Australian Government

PROGRESS REPORT ON THE AUSTRALIAN GOVERNMENT RESPONSE TO THE RECOMMENDATIONS OF THE:

SENATE COMMUNITY AFFAIRS REFERENCES COMMITTEE REPORT:

THE NUMBER OF WOMEN IN AUSTRALIAN WHO HAVE HAD TRANSVAGINAL MESH IMPLANTS AND RELATED MATTERS

OCTOBER 2019

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Introduction:

The Senate Community Affairs References Committee report into the *'Number of women in Australia who have had transvaginal mesh implants and related matters'* was published on 28 March 2018. The 13 recommendations focussed on enhanced safety and increased information of the medical devices to patients, improved post market vigilance and adverse event reporting including mandatory reporting by doctors/surgeons, ensuring quality, training and appropriate accreditation of doctors. The Australian Government (the Government) tabled its response on 10 October 2018.

The Government supported or supported-in-principle, 12 of the 13 recommendations. Recognising the logistical complexities including the involvement of the states and territories' private and public health systems to progress recommendation 11, which referred to undertaking an audit of transvaginal mesh procedures and their outcomes since the introduction of the transvaginal mesh procedures in Australia, the Government noted this recommendation. The Australian Commission on Safety and Quality in Health Care (ACSQHC) established a jurisdictional group that discussed this matter at length, along with the other recommendations – the outcomes of those discussions directly informing the Australian Government response tabled.

The Minister for Health, the Hon Greg Hunt MP and the Chief Medical Officer wrote to a number of specialist colleges, the Medical Board of Australia, state and territory health ministers and the Australian Health Practitioner Regulation Agency (AHPRA) in relation to the recommendations, expressing support for and seeking cooperation to implement recommendations that extend beyond the responsibility of the Commonwealth.

The Minister for Health also wrote to the Senate Community Affairs References Committee providing an overview of progress in relation to Recommendations 3 and 5 in December 2018 in accordance with the Committee's request.

The Therapeutic Goods Administration (TGA) has imposed more stringent conditions of inclusion for urogynaecological mesh devices that remain in the Australian Register of Therapeutic Goods, including annual mandatory reporting of all device sales, adverse events and complaints for the next five years; mandatory reporting to the TGA of all Australian adverse events related to these devices; restricted supply of future devices without prior evidence review and approval by the TGA. Transitioning in from 1 December 2018, all surgical mesh (including urogynaecological mesh) were reclassified from medium risk (class IIb) to high risk (class III), increasing the rigour applied to these devices. Patient cards and patient information leaflets have also been made mandatory since 1 December 2018 for new surgical mesh devices, improving the availability of information to patients about these devices.

A number of resources have been developed by the ACSQHC, in partnership with jurisdictions and clinical groups to guide clinical practice and decision making including patient informed consent; hospital credentialing and health practitioners' accreditation for those involved in implanting mesh medical devices. The jurisdictions continue to be involved in an inter-jurisdictional committee established to assist development and ongoing monitoring of the implementation of hospital credentialing for hospitals. Service delivery models have been developed for the use, removal and management of mesh-related complications. A number of medical officers have travelled to the USA for further technique training to enhance their skills in mesh surgery, specifically removal. There are now 14 mesh specific units established in Australia by the jurisdictions, whilst mesh patient support services and information services are in place.

Working with healthcare professionals and consumers, the TGA has simplified its online adverse event reporting systems and processes to encourage higher rates of voluntary reporting. In addition, the Australian Health Ministers Advisory Council (AHMAC) has endorsed and funded a Clinical

Principle Committee project relating to medical devices inter-jurisdictional information sharing and adverse event reporting, signal detection and post market surveillance activities. This will support regulatory action and a more coordinated national action in response to medical device issues.

A transvaginal mesh hub has been established on the TGA website to be a central point to find information about resources and support services available around Australia for patients. The hub has information provided by a range of contributors including a number of Commonwealth Departments, state and territory governments and the ACSQHC.

There have been a number of other developments during 2019. On 5 April 2019 the Government announced funding for a three-year pilot trial of the Australian Pelvic Floor Procedures Registry (APFPR). This registry will consider prospective audits of pelvic floor procedures. The APFPR has flagged it may examine the feasibility of retrospective audits, but this will require extensive engagement with jurisdictions. The Health Council of COAG is scheduled in 2020, to consider the draft National Clinical Quality Registry Strategy. The Strategy maximises the potential of clinical quality registries such as the APFPR.

The TGA is facilitating the patient informed consent process by implementing the Government's changes to regulations to require supply of patient information materials (patient implant card and patient information leaflets) with medical devices. These materials provide patients with the name, make, model of the device and lists potential side effects, as well as information about where to report problems.

There continues to be interest amongst stakeholders and consumers on progress being made. A National Forum on Mesh *'Unfinished Business'* was held on 5 April 2019 and on 20 September 2019, another mesh related conference was held; *Hernia Repair in 2019: The Good, Bad and Ugly*.

To assist communicating progress being made to implement the recommendations, this progress report provides an update on actions taken to date.

This progress report has been structured so that an update on actions taken is provided after each of the Senate Committee's recommendations and the Government's response (as tabled in October 2018).

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;**

Government Response: *The Government supports in principle this recommendation but notes that it poses a number of policy and implementation issues that would need to be considered further.*

Progress Report: The Government supported this recommendation in principle as some policy and implementation issues require further consideration, noting the Commonwealth does not regulate the clinical practice of healthcare providers using or prescribing medical devices. There are 15 National Boards that are responsible for regulating the health professions. These National Boards are supported by the Australian Health Practitioner Regulation Agency (AHPRA).

In October 2018, the Chief Medical Officer (CMO) wrote to the Medical Board of Australia and the AHPRA, professional colleges and societies to encourage reporting of all adverse events associated with medical devices to the Therapeutic Goods Administration (TGA). The Australian Commission on Safety and Quality in Healthcare (ACSQHC) has also published resources to guide clinical practice on adverse event reporting.

The TGA commenced a program of improvements to adverse event reporting. Feedback from consumers, consumer advocacy groups and healthcare professionals has informed changes to online reporting forms to simplify and make them more user friendly. Further changes will occur during 2019-20, including the release of consultation papers on proposed enhanced reporting mechanisms, earlier identification of issues and greater information sharing between the TGA and healthcare facilities.

The Australian Consensus Framework for Ethical Collaboration (ACF) was developed by healthcare professional bodies in July 2018. The Framework is a sector-led, government-supported initiative developed collaboratively by professional bodies, industry organisations, hospital and health services associations, regulators, patient and advocacy groups and other health related organisations. The Australian Ethical Health Alliance which oversees the ACF comprises 71 signatories who aim to improve healthcare in Australia through articulation and affirmation of ethical principles that promote the interests of patients and consumers, enhance access to safe and effective healthcare, encourage ethical collaboration in the healthcare sector and build public trust.

On 4 April 2019, *An Action Plan for Medical Devices* was published on the TGA website. Strategy 2 in the Action Plan – strengthening the monitoring and follow up of devices already in use – includes undertaking further consultation by the TGA on a range of post market reforms, including

mandatory adverse event reporting by healthcare facilities. This consultation is planned to occur in late 2019.

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.

Government Response: *The Government supports this recommendation.*

Progress Report: From 1 December 2018, there is a new regulatory requirement for manufacturers of implantable medical devices to provide patient implant cards and information leaflets. Implementation is staged over three years until December 2021. Consultation and awareness raising with hospitals, consumer groups and healthcare professionals were completed prior to the commencement.

The leaflet encourages consumers to contact health professionals and where to report adverse events associated with the device, including to the manufacturer and the TGA.

Guidance was developed by ACSQHC and released in late 2018. www.safetyandquality.gov.au/our-work/health-conditions-and-treatments/transvaginal-mesh

Discussions about how to include device information in the MyHealth Record are continuing. A workshop between the TGA and the Australian Digital Health Agency was held in June 2019 to map a possible way forward.

The TGA continues awareness raising activities including through social media to increase patients, consumers and healthcare practitioners' awareness of the importance of reporting adverse events associated with implantable medical devices.

The TGA established a transvaginal mesh hub on its website to provide a central source for consumers and health practitioners to access information about resources, support services and other useful information: https://www.tga.gov.au/hubs/transvaginal-mesh.

Strategy 3 in *An Action Plan for Medical Devices* – providing more information to patients about the devices they use - includes working closely with consumers and partnering with consumer groups to co-design a range of improvements to enhance consumer awareness. A workshop with consumer groups was held in September 2019, with further work occurring during 2019-20.

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.

Government Response: *The Government supports considering the feasibility of establishing a clinical quality registry for urogynaecological procedures with relevant medical specialty colleges (craft groups). The Government recognises the benefits a registry may provide but notes that the practical elements and broader impact of Recommendation 22 must be comprehensively considered to ensure the best possible outcomes for consumers.*

Progress Report: In October 2018, Minister Hunt wrote to state and territory health ministers seeking cooperation to establish the urogynaecological procedures clinical quality register.

In December 2018, a progress report was provided to the Senate as requested.

Government funding of $2.3 million over a period of three years was announced by Minister Hunt on 5 April 2019, at the National Mesh Forum.

The first meeting of the Australian Pelvic Floor Procedure Registry's (APFPR) Steering Committee was held on 29 July 2019.

In parallel, the COAG Health Council (AHMAC) is developing a draft National Clinical Quality Registry (CQR) Strategy. Consultations with the states and territories, the ACSQHC have occurred. The Health Council of COAG will consider the draft National Clinical Quality Registry Strategy in 2020. The Strategy maximises the potential of clinical quality registries such as the APFPR.

The TGA has commenced consultations on establishing a Unique Device Identification system in Australia. If adopted in the healthcare system, the UDI can be used to accurately identify and track individual devices. A public consultation paper was released in late 2018 and work to progress the feedback from the consultation to introduce the UDI has commenced.

RECOMMENATION 4
The committee recommends that the Medicare Benefits Schedule Taskforce prioritise release of the report of the Gynaecology Clinical Committee for consultation.

Government Response: *The Government supports in principle this recommendation.*

Progress Report: Medical Benefits Schedule (MBS) changes took effect from 1 July 2018 to:

- prohibit the payment of MBS rebates for pelvic organ prolapse repair where transvaginal mesh is used (rebates for native tissue repair without mesh continue to apply); and
- introduce three new interim MBS items for the surgical excision of mesh in symptomatic patients

Rebates for non-mesh treatments are still available.

The MBS Taskforce Gynaecology Clinical Committee recommendations are being considered by the Government.

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.

Government Response: *The Government supports this recommendation.*

Progress Report: Work to address this recommendation has been prioritised. More stringent reporting requirements have been imposed by the TGA on suppliers of all surgical mesh devices available in Australia.

In December 2018, a progress report was provided to the Senate as requested.

An independent expert has comprehensively reviewed the TGA's adverse event risk assessment and signal detection and analysis processes. Targeted consultation with a range of stakeholders was undertaken as part of the review. Recommendations are being considered and public consultation will occur in late 2019 to inform implementation.

Further enhancements to the TGA's post market surveillance IT systems are expected to be implemented in early 2020.

A cross jurisdictional project co-led by Victoria (Safer Care Victoria) and the Commonwealth (through the TGA), to better collaborate and share information between jurisdictions and the TGA, and to complement the reform work underway was agreed to by the AHMAC. The project was approved in June 2019 and seeks to strengthen Australia's ability to identify and take action faster when issues are identified with medical devices. The project will provide regulator reports to the AHMAC.

Strategy 2 in *An Action Plan for Medical Devices* – strengthening the monitoring and follow up of devices already in use - includes undertaking consultation by the TGA on a range of further potential changes such as enhancing inspection regimes, removing reporting barriers by sponsors, use of smartphone apps for reporting. Feedback on these further changes is planned to occur in late 2019 into 2020.

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.**

Government Response: *The Government supports this recommendation.*

Progress Report: Work on this recommendation has been completed. The ACSQHC issued resources and guidance to jurisdictions, relevant colleges and speciality societies, primary health networks and health consumer councils regarding effective informed consent processes. The resources have been published on the ACSQHC website.

State and territories health departments are well-placed to address clinical governance issues including as part of the informed consent processes.

Also refer to Recommendation 2: patient information leaflets.

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.

Government Response: *The Government supports this recommendation.*

Progress Report: Work on this recommendation has been completed. The ACSQHC issued guidance to jurisdictions to assist clinical decision making, including care pathways for pelvic organ prolapse (POP) and stress urinary incontinence (SUI) using an evidence based traffic light approach (red, yellow, green) to identify surgical treatments options; and that non-surgical treatments are recommended as the first line of treatment relevant health profession bodies.

The TGA cancelled ARTG entries for transvaginal POP and mini incision slings for SUI mesh devices in January 2018. This was based on medical evidence that showed the risk benefit profile had changed to unfavourable. This decision was published by the TGA in December 2017.

The TGA imposed stricter conditions including monitoring requirements on suppliers of any urogynaecological mesh devices to treat POP approved for supply in Australia.

Also refer to Recommendation 2: patient information leaflets.

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.

Government Response: *The Government supports this recommendation but notes its implementation is a role for medical professional colleges and specialist societies.*

Progress Report: Although Commonwealth power to require the implementation of this recommendation was limited, it has been completed. Ongoing review work will continue. The ACSQHC distributed a suite of resources to the relevant professional colleges and societies and recommended wide promulgation. ACSQHC wrote to the AHPRA advising of the resources and sought support to promote the resources and reiterate the importance of informed consent processes.

The Chief Medical Officer wrote to the AHPRA to encourage uptake.

TGA launched a webpage to consolidate information, which provides a link to the relevant resources developed by the ACAQHC in October 2018 at: www.tga.gov.au/hubs/transvaginal-mesh

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.

Government Response: *The Government supports this recommendation.*

Progress Report: Minister Hunt wrote to state and territory health ministers promoting the utilisation and adoption of the resources developed by the ACSQHC.

The ACSQHC finalised and published guidance for hospital credentialing of senior medical practitioners who implant mesh for POP and SUI.

Guidance has been provided to public and private hospitals and relevant surgical societies and colleges. States and territories have indicated support for use of the credentialing guidance.

Work on this recommendation has been completed with ongoing review through an inter-jurisdictional committee which continues to monitor the implementation.

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 outcome of such procedures, including any complications.**

Government Response: *The Government supports this recommendation but notes its implementation is a role for medical professional colleges and specialist societies.*

Progress Report: There is limited Commonwealth power to enforce implementation, however the work undertaken by the ACSQHC and jurisdictions (refer to Recommendation 9 above) has been completed, adoption has been widespread but will be ongoing. Regulation and governance arrangements of medical practitioners are matters for the AHPRA and the Medical Board of Australia. Also refer to recommendation 1.

The Chief Medical Officer wrote to medical professional colleges and specialist societies encouraging stronger oversight and reminding them of best practice.

The ACSQHC continues to support the adoption of the materials, including through the jurisdictional committee.

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.

Government Response: *The Government notes this recommendation.*

Progress Report: The feasibility of this recommendation was thoroughly explored by the ASCQHC and the jurisdictional committee. The proposed retrospective audit of procedures is a matter for jurisdictions and private health service providers. There are some logistical challenges such a medical record accessibility and accuracy.

In October 2018, Minister Hunt wrote to state and territory health ministers to seek cooperation at local levels and the ACSQHC continues to work collaboratively with jurisdictions on consistent prospective data collections. Some jurisdictions are further exploring a retrospective audit where possible, for example South Australia who is undertaking a parliamentary enquiry to receive submissions that relate to many of the Senate Committee's recommendations such as medical practitioner credentialing, registries, audits, reporting and patient consent processes across public and private hospitals in South Australia.

Also refer to Recommendation 3. The pelvic floor registry (APFPR) will assist in prospective data collection for pelvic floor procedures and may consider opportunities to include retrospective data inclusion.

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.

Government Response: *The Government supports in principle this recommendation.*

Progress Report: In July 2018, the Department of Health provided funding to support the development of the Australian Consensus Framework for Ethical Collaboration (ACF). The Framework supports stronger industry self-regulation, better collaboration, integrity and trust in the healthcare sector. The ACF is a sector-led, federal and jurisdictional government-supported initiative developed collaboratively by professional bodies, industry organisations, hospital and health services associations, regulators, patient and advocacy groups and other health related organisations.

Also refer to Recommendation 1. The Australian Ethical Health Alliance, which oversees the ACF, comprises 71 signatories who aim to improve healthcare in Australia through articulation and affirmation of ethical principles that promote the interests of patients and consumers, enhance access to safe and effective healthcare, encourage ethical collaboration in the healthcare sector and build public trust.

In October 2018 the Chief Medical Officer wrote to the Medical Board of Australia's to ensure medical professions continue to practice ethically and responsibly.

In late 2019, the Medical Technology Association of Australia consulted on enhancements to its Code of Practice, including strengthening expectations on demonstrating ethical standards. The release of the revised Code is anticipated in late 2019.

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.**

Government Response: *The Government supports this recommendation in principle but notes a review of the services for the use and removal of transvaginal mesh devices is a matter for the states and territories and the healthcare profession.*

Progress: A review of the services for the use and removal of transvaginal mesh devices is a matter for the states and territories and the healthcare profession. Minister Hunt wrote to state and territory health ministers seeking cooperation in the review of transvaginal mesh devices use and removal services.

The ACSQHC developed and published on its website, a framework aimed at supporting jurisdictions to plan the delivery of services for the use and removal of transvaginal mesh devices and management of mesh-related complications. www.safetyandquality.gov.au/publications-and-resources/resource-library/treatment-options-complications-transvaginal-mesh-including-options-mesh-removal

Most jurisdictions have established services for transvaginal mesh implantation and removal, and information supports. In addition, for example, South Australia is undertaking a parliamentary enquiry to receive submissions that relate to many of the Senate Committee's recommendations such as medical practitioner credentialing, registries, audits, reporting and patient consent processes across public and private hospitals in South Australia.

The TGA continues to work on improving adverse events reporting processes, and is collaborating with the ACSQHC and jurisdictions to enhance communication of adverse events.

On 4 April 2019, *An Action Plan for Medical Devices* was published on the TGA website. Strategy 2 in the Action Plan – strengthening the monitoring and follow up of devices already in use – includes undertaking further consultation by the TGA on a range of post market reforms, including mandatory adverse event reporting by healthcare facilities. This consultation is planned to occur in late 2019.