Australian Government

Final Report on the Australian Government Response to the Recommendations of the Senate Community Affairs References Committee Report:

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

July 2021

Preamble:

The Australian Government remains committed to the safety, health and wellbeing of all Australians. The Government recognises health is central to our overall wellbeing and ability to participate and contribute in society. At the same time the Government understands regulation of medical devices is based on a risk-benefit analysis of the devices because it is not possible to perform systematic randomised controlled clinical trials on implanted devices.

Balancing timely access to new medical devices that may significantly improve health outcomes and protecting consumers in an environment of fast paced and increasingly complex medical technology evolvement remains an on-going challenge faced by regulators of medical devices around the world. Notwithstanding this, the Government and the Department of Health continued to implement initiatives to support patient care and safety.

Since the last progress report tabled in October 2019, on the Government's response to the Senate Inquiry on '*The Number of Women in Australia who have had Transvaginal Mesh Implants and Related Matters (Senate Report)'*, the *National Clinical Quality Registry (CQR) and Virtual Registry (VR) Strategy 2020-2030* was endorsed by all state and territory governments in December 2020. Registries support improvements in clinical practice through routinely collecting data about health care (including medical devices) and patient outcomes, and providing benchmarked feedback to clinicians, hospitals, health system managers, the Therapeutic Goods Administration (TGA) and medical device/pharmaceutical companies. The feedback will reveal whether the care provided aligns with national standards, including clinical care standards, and how their patient outcomes compare to that of their peers.

The Commonwealth funded Australasian Pelvic Floor Procedure Registry (the APFPR), announced by Minister Hunt in April 2019 is operational in Victoria and New South Wales and is being rolled out nationally across the public and private healthcare sectors. The APFPR is clinician-led, and will monitor urogynaecological mesh devices and related procedures for women with stress urinary incontinence and pelvic organ prolapse. The focus is on device safety, complications, revisions and explantations (mesh removal) and the APFPR will assist with the early identification of device related complications, ensuring that women and surgeons can be contacted as quickly as possible in the event of an identified risk or issue with a particular device.

In October 2020, the Government approved an investment of $7.73 million for the TGA to establish an Australian unique device identification database (AusUDID) for medical devices. The AusUDID system will play a key role in strengthening patient safety and Australia's post-market medical device adverse event reporting system. If adopted throughout the healthcare system, the UDI will enable medical devices that have been implanted in patients to be tracked more easily, enhancing the ability for doctors to notify patients quickly if necessary.

Eleven out of the twelve Government supported or supported-in-principle recommendations from the Senate Committee's Report are completed. Recommendation 1, relating to mandatory reporting of adverse events by medical practitioners and providing guidance on what constitutes an adverse event, is partially completed. Subject to Government's agreement, a public consultation on the potential for mandatory reporting of adverse event reporting by healthcare facilities is due for release by the TGA later in 2021.

The Australian Commission on Safety and Quality in Health Care has completed implementation of the Senate's recommendations and has promulgated guidance and other resources amongst the medical fraternity.

The TGA has implemented reforms over the past three years including working closely with a newly created Consumer Working Group on a number of additional strategies and actions outlined in *An Action Plan for Medical Devices* to further strengthen our regulatory system, with a focus on patient safety. A report card of progress was published on the TGA's website in April 2020 and an updated report card is expected shortly. The Government, state and territory governments and the TGA are balancing the pace of reforms initiatives within the context of supporting the COVID-19 pandemic response.

The Government acknowledges the efforts and actions detailed in this progress report to implement the Senate Committee's recommendations and thanks the Committee for raising the issues on behalf of the women who have had transvaginal mesh implants.

This progress report has been structured to provide a status and description of activities undertaken against each of the Senate Committee's recommendations and the Government's response (as tabled in October 2018). Activities and actions that were reported in previous progress reports (ie: in December 2018 and October 2019) are generally not repeated below.

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.*

Status: SUBSTANTIALLY COMPLETED

Actions requiring regulatory changes are continuing and will transition to the Therapeutic Goods Administration's (TGA) ongoing post market surveillance enhancements program.

The TGA continued its program of improvements to adverse event reporting since publishing the Government's progress report in December 2019. Recommended changes and suggestions from a post market monitoring and surveillance systems independent review were implemented in 2019-2020. Consequently, the TGA's post-market surveillance information technology (IT) systems have been enhanced to improve data sharing and analytic capabilities. The online adverse event reporting systems and processes were simplified to allow faster reporting, tracking and analysis.

In October 2020, the Government approved an investment of $7.73 million to establish a unique device identification (AusUDID) database for medical devices. The AusUDID system will strengthen patient safety and strengthen Australia's post-market medical device adverse event reporting system. If adopted in the healthcare system, the new identifiers may allow medical devices that have been implanted in patients to be tracked, enhancing the ability for doctors to notify patients quickly if there is a safety issue with a medical device. The unique identifiers could be incorporated into patient records, discharge summaries, implant registries and MyHealth Record. The TGA has established an UDI hub on its website to support the implementation of this initiative.

Public comment on five additional proposed enhancements to the current TGA processes for adverse event reporting of medical devices was undertaken in 2020. The five proposals relate to:

- changing the current adverse event reporting exemptions
- strengthening reporting requirements for medical device adverse events
- implementing a program of TGA inspections and audits of sponsor activities and premises to confirm they comply with their post market obligations
- review of post market definitions in the medical device regulations, and
- ways to enhance communication between the TGA and the consumers of medical devices.

Submissions are published on the TGA website and work is now underway to refine the options for implementation through targeted follow-up consultations with relevant stakeholders including consumers. Additionally, preliminary consultations have occurred with state and territory governments, private and day hospitals, the Australian Commission on Safety and Quality in Health Care (ACSQHC) and international regulators about the feasibility of potential mandatory reporting of medical device adverse events by healthcare facilities. The Government is aware of the heavy burden of care and reporting carried by some in the healthcare sector and is mindful to balance any proposed measures appropriately. Broader public consultation is proposed to occur on this topic later in 2021.

In November 2020, the TGA hosted an '*Australian Recall Processes*' workshop to discuss improving the medical devices safety warning notification and recall processes. This was attended by over 80 stakeholders representing 30 companies, peak industry organisations, state/ territory health departments and the Australian Commission on Safety and Quality in Health Care (ACSQHC). Feedback from the workshop is guiding the development of options for the replacement or enhancement of the TGA's recalls database and processes.

The Australian Consensus Framework for Ethical Collaboration (ACF) developed by healthcare professional bodies in July 2018, comprises 75 signatories including the Australian Medical Association. The Australian Ethical Health Alliance (AEHA) which oversees the ACF affirms ethical principles that promote the interests of patients and consumers, enhance access to safe and effective healthcare and encourages ethical collaboration in the healthcare sector. Information about the ACF is available on the AEHA website.

The TGA published a report card of progress for *An Action Plan for Medical Devices* on its website in April 2020. Strategy 2 in the Action Plan – centred on strengthening the monitoring and follow up of devices already in use. The next report card will be published in 2021, having been delayed due to TGA's efforts pivoted to the COVID-19 response.

RECOMMENDATION 2

The committee recommends that the Therapeutic Goods Administration and the Australian Commission on Safety and Quality in Health Care (ACSQHC) 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.*

Status: COMPLETED

The ACSQHC published guidance as recommended in late 2018.

New regulatory requirement for manufacturers of implantable medical devices to provide patient implant cards and information leaflets has been in place since 1 December 2018, commencing with urogynaecological mesh devices. The patient information leaflet encourages consumers to contact health professionals and to report adverse events associated with the device, including to the manufacturer and the TGA. The TGA is continuing to work with manufacturers as the regulatory requirement progresses towards full implementation for all implanted medical devices included in the Australian Register of Therapeutic Goods by 1 December 2021.

In October 2020, the Government approved the investment of $7.73m from the TGA's cash reserves to establish the Australian Unique Device Identification (UDI) Database (AusUDID). Amendments to the *Therapeutic Goods Act 1989* received Royal Assent in January 2021,that mandates medical devices supplied in Australia to have an UDI. Building of the AusUDID commenced in May 2021 and will be implemented over the next four years. Information stored in the database will be publicly available to assist the use of medical device identifiers throughout the health care system, including in hospital records, registries (such as the Australian Pelvic Floor Procedure Registry, the Cardiac Device Registry, the National Joint Replacement Registry and the Australian Breast Device Registry) and patients' MyHealth Record.

The transvaginal mesh information hub established in 2019 with input from patients, available on TGA's website continues to be a useful resource for consumers and healthcare practitioners. Amongst other things, the hub provides information on how consumers and healthcare practitioners can find support services and how to report problems and side effects related to medical devices including urogynaecological mesh to the TGA. www.tga.gov.au/hubs/transvaginal-mesh.

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.*

Status: COMPLETED

Funding of $2.3m from the Government has established a new Australasian Pelvic Floor Procedure Registry (the APFPR), operational in Victoria and New South Wales and being rolled out nationally across all states and territories, in the public and private healthcare sectors. Roll-out has steadily progressed, with some delays due to the focus of healthcare professionals being on supporting the COVID-19 pandemic response during 2020.

The APFPR will monitor urogynaecological mesh devices and related procedures for women with stress urinary incontinence (SUI) and pelvic organ prolapse (POP). It will particularly focus on device safety, complications, revisions and explantations (mesh removal).

The APFPR will assist with the early identification of device related complications and ensure that women and surgeons can be contacted as quickly as possible in the event of an identified risk or issue with a particular device. It will provide tailored information to surgeons, hospitals, the TGA, the medical device industry and women on the safety and quality of mesh devices and related procedures.

The APFPR's steering committee includes clinician craft groups, consumers, governments and TGA representatives. Consumer involvement in the APFPR has included regular formal and informal participation by consumer representatives, including input into suitable patient reported

outcome measure questionnaires. The APFPR is hosted by Monash University, which manages 40 clinical registries and has significant expertise and experience in this field.

The ACSQHC monitors progress of the development of the APFPR, as part of its ongoing work in relation to clinical safety and quality and the Australian Register of Clinical Registries.

The *National Clinical Quality Registry (CQR) and Virtual Registry (VR) Strategy 2020-2030* was endorsed by all governments in December 2020. The Strategy aims to drive continuous improvements in the value and quality of patient-centred health care to achieve better health outcomes for all Australians. A key foundation of the Strategy and all CQRs/VRs is to support improvements in clinical practice through routinely collecting data about health care (including medical devices) and patient outcomes, and providing benchmarked feedback to clinicians, hospitals, health system managers, the TGA and medical device/pharmaceutical companies. This feedback reveals whether the care provided aligns with national standards, including clinical care standards, and how their patient outcomes compare to that of their peers.

Where relevant, the feedback also reveals how medical devices performed, compared to other devices. For example, Australia was the first country in the world to withdraw a metal-on-metal hip replacement device from the market in December 2009. This was informed by data from the Australasian Orthopaedic Association National Joint Replacement Registry (AONJRR), which revealed high rates of revision surgery for this device. A worldwide recall followed in August 2010.

The Strategy seeks to build the capacity of national CQRs/VRs to undertake this quality improvement role and achieve this level of benefit for patients and the community. It also aims to facilitate the systematic provision of this de-identified, real world, benchmarked outcomes data, across the healthcare system, to ensure that all Australians benefit. Linking and integrating CQR/VR data with Australia's major healthcare datasets and infrastructure, will provide the outcomes data that is a critical component of a continuously improving healthcare system.

The Strategy was developed in partnership with the states and territories, the ACSQHC, the Australian Institute of Health and Welfare (AIHW), an Expert Advisory Group, clinicians and other key stakeholders. Its development was also informed by the 2019 consultation process, which received more than 80 submissions from a broad range of stakeholders, including from the medical device industry. A Strategy implementation plan will be developed in consultation with key stakeholders, including the medical device industry.

The adoption of the UDI in registries that collect information about implanted devices may assist to more accurately identify and track medical devices.

RECOMMENDATION 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.*

Status: COMPLETED

The MBS Review Taskforce Report on Gynaecology was undertaken during 2018. From this report, the Government brought forward three recommendations to address urgent safety concerns

relating to the use of transvaginal mesh for pelvic organ prolapse surgery. Three item numbers were introduced for POP and SUI removals.

A number of changes were also recommended by the taskforce to increase the list of reasons for removal of mid-urethral slings and to include issues such as urethral or sling related pain or infection. MBS items were amended to clarify that MBS rebates will only be payable for procedures that use for example, native tissue repairs. These recommendations were implemented on 1 July 2018.

The final report was published on the Department of Health's website on 14 December 2020.

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*.

Status: COMPLETED

A progress report was provided to the Senate in December 2018 and in October 2019 and is available on the Senate's website. Work to address this recommendation was prioritised, and suppliers of all surgical mesh devices available in Australia are now subject to more stringent reporting requirements since 2018.

Actions including amendments to Medical Device Regulations are continuing as other types of devices are identified, by a dedicated new section within the TGA which is tasked with post market reviews and more comprehensive surveillance activities, including establishing an international collaboration working group so that issues identified in larger markets can be signalled earlier.

Recommended changes and suggestions arising out of an independent review to improve TGA's adverse event risk assessment and signal detection and analysis processes were implemented in 2019-2020. The TGA's post-market surveillance IT systems including to support the post market review activities and the System for Australian Recall Actions (SARA) database were enhanced to improve data sharing and analytic capabilities and online adverse event reporting systems and processes were simplified to allow faster sponsor reporting, tracking and analysis.

Regular meetings between states and territory health departments, the TGA and the ACSQHC are used to share information and collaborate better to identify and discuss devices of concern.

Public consultations by the TGA on proposals under Strategy 2 in *An Action Plan for Medical Devices* – strengthening the monitoring and follow up of devices, occurred during 2020. Submissions and feedback are published on the TGA website and follow up work to refine the implementation options are being undertaken. See Recommendation 1.

RECOMMENDATION 6

The committee recommends that the Australian Commission on Safety and Quality in Health Care (ACSQHC) 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.*

Status: COMPLETED

Resources and guidance to jurisdictions, relevant colleges and speciality societies, primary health networks and health consumer councils regarding effective informed consent processes have been issued and published on the ACSQHC's website. State and territories health departments are well-placed to address clinical governance issues including as part of the informed consent processes.

In collaboration with consumer representatives, the TGA developed and published *'Five questions to ask your health professional before you get a medical implant.'* This and the patient information leaflet which provides more information about the medical device that may be used in the treatment (See Recommendation 2), can assist in patient informed consent processes.

RECOMMENDATION 7

The committee recommends that treatment guidelines developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) 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.*

Status: COMPLETED

The ACSQHC has 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.

On 1 December 2020, all existing urogynaecological meshes were upclassified to Class III (highest risk) medical devices. Four devices that could demonstrate and provide evidence to meet the highest risk requirements remain on the ARTG. These are for the treatment of stress urinary incontinence (SUI). The approval by the TGA is conditional and must include:

- express provision of patient-informed consent
- provenance of patient information materials

- use by appropriately credentialed health professionals
- consistency with the guidelines previously issued by the ACSQHC; and
- increased reporting obligations, including of incident rates of adverse events, that would be published on TGA's website, for transparency.

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 (ACSQHC) 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.*

Status: COMPLETED

As previously advised the ACSQHC has distributed a suite of resources to relevant professional colleges and societies and recommended wide promulgation. Letters were written to the Australian Health Practitioner Regulation Agency (AHPRA) advising of the resources and support to promote the resources.

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

The resources developed by the ACSQHC in 2018 are available on the TGA's transvaginal (urogynaecological) mesh information site: 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 (ACSQHC) 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.*

Status: COMPLETED

As advised in October 2019, Minister Hunt wrote to state and territory health ministers promoting the utilisation and adoption of the resources developed by the ACSQHC. The published guidance for hospital credentialing of senior medical practitioners who implant mesh for POP and SUI, was provided to public and private hospitals and relevant surgical societies and colleges.

States and territories have supported and implemented the use of the credentialing guidance.

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.*

Status: COMPLETED

The Chief Medical Officer wrote to medical professional colleges and specialist societies in October 2018, encouraging stronger oversight and reminding them of best practice.

The Commonwealth is limited in its power to enforce implementation of Recommendation 10. However the work undertaken by the ACSQHC and jurisdictions (refer to Recommendation 9 above) is completed. Adoption of the ACSQHC's guidance has been widespread and will be ongoing. Private and public hospitals are obligated to meet the National Safety and Quality in Health Services Standards (NSQHS). The NSQHS' Clinical Governance Standard aims to ensure that a clinical governance framework is implemented to ensure that patients and consumers receive safe and high-quality health care.

The Government notes that the regulation and governance arrangements of medical practitioners are matters for the AHPRA and the Medical Board of Australia.

RECOMMENDATION 11

The committee recommends that Commonwealth, states and territory governments commission the Australian Commission on Safety and Quality in Health Care (ACSQHC) 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.*

Status: NOTED

As previously reported, the feasibility of this recommendation was thoroughly explored by the ACSQHC and the jurisdictional (state and territory) committee. The logistical challenges such a medical record accessibility, differing policies and record keeping requirements and accuracy were recognised in the recent the South Australian Social Development Committee's, *'The Surgical Implantation of Medical Mesh in South Australia inquiry report'*, published, 25 May 2021 (page 50-51). The outcomes of a South Australian audit of patients admitted for pelvic organ treatments in SA health facilities with transvaginal mesh devices from 2003 to 2018 (the TVM audit), affirmed the challenges.

Minister Hunt wrote to state and territory health ministers in October 2018 to seek cooperation on prospective data collections. The now established Australian Pelvic Floor Procedure Registry

(APFPR) will assist in prospective data collection for pelvic floor procedures and could consider opportunities to include retrospective data inclusion.

However, the commencement of the APFPR will assist in prospective data collection - See Recommendation 3. In addition, state and territory governments continue to implement improved mechanisms for recording procedures that include implanted medical devices.

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.*

Status: COMPLETED

The Government supported the establishment of the Australian Consensus Framework for Ethical Collaboration (ACF), which was developed in 2018. The cross-sectorally developed ACF is overseen by the Australian Ethical Health Alliance (AEHA) and encourages stronger industry self-regulation, better collaboration, integrity and trust in the healthcare sector. The AEHA comprises 75 signatories including the Australian Medical Association and the Medical Technology Association of Australia (MTAA). The AEHA leads efforts in the Asia-Pacific Economic Cooperation region and aims to improve healthcare through amongst others; articulation and affirmation of ethical principles that promote the interests of patients and consumers and ethical collaboration in the healthcare sector.

As at June 2021, 31 percent of AEHA's members, were reported to have submitted the first annual Self-Evaluation Form which assists members in evaluating alignment with the ACF principles. The engagement rate in the first year following the pilot of the Form is positive and encouraging.

MTAA has implemented the ACF self-evaluation form and confirmed that MTAA and its members have adopted the ACF principles. The MTAA Code of Practice (the Code) which was reviewed and updated in 2020 is aligned to the ACF principles. The Code covers many areas of interaction between doctors, nurses and other healthcare professionals and the medical technology industry including company-sponsored training and education products, sponsorship of third-party educational events etc. Code training is mandatory for all MTAA employees and Healthcare Professionals facing employees of MTAA.

RECOMMENDATION 13

The committee recommends that State and Territory governments continue to work with the Australian Commission on Safety and Quality in Health Care (ACSQHC) 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.*

Status: COMPLETED

The ACSQHC continues to maintain the currency of the Service Model Framework developed with the aim of supporting jurisdictions to plan the delivery of services for the use and removal of transvaginal mesh devices and management of mesh-related complications. The Framework supports sustainable and appropriate service delivery. The Framework also includes information regarding services provided by states and territories, which is regularly updated with their input. The Framework is available, along with the other resources for clinicians and consumers, on the ACSQHC's website. Most jurisdictions have established services for transvaginal mesh implantation and removal, and information supports. Information about these services are available on the ACSQHC's and TGA websites.

The Royal Australia and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) the Urogyanecology Society of Australia (UGSA) have developed resources for consumers including mesh removal information sheet and 'Help after mesh surgery'.

The TGA is refining proposals to enhance communication of adverse event and continue to collaborate with the ACSQHC and jurisdictions. The establishment of the AusUDID has commenced, see Recommendation 1 and 2).