act s 41FN): https://www.legislation.gov.au/Details/F2018C00292
[5] TGA website: Reporting adverse events, accessed on 22 June 2018 - https://www.tga.gov.au/reporting-adverse-events

Recommendation 2

> *The committee recommends that the Therapeutic Goods Administration and the Australian Commission on Safety and Quality in Health Care develop an information sheet to be provided to recipients of patient cards for implantable devices providing guidance on appropriate action to take in the event of an adverse event, including guidance on seeking appropriate treatment and support and on reporting the event.*

MTAA agrees with the recommendation, which is expected to be implemented in the context of and in alignment with recent measures to strengthen the assessment of medical devices and information for consumers.[6]

Consumers and patients should be encouraged to report adverse events, and appropriate educational programs should be put in place to assist them with understanding the reporting framework.

Recommendation 3

> *The committee recommends that the Australian Government prioritise consideration of the implementation of Recommendation 22 of the report of the Review of Medicines and Medical Devices Regulation recommending the establishment of a registry for all high-risk implantable devices, together with consideration of the feasibility of establishing such a registry on a cost recovery basis, and provide to the Senate by 29 November 2018 a progress report on work to date.*

MTAA believes that any registry for high-risk implantable devices needs to be set up and operated in accordance with the principles for Australian Clinical Quality Registries[7]. Appropriate and fair access to data and transparency on both devices and surgeons is essential to ensure accurate assessment of safety outcomes.

[6] TGA website, accessed on 22 June 2018: https://www.tga.gov.au/media-release/strengthening-assessment-medical-devices-and-information-consumers

[7] Australian Commission on Safety and Quality in Health Care website, accessed on 22 June 2018: https://www.safetyandquality.gov.au/publications/framework-for-australian-clinical-quality-registries/

It is well known that clinical quality registries are extremely costly to set up and manage. Careful consideration needs to be given to prioritise areas of high risk for selection and implementation of a registry[8].

Funding of registries should recognise they provide benefits to a range of stakeholders, including hospitals and patients. All those that benefit should pay for it – including regulators, healthcare professionals, insurers, hospitals and policy makers.

Recommendation 4

> *The committee recommends that the Medicare Benefits Schedule Taskforce prioritise release of the report of the Gynaecology Clinical Committee for consultation*

MTAA supports this recommendation aimed at improving the accuracy of other data sources – Medicare Benefits Schedule (MBS), private health insurance companies, Prostheses List (PL) data, hospital records and databases maintained by medical professional colleges. Digitisation of healthcare represents an opportunity for improving data collection across the whole healthcare system, and throughout the patient journey.

Recommendation 5

> *The committee recommends that the Australian Government prioritise the establishment of a more comprehensive post-market monitoring scheme and provide to the Senate by 29 November 2018 a progress report on work undertaken to date.*

MTAA supports this recommendation, which echoes Recommendation 27 of the March 2015 Medicines and Medical Devices Review[9]. Digitisation and better integration of health data from PBS, MBS, eHealth records, hospital records and device and other relevant registries and datasets will

[8] Recommendations for a National Medical Device Evaluation System, A Report from the Medical Device Registry Task Force & the Medical Devices Epidemiology Network, August 20, 2015, p.81: https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM459368.pdf

[9] Review of Medicines and Medical Devices Regulation, March 2015, p.160: http://www.health.gov.au/internet/main/publishing.nsf/Content/8ADFA9CC3204463DCA257D74000EF5A0/$File/Review%20of%20Medicines%20and%20Medical%20Devices%20Stage%20One%20Report.pdf

increase the effectiveness and efficiency of post-market safety monitoring. MTAA believes that the Government should prioritise inclusion of medical device information in the My Health Record.

Recommendation 6

> *The committee recommends that the Australian Commission on Safety and Quality in Health Care prepare guidance material on effective informed consent processes, with a view to ensuring that a dialogue between a medical practitioner and patient should:*
>
> - *clarify the rationale for the proposed treatment;*
> - *discuss the range of alternate treatment options available and their attendant risks and benefits;*
> - *discuss the likely success and potential complications of the recommended treatment as they relate to the individual patient;*
> - *provide an opportunity for the patient to ask questions; and*
> - *confirm that the individual patient has understood the information discussed.*

This recommendation is aimed at improving the informed consent process, and it is expected to be implemented in the context of and in alignment with recent measures to strengthen the assessment of medical devices and information for consumers[6].

MTAA supports this recommendation and reiterates its members' commitment to working with the Department of Health to progress recommendations related to informed consent and information provided to patients about medical devices.

Recommendation 7

> *The committee recommends that treatment guidelines developed by the Australian Commission on Safety and Quality in Health Care should clearly indicate that transvaginal mesh implantation should only be undertaken with fully informed consent and as a last resort when other treatment options have been properly considered and determined unsuitable.*

This recommendation is aimed at improving the ACSQHC treatment guidelines. MTAA supports this recommendation and reiterates its members' commitment to working with the Department of Health to progress recommendations related to informed consent and information provided to patients about medical devices.

Recommendation 8

> *The committee recommends that the medical professional specialist colleges and societies ensure that processes are in place to draw their members' attention to the resources released by the Australian Commission on Safety and Quality in Health Care and implement arrangements which require members to consider the resources in their practice.*

This recommendation is aimed at strengthening professional development of specialist doctors. MTAA supports this recommendation and reiterates its members' commitment to working with the Department of Health to progress recommendations related to training and information provided to medical practitioners about medical devices.

Recommendation 9

> *The committee recommends that the Commonwealth, state and territory health Ministers require that guidance developed by the Australian Commission on Safety and Quality in Health Care for the credentialing of medical practitioners who perform transvaginal mesh procedures should underpin credentialing processes in all public hospitals and work with private hospitals to encourage the adoption of a similar requirement.*

This recommendation is aimed at strengthening of training and credentialing procedures for senior medical practitioners by professional medical colleges and specialist societies. MTAA supports this recommendation and reiterates its members' commitment to working with the Department of Health to progress recommendations related to training and information provided to medical practitioners about medical devices.

Recommendation 10

> *The committee recommends that medical professional colleges and specialist societies implement governance arrangements for transvaginal mesh procedures which require that their members:*
>
> - *are trained in the use of the specific device;*
> - *are adequately skilled to perform the specific procedure, including procedures for partial or full removal of transvaginal mesh devices;*
> - *work within a multidisciplinary team;*
> - *monitor and report patient outcomes; and*

> - *maintain a record of the outcomes of such procedures, including any complications.*

MTAA agrees with this recommendation, however we consider that it is not applicable to our members. Implementation of appropriate governance arrangements for transvaginal mesh procedures is the responsibility of medical professional colleges and specialist societies.

Recommendation 11

> *The committee recommends that Commonwealth, states and territory governments commission the Australian Commission on Safety and Quality in Health Care to undertake an audit of transvaginal mesh procedures undertaken and their outcomes since the introduction of transvaginal mesh devices for use in the Australian market.*

MTAA agrees with this recommendation, however we consider that it is not applicable to our members. Auditing of transvaginal mesh procedures undertaken and their outcomes is the responsibility of the ACSQHC.

Recommendation 12

> *The committee recommends that the Department of Health work with the Medical Technology Association of Australia and the Medical Board of Australia to review the systems in place within the device manufacturing industry and the medical professions to support consistent, high ethical standards, with specific emphasis on systems in place to prevent the payment of inducements to medical professionals and teaching hospitals.*

MTAA members are bound by the Code of Practice that sets high standards for ethical interactions with healthcare practitioners[10]. The MTAA Code states: "*Medical Technologies occupy a special place in the healthcare system. They often require Companies to provide 'hands-on' education, supervision and technical support to Health Care Professionals. Company Representatives are very often present in theatre to train and advise physicians in the proper use of new tools, products and techniques.*"

[10] MTAA website, accessed on 22 June 2018: https://www.mtaa.org.au/about-the-code

MTAA is proposing implementation of a harmonised industry code of ethics, based on the existing MTAA Code, that is binding for all device manufacturers and suppliers/ distributors by law or regulation. MTAA is looking forward to working together with the Government and the Medical Board of Australia towards achieving this goal.

Recommendation 13

> *The committee recommends that State and Territory governments continue to work with the Australian Commission on Safety and Quality in Health Care to review the provision of services for the use and removal of transvaginal mesh devices. In particular, the committee recommends that consideration be given to the establishment of:*
>
> - *information and helplines that women who have received transvaginal mesh implants can contact for advice on the availability of treatment and support services, including financial support programs, in their state;*
> - *specialist counselling programs, to assist women who have sustained injuries following transvaginal mesh procedures;*
> - *specialist multidisciplinary units for the assessment and management of complications associated with transvaginal mesh procedures, comprising:*
> - *comprehensive diagnostic procedures, including relevant diagnostic imaging facilities and expertise;*
> - *specialist pain management expertise; and*
> - *high level expertise in the partial or full removal of transvaginal mesh;*
> - *advice and practical assistance for women who are seeking to access their medical records; and*
> - *the provision of further guidance for medical professionals on recording the use of implantable devices on medical records and reporting adverse events to the Therapeutic Goods Administration.*

MTAA agrees with this recommendation and reiterates its members' commitment to working with the Department of Health to assist with relevant information about medical devices as appropriate and applicable.