Australian Government

Australian Government response to the Senate Community Affairs References Committee report:

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

October 2018

Introduction

The Australian Government welcomes the Senate Community Affairs References Committee report on the *Number of women in Australia who have had transvaginal mesh implants and related matters*.

The Inquiry has raised awareness of the serious and long standing impacts reported by women following mesh related procedures and strongly identified to those entities and individuals participating in or supporting Australia's healthcare system, where improvement can be made to recognise and support these women.

The Australian Government thanks the women who presented at public hearings, recognising their significant effort in recounting their deeply private and frequently traumatic experiences, and acknowledges the seriousness of the adverse events that affected them.

The Government is deeply invested in women's health and well-being and has committed to improve the health, diagnosis and treatment options for them. The Government also supported the expansion of breast and cervical cancer screening to improve detection, treatment and survival outcomes for women with cancer.

The Senate Committee made 13 recommendations in a number of areas, including enhancing the safety and transparency for patients and medical practitioners through improved information for patients as well as enhancing ways to report adverse events.

Recommendations to strengthen post-market vigilance and reinforce the roles and responsibilities of health practitioners and sponsors are supported by the Government. High ethical standards, good governance and strong partnership across health provision, from the medical device sponsor/manufacturer to the training of medical professionals and regulatory staff at the Therapeutic Goods Administration (TGA) within the Department of Health, is important for effective and safe delivery of public health outcomes.

Regulation of medical devices is based on managing risk through a combination of pre-market assessment and post-market monitoring of medical devices. This approach is taken by regulators across the globe and is different to the regulation of medicines because it is not possible to perform systematic randomised controlled clinical trials on implanted medical devices. Similar to other regulators, the on-going challenge for the TGA in regulating medical devices is finding an appropriate balance between providing the public with timely access to new medical devices which may significantly improve health outcomes and protecting consumers in the constantly evolving and increasingly complex medical technology sector.

The TGA is committed to improving its post-market vigilance mechanisms but relies heavily on reporting in Australia and internationally for the thousands of medical devices used in Australia. Acting on evidence provided by medical experts, the TGA announced the up-classification of all surgical mesh on 26 October 2017.

The Government has also acted by enhancing the provision of medical device information to patients from 1 December 2018. The Australian Commission on Safety and Quality in Health Care has implemented a number of measures and continues to support better clinical

practices, improve training guidelines particularly with respect to patient selection and information about mesh devices.

The Government has amended the Medicare items to restrict the use of urogynaecological mesh in the surgical repair of pelvic organ prolapse. Additionally it has created new interim services for the surgical excision of urogynaecological mesh to address safety concerns. The changes to the Medicare Benefits Schedule (MBS) commenced from 1 July 2018.

The Government is committed to partnering with stakeholders to improve medical device awareness and facilitate patient-centred care and safety. State and Territory governments are implementing measures to support women who continue to struggle with adverse experiences following their surgery, as well as improving patient awareness more generally about medical devices. The Government has confidence in the states and territories ensuring that these measures work effectively to demonstrate their commitment to the care and safety of Australian women.

A number of the recommendations extend beyond the direct responsibility of the Commonwealth. The Government however is strongly committed to taking a leadership role in supporting the progress of recommendations that require cross-jurisdictional, inter-agency activities or interaction with professional organisations and will explore bilateral or other mechanisms to achieve the best outcomes for patients. The federal Minister for Health and the Commonwealth Chief Medical Officer (CMO) will continue to discuss the importance of progressing the recommendations with relevant stakeholders, emphasising the importance of the healthcare professional, industry and regulatory systems working together to restore the confidence of Australian women in our healthcare system.

The Government commends the courageous women who persisted in the face of an extremely challenging and difficult set of circumstances. Australians deserve and expect a high quality healthcare system and the Government is committed to pursue a system that is professional, underpinned by a rigorous evidence based regulatory framework and which treat patients with respect. The Government has considered the Senate Committee's findings and recommendations in detail and provides the following response.

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**

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.

The Inquiry identified that there was limited awareness amongst consumers and healthcare practitioners about adverse event reporting and using TGA process. Under the *Therapeutic Goods Act 1989* (the Act), the TGA has no regulatory authority to mandate medical practitioners to report adverse events. The Act provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are (i) used in Australia whether produced in Australia or elsewhere or (ii) exported from Australia.

The National Registration and Accreditation Scheme (NRAS) for registered health practitioners was established in 2008 by the Council of Australian Government. The NRAS is responsible for the education, training and registration of health practitioners and works through corresponding National Boards (the Medical Board of Australia (MBA) represents the National Boards) which sets standards that practitioners must meet in order to register. The National Boards are supported by the Australian Health Practitioner Regulation Agency (AHPRA).

Whilst adverse event reporting is vital for therapeutic goods post-market surveillance the Government notes that post market surveillance of therapeutic goods is a shared responsibility. Successful post-market surveillance is achieved through cooperation and input from many stakeholders including industry, the states and territories, medical practitioners, regulatory and registration bodies, professional boards and colleges. Each have a role and responsibility to understand the importance of reporting adverse events concerning medicines and medical devices and to improve patient awareness of how and when to give feedback when a medical intervention did not proceed as intended.

The TGA has taken actions to improve the awareness of adverse event reporting within the consumer and healthcare practitioner groups. Workshops and information have been provided to consumer groups, healthcare and dental professionals about reporting adverse events to the TGA. The Government through the CMO will improve awareness and encourage adverse event reporting amongst healthcare practitioners, professional bodies, and consumers. The CMO undertakes to write to the MBA, AHPRA and respective professional colleges and

societies to encourage reporting of adverse events to the TGA. The TGA will also increase its consumer awareness program with specific education activities for consumer adverse event reporting during 2018.

The TGA publishes information about adverse events on its website and provides advice on how these can be reported. The Government notes that there is room for greater awareness and the TGA is reviewing its adverse event reporting exemptions guidelines and the processes to report adverse events for medical devices sponsors to ensure that it is relevant to Australian community expectations.

On-line reporting to the TGA of adverse events has been simplified and there is an on-line learning module to support health professionals in reporting adverse events. The TGA will also update its website to make these learning modules more visible.

Following Recommendation 27 of the Expert Panel Review on Medicines and Medical Devices Regulation, the TGA reviewed its Therapeutic Goods Vigilance Framework and continues to enhance its data analytics capability to better support medical device monitoring and compliance activities, including identifying opportunities to draw from externally de-identified data to detect adverse event signals earlier.

The TGA is intending to develop an integrated electronic medical device adverse event reporting system to link reports across medical software platforms directly from hospitals to TGA's system. The streamlined system is expected to increase the quality, efficiency and quantities of reports received by the TGA and reduce the administrative burden on healthcare professionals. The system will use the same electronic reporting standards manufacturers use for reporting adverse events to overseas regulators, benefitting Australian medical device sponsors. The electronic submission forms will enable direct loading of sales and complaints data, permitting expedited signal detection.

Over the last two years, the TGA has enhanced its post-market monitoring systems to allow data capture from TGA's medical device incident report and investigation scheme (IRIS), recall actions database, the Australian Register of Therapeutic Goods (ARTG) and post market review database. Having the data consolidated in one place will improve TGA's assessment of adverse events and other signals. The TGA is investigating inter-linking other related health datasets.

The TGA will also continue to work with stakeholders to improve the utility of its reporting forms.

The Government notes the *Australian Consensus Framework for Ethical Collaboration in the Australian Healthcare Sector* has been developed with input from over 50 health care entities, including those from the medical device industry, the Australian Medical Association, various medical professional societies, colleges, hospitals and state governments. Implementation of this health-system wide initiative aims to increase ethical behaviour characterised by values and principles such as honesty, integrity, transparency, accountability and oversight. Reporting of adverse events has been discussed as part of the development of the Consensus

Framework and implementation will be through adoption in relevant Codes of Conduct and other mechanisms.

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.

Response: The Government supports this recommendation.

The Government has amended the medical device regulations to require consumer medical device information leaflets (information leaflets) to be made available by manufacturers for all new permanently implantable medical devices from 1 December 2018. From 1 December 2019, this will apply to all existing urogynaecological mesh devices and from 1 December 2021, to all other existing implantable devices.

The information leaflets must contain important information about the device including the device name and model, the intended purpose of the device and information explaining how to use the device safely. The information leaflets are required to be updated as new evidence emerges of safety issues, side effects, warnings and risks associated with the medical device. It will also give guidance to consumers about circumstances in which they should contact health professionals and advise that if any serious incident occurs in relation to the device, it should be reported to the manufacturer and the TGA.

In addition, the TGA is working with consumer groups to develop guidance material to empower patients to ask the relevant questions of health professionals prior to making a decision to have a medical device implanted, and where to find further information or support. The guidance material will also incorporate input from the Australian Commission on Safety and Quality in Health Care (the Commission). Once completed these consumer materials will be widely promoted in late 2018. These guidance materials will be available on-line on the TGA website. The Commission will also link to these resources.

The TGA and the Australian Digital Health Agency (ADHA) are also exploring the feasibility of medical device information being included in the MyHealth Record future work-plan.

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.

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.

The Government is carefully considering the scope and appropriateness of different types of registries as recommended by the Committee in the context of developing a National Clinical Quality Registry (CQR) Policy and Funding Strategy. CQRs systematically monitor the safety and quality of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information (including devices where appropriate). A defining feature of a well-designed CQR is that it provides ongoing, risk adjusted, benchmarked feedback to clinicians on their clinical performance.

A CQR could potentially monitor the safety, quality and variations in care for urogynaecological procedures, including those using transvaginal mesh implants, and maintain a record of the device/s used and individual recipients to enable tracking should the device be faulty.

CQRs take time to establish and require ethics and local governance approvals to establish arrangements to collect and analyse data. It also takes a number of years before the data collected reaches a critical mass to enable meaningful interpretation.

The CQR Strategy is being developed by the Commonwealth together with the Commission and states and territories. This work complements and builds upon the Commission's Framework for Australian Clinical Quality Registries and will consider ways to provide a nationally consistent approach to the selection, funding, implementation, management and performance of CQRs to improve health outcomes. An approach to funding of CQRs is being developed as part of the Strategy. It is anticipated that a draft CQR Strategy will be provided to the Australian Health Ministers' Advisory Council and the Council of Australian Governments Health Council for consideration in late 2018.

Additionally, options such as recording a consumer's medical device information in medical practitioner software could be explored to ensure this information is captured. The TGA and the ADHA)are working towards including medical device information in the MyHealth Record future work-plan.

RECOMMENDATION 4

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

Response: The Government supports in principle this recommendation.

To address patient safety concerns regarding the use of transvaginal mesh, the Government is drawing forward recommendations from the Medicare Benefits Schedule Taskforce Gynaecology Clinical Committee in relation to the surgical repair of pelvic organ prolapse.

At the time of the Senate inquiry, the MBS contained a number of items where surgeons may or may not apply techniques involving urogynaecological mesh, including items specifically for the repair of pelvic organ prolapse by vaginal approach.

On 29 April 2018, the Government announced changes to the MBS to prohibit the payment of MBS rebates for pelvic organ prolapse repair where transvaginal mesh is used. Items for the repair of pelvic organ prolapse via vaginal approach will continue to be available for native tissue repairs without mesh.

These changes to the MBS align with the TGA's cancellation of certain urogynaecological mesh products from the ARTG on 4 January 2018.

In addition, the Government is introducing three new interim MBS items for the surgical excision of mesh in symptomatic patients. The new, interim items will allow appropriate rebates for the surgical removal of mesh and help facilitate the collection of Medicare data on the number of women requiring mesh removal in Australia. The items are being introduced on an interim basis as the items may require refinement following the release of the MBS Review Taskforce's final recommendations on MBS gynaecological services.

The changes to the MBS came into effect on 1 July 2018.

The Medicare Benefits Schedule Taskforce Gynaecology Clinical Committee is finalising its remaining recommendations on MBS gynaecological services and the report will be available for consultation in due course.

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.

Response: The Government supports this recommendation.

In 2016, the Government accepted Recommendation 27 of the MMDR relating to developing a more comprehensive post-market monitoring framework. To enhance post-market monitoring, the TGA has commenced development work to improve data collection and enhanced web-based reporting of adverse events (see the response to Recommendation 1).

The TGA continues to enhance its post-market monitoring systems including the ability to capture data from different datasets such as the medical device incident reporting and investigation system, the recall actions database and the ARTG. The TGA is investigating options for gaining access to, integrating and/or the ability to analyse other relevant datasets, including registry data to improve the post monitoring framework. Engagement with the ADHA, state and territories, private hospitals and stronger cooperation with overseas regulators support improved mechanisms for reporting and to better respond to adverse events, is underway.

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.**

Response: The Government supports this recommendation.

The Commission has completed the development of a suite of resources which support improved informed consent processes and support dialogue between medical practitioners and patients. These include consumer information resources on treatment options for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) and hospital credentialing guidance for senior medical officers.

The resources were developed following consultation with women who had mesh implanted; the majority of these women had been affected by complications of transvaginal mesh for SUI. Women who had successful surgical outcomes with mesh devices were also consulted. This development and consultation process also included representatives of health consumer organisations, clinicians, and state and territory health departments.

The guidance for hospital credentialing of surgeons also includes reference to the need to ensure appropriate consent processes. The care pathways for POP and SUI also provide a resource to support doctors in their discussions with individual patients about their options for treatment.

These resources include:

- discussion of the range of non-surgical and surgical treatment options available and their risks, benefits and potential complications the rationale for the treatment
- questions that patients may wish to ask their doctor.

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.

Response: The Government supports this recommendation.

The care pathways for pelvic organ prolapse (POP) and for stress urinary incontinence (SUI) developed by the Commission describe the clinical considerations to be made when assessing treatment options for women with POP and SUI.

The pathways have two components; the first section is predominantly for general practitioners, and the second section supports specialists. These pathways will be shared with Primary Health Networks and Local Hospital Networks for integration into primary and acute care.

An interactive web version for the specialist pathways are currently in final design phase for publication.

The specialised surgical elements of the pathways for POP and SUI use a traffic light approach (red, yellow, green) to identify options for surgical treatments based on the level of evidence for each type of procedure.

The consumer resources also provide information on treatment options to assist decision making and in discussions with their healthcare provider. The care pathways and the consumer information resources have been developed in a way to support clinicians in discussing options for treatment with women and inform the consent process.

Non-surgical treatments are recommended as the first line of treatment for SUI by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Urological Society of Australia and New Zealand (part of the Royal Australasian College of Surgeons).

The Government notes that ultimately the decision to undertake surgical implantation is a clinical decision which is informed by the treatment guidelines and the personal circumstances of the patient.

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.

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

The Commission has distributed the suite of resources to the relevant professional colleges and societies and recommend that they be widely promulgated. The Commission has also written to the AHPRA to advise of the resources and seek its support to promote the resources and the importance of informed consent processes. In undertaking these communications, the Commission has no legal capacity to require uptake by members of medical professional specialist colleges and societies.

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.

Response: The Government supports this recommendation.

The Commission has finalised and published guidance for hospital credentialing of senior medical practitioners who implant transvaginal mesh for treatment of pelvic organ prolapse and stress urinary incontinence, and for the removal of transvaginal mesh. The guidance has been provided to all Australian health departments, the Australian Private Hospitals Association and relevant surgical societies and colleges for use in their local credentialing processes.

The states and territories have indicated support for use of the credentialing guidance to inform local relevant hospital credentialing processes via the Commission Inter-Jurisdictional Committee. The local application of the detail of the guidance is a matter for local credentialing committees, both public and private.

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.**

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

The Government notes that the regulation and governance arrangements of medical practitioners are managed by the AHPRA and the MBA. The Department of Health through the Office of the CMO will support and encourage stronger oversight and better governance for transvaginal mesh procedures. The CMO will write to the medical professional colleges and specialist societies reminding them of community expectations and best practice in the field.

The Commission will support the Office of the CMO by reaffirming these messages.

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.

Response: The Government notes this recommendation.

The Government notes that the proposed retrospective audit of procedures presents several policy and implementation issues, and would be a matter for state and territory health departments and private health service providers.

The Commission is not able to directly access individual patient health records, but could work with the public and private systems to coordinate such audits, if commissioned by state and territory governments. The Government recognises the importance of the recommendation to take stock of transvaginal mesh procedures to inform and improve the use of the devices. The Government recognises the challenges associated with effectively collecting this information, including: data being stored on paper-based records, lack of information held as to whether procedures involved mesh, time to examine non-electronic records, and lack of some records where these are over seven years old.

The Commission is working collaboratively with the states and territories to support prospective data collection for women having mesh procedures now and into the future; improved data collection by senior medical officers being credentialed to undertake these procedures; and the establishment of appropriate services for women experiencing complications following mesh procedures. States and territories have indicated via the the Commission Inter-Jurisdictional Committee that these activities have already commenced, which will better support women who undertake these procedures.

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.

Response: The Government supports in principle this recommendation.

The Government was disappointed to hear of the lack of support from some in the medical profession when women presented with complications and sought advice from a trusted medical professional. The Government will seek the support of the profession to build consumer confidence and to ensure practitioners operate with strong ethical standards.

The Government notes the *Australian Consensus Framework for Ethical Collaboration in the Australian Healthcare Sector* (*Consensus Framework)* was recently launched on 20 July 2018. This framework is a joint commitment by health care entities including the Medical Technology Association of Australia (MTAA), the AMA, various medical professional

societies, colleges, hospitals and state governments to put the interest of patients' first. The framework promotes transparency, cooperation and ethical business practice in the interactions between health care professionals, including with the medical device and biopharmaceutical industry in the Asia-Pacific Economic Cooperation (APEC) countries.

The Department of Health is committed to work with the MTAA to support stronger self-regulation and better communication. In addition the Department through the Office of the CMO will liaise with the Commission to seek the MBA's support to ensure the medical professions continue to practice ethically and responsibly.

The Government notes MTAA's advice that its members are bound by a Code of Practice which aims to ensure that healthcare providers are not influenced in their decision making through financial or other inducements which may be offered by the medical device industry.

The Department will continue to discuss with the MTAA, the implementation and monitoring of the effectiveness of its self-regulatory and disciplinary process for non-compliance procedures. The MTAA code promotes ethical interactions with healthcare providers. Specifically, it requires that a company must ensure that sales of medical technology are made solely on the basis of efficacy, safety, quality, price and service and never on the basis of a healthcare professional receiving payments, gifts or hospitality.

The code stipulates compliance with the laws and regulations applicable to medical devices including the Therapeutic Goods Advertising Code (the code).Compliance with the code is monitored by a committee that includes independent representatives and consumer representatives, and all MTAA member companies are required to participate in the monitoring process.

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.**

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.

The Commission has completed a framework to support state and territory health departments plan the delivery of services for the use and removal of transvaginal mesh devices and management of mesh-related complications. This service model has been developed with input from the reference group convened by the Commission to advise on a range of resources, and which also has been informed by the states and territories.

The Government notes that the states and territories have a number of services in place and/or are in development for transvaginal mesh implantation and removal services. The states and territories are also providing a range of information and services that provide a point of contact for women experiencing adverse effects, to seek guidance and support. This includes initiatives such as fact sheets on websites, links on their websites, information about treatment options and telephone information lines to assist women to find out where to get help and referrals to professional assistance and guidance.

It is noted that the planning and delivery of health services, appropriate to the needs of the populations they serve, is the responsibility of state and territory health departments. Having said that, the Government acknowledges the complexity of the healthcare system and recognises states and territories are at varying stages of establishing support systems. These

services are a critical step in helping women who have had a procedure and continue to experience difficulties. Where possible for good patient centred care, patient input and feedback should be considered as part of the establishment and delivery of these services.

The TGA is leading work in relation to improving adverse event reporting processes, and the Commission is collaborating with the TGA and state and territory health departments on mechanisms to enhance communication of adverse events. The TGA's pilot Insite Program currently operating in NSW is aimed at supporting greater awareness amongst health professionals and within hospitals. The TGA will review the effectiveness of the Insite Program to inform potential expansion to other jurisdictions. The TGA will also review its website to make available further patient focused information, links to relevant resources to help women to find the appropriate information; and contacts within the healthcare system.