

Chapter 5

Responding to the evidence

[W]e believe this is a catastrophic failure of the health system to protect women and ensure they have access to safe health care. We feel that women have been let down by their doctors, by the manufacturers of mesh and by the TGA as the regulator.¹

5.1 The committee concurs with the Public Health Association of Australia's (PHAA) description of the complications resulting from transvaginal mesh implants as constituting a serious public health issue requiring a response at both an individual and at a population level, including counselling, public education, clinical interventions and long-lasting protective mechanisms.² The committee also considers that this inquiry has highlighted significant shortcomings in Australia's reporting systems for medical devices, with flow-on consequences for the health system's ability to respond to in a timely and effective way to concerns arising from the use of medical devices.

5.2 The committee is acutely aware that at the heart of this serious public health issue is a group of women who have borne a great cost: the cost of living with, and trying to seek treatment for, debilitating complications that have undermined their quality of life and that of their families. As the committee has heard, this in turn has exacted an enormous toll on their emotional wellbeing.

5.3 These women have also shouldered the burden of drawing attention to their plight and mobilising action to address it. In the process, they have borne the opprobrium of those who fear transvaginal mesh devices will be banned. It has taken a great deal of courage for women to come forward and discuss these most intimate and traumatic details in public. The committee makes no apology for placing these women and their lived experience at the forefront of this inquiry.

5.4 The committee is aware that, concurrent with this inquiry, a number of initiatives have been being progressed to respond to the concerns raised. In some cases, this work spans the period from the introduction of urogynaecological mesh for use in Australia. In other cases, the initiatives under consideration are a direct response to more recent accounts of pain and suffering from women living with complications from transvaginal mesh implants.

5.5 At the same time, the committee is acutely aware that for many of the women suffering as a result of transvaginal mesh implants, the responses to date have been slow in addressing the concerns they have raised and, for some, will make little difference to their circumstances.

1 Ms Josephine Root, Policy Manager, Consumers Health Forum of Australia, *Committee Hansard*, 3 August 2017, p. 16.

2 Associate Professor Angela Dawson, Convenor of the Women's Health Special Interest Group, Public Health Association of Australia, *Committee Hansard*, 3 August 2017, p. 8.

5.6 This final chapter considers the responses of regulators, the medical profession and device manufacturers and presents the committee's conclusions and recommendations.

Regulation of the introduction and use of transvaginal mesh implants

5.7 As noted in Chapter 1, responsibility for investigating the suitability of medical devices for use in Australia rests with the Therapeutic Goods Administration (TGA).

5.8 Throughout this inquiry, the committee has heard criticism of the TGA's management of the introduction and regulation of transvaginal mesh products.³

5.9 The key concerns raised in submissions to the committee have focused on:

- the stringency of the TGA's premarket assessment of transvaginal mesh devices for use in Australia;
- the pace of the TGA's response to evidence regarding serious complications associated with transvaginal mesh products; and
- the effectiveness of the TGA's adverse event reporting system, as discussed in Chapter 3.

5.10 However, Professor John Skerritt told the committee that, while no one should be proud or happy about the sequence of events that have happened, Australia's response has been ahead of that of the United States Food and Drug Administration (US-FDA) and ahead of Europe in many cases.⁴

5.11 In evidence to the inquiry, the TGA explained that assessment of the safety and efficacy of medical devices is undertaken on the basis of a combination of pre-market assessment and ongoing post market review. Professor Skerritt explained that:

the evidence that you use to look at whether it is appropriate for a product to be on the register [Australian Register of Therapeutic Goods (ARTG)] is a combination of the evidence that was provided and reviewed at the time of the application to be put on the market as well as the continuously evolving nature of evidence from clinical studies and day-to-day experience with these products worldwide.⁵

5.12 In its submission to the inquiry, the Department of Health (Department) advised that the TGA has continued to monitor evidence regarding the safety of urogynecological mesh devices as it has evolved. As new evidence has emerged, the TGA has taken steps to apply greater stringency to pre-market assessment processes.

3 See, for example: Health Consumers Councils across Australia, *Submission 23*; Consumers Health Forum of Australia, *Submission 26*; Health Issues Centre, *Submission 115*, Australian Pelvic Mesh Support Group, *Submission 140*.

4 Adjunct Professor John Skerritt, Deputy Secretary, Therapeutic Goods Administration, *Committee Hansard*, 6 February 2018, p. 2.

5 *Committee Hansard*, 3 August 2017, p. 50.

In some cases, this has resulted in devices being removed from the register, either by the TGA or the device manufacturer or sponsor.⁶

Pre-market assessment

5.13 Submitters and witnesses to the inquiry have questioned the TGA's pre-market assessment of transvaginal mesh devices, suggesting that the TGA has approved mesh devices for use in the Australian market without a strong evidence base and on the basis of substantive equivalence.⁷

5.14 In responding to these criticisms, the TGA told the committee that there is a tension for regulators between acceding to the desire to gain timely access to new treatments and the need to assess the evidence regarding the efficacy and safety of each device.⁸

Clinical trials

5.15 A commonly expressed concern throughout the inquiry has been that transvaginal mesh devices were introduced without rigorous clinical trials.⁹

5.16 Professor Skerritt explained that one of the challenges in the assessment of medical devices is the time it takes to establish the safety and performance of a new technology. He explained that it is not possible to conduct 'double blind, randomised clinical controlled trails on a device, especially an implanted device' in the same way as can be done with medicines.¹⁰

...one of the challenges with medical devices, especially those used in fairly specialised surgical techniques, is that you'll never be able to go out and say, 'We'll do a trial of a thousand people,' and then come back when you've done a trial of a thousand people and it's all one big trial. The evidence base is always evolving. I know that sounds easy to say but that's just the nature of it. It is the same with medicines for rare diseases—because the disease is rare you're never going to get enough people to do a trial with 1,000 people before you put it on the market.¹¹

5.17 The committee notes evidence received from medical practitioners proposing that new medical devices should, in the first instance, be approved for use in carefully

6 Department of Health (Department), *Submission 19*, p. 5.

7 See, for example: APMSG, *Submission 130*, p. 23; Associate Professor Christopher Maher, *Submission 154*, p. [10]; Kathryn, *Committee Hansard*, 19 September 2017, p. 4.

8 Dr Tim Greenaway, First Assistant Secretary, Therapeutic Goods Administration (TGA), *Committee Hansard*, 19 September 2017, p. 45.

9 See, for example: RANZCOG, *Submission 36*, p. 11; Health Issues Centre, *Submission 115*, p. 25; Name withheld, *Submission 28*, p. 2; Name withheld, *Submission 101*, p. [2]; Chantal, *Committee Hansard*, 3 August 2017, p. 24; Kathryn, *Committee Hansard*, 19 September 2017, p. 4.

10 Adjunct Professor John Skerritt, *Committee Hansard*, 3 August 2017, p. 46.

11 Adjunct Professor John Skerritt, *Committee Hansard*, 6 February 2018, p. 10.

monitored clinical trials with ethics approval and by surgeons who have adequate training.¹²

Substantive equivalence

5.18 Submitters have also raised concerns that some transvaginal mesh devices appear to have been introduced to the Australian market without a thorough pre-market assessment purely because they were considered similar to a device already listed on the Australian Register of Therapeutic Goods (ARTG), known as substantive equivalence.¹³

5.19 Ms Adriana Platona explained that, in order for the TGA to approve an application on the basis of substantive equivalence, the sponsor of the device would need to provide comparative analysis to demonstrate that any differences between the products—in materials, design, clinical evidence—would not impact on the safety and efficacy of the device. Ms Platona explained that the two devices would need to have the same intended purpose, in the same anatomy and have the same manufacturer.¹⁴

5.20 Professor Skerritt explained that the TGA's approach is not the same as the process applying in the United States:

All medical device products—and these were class IIb or class III, depending on whether they contained a biological origin component—all class IIb products, are required to have undergone conformity assessment either within Australia or by a European organisation. The Americans have a process that's a 'me too'. They call it their 52K process. We don't have such a process. When our regulatory system was reviewed by government, or by a panel of three experts who reported to government, over the last three years, it was recommended that we did not adopt such a process. We've never had one. So any product that has been put onto our register in the last decade or more has been through a review, either in Europe or by ourselves.¹⁵

5.21 The TGA advised that whether or not the assessment of a device is conducted overseas, the decision to include it on the ARTG is always a decision of the TGA.¹⁶

Re-classification of surgical mesh devices and introduction of patient implant cards

5.22 As part of the government's agreement that the TGA should align its processes with the European Union regulatory framework,¹⁷ the TGA recently

12 See, for example: Dr Anna Rosamilia, Urogynaecologist, Monash Health *Committee Hansard*, 3 August 2017, p. 34; Professor Robson, President, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, *Committee Hansard*, 19 September, pp. 22-23.

13 See, for example: APMSG, *Submission 130*, p. 23; Associate Professor Christopher Maher, *Submission 154*, p. [10].

14 Ms Adriana Platona, First Assistant Secretary, TGA, *Committee Hansard*, 19 September 2017, p. 45.

15 *Committee Hansard*, 6 February 2018, p. 3.

16 Ms Adriana Platona, *Committee Hansard*, 19 September 2017, p. 49.

announced that surgical mesh devices would be reclassified as Class III (high risk) from 1 December 2018. As noted in Chapter 1, in Australia, synthetic surgical meshes are currently classified as Class IIB. The change in classification means that all new applications for marketing approval for surgical mesh in Australia will require additional conformity assessment certification. Manufacturers of existing urogynaecological devices will need to lodge a reclassification application no later than December 2020.¹⁸

5.23 In announcing the measures, the TGA advised that:

In light of concerns expressed by many women who have undergone surgery with an urogynaecological mesh device, a two years transition period applies for this up-classification measure from the commencement of the regulations.¹⁹

5.24 At the same time, measures were introduced to address concerns about the level of information provided to consumers about surgical devices. These measures comprise:

- patient cards for implantable medical devices (patient implant cards): to be implemented from 1 December 2018 for all new urogynaecological mesh devices and from December 2021 for all existing implantable devices; and
- a patient information leaflet for all implantable medical devices: to be implemented from 1 December 2018 for all new permanently implantable devices, from 1 December 2019 for all existing urogynaecological mesh devices and from 1 December 2021 for all other existing surgical mesh devices.

5.25 The TGA told the committee that, while, the regulatory framework finalised by the European Union in May 2017 includes extensive revisions, these two measures were progressed first due to their ability to positively impact on patient safety around mesh devices.²⁰

5.26 Patient implant cards are intended to ensure that patients are aware of the details of the device they have been implanted with. The committee notes that this should assist the traceability of devices and patients in the event of the need to alert

17 The government accepted the recommendation of the 2015 Review of Medicines and Medical Devices Regulation (MMDR Review) that the TGA should align itself more closely with the European Union regulatory framework in September 2016.

18 Department of Health, Therapeutic Goods Administration, *Strengthening the assessment of medical devices and information for consumers*, 26 October 2017, <https://www.tga.gov.au/media-release/strengthening-assessment-medical-devices-and-information-consumers> (accessed 19 March 2018).

19 Department of Health, Therapeutic Goods Administration, *Strengthening the assessment of medical devices and information for consumers*, 26 October 2017, <https://www.tga.gov.au/media-release/strengthening-assessment-medical-devices-and-information-consumers> (accessed 19 March 2018).

20 Adjunct Professor John Skerritt, *Committee Hansard*, 6 February 2018, p. 5.

patients and health practitioners to safety issues such as precautions or recalls. Under the Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017 (regulations), the patient implant card must include the name and model of the device, either the batch code, lot number or serial number of the device, the device's unique device identifier and the manufacturer's name, address and website.²¹

5.27 The patient information card will be complemented by a patient information leaflet which must also be provided with each device. The leaflet will provide more detailed information and must identify the device, its intended purpose and include information such as the kinds of patients for whom the device is intended to be used and warnings about potential adverse effects and relevant precautions. The regulations also provide that the leaflet must be able to be readily understood by patients.²²

Committee view

5.28 The committee welcomes the recently announced measures to increase the level of pre-market scrutiny applied to all surgical mesh devices. While noting the breadth of devices captured by the measures, the committee considers that the reclassification of these devices as high risk is an appropriate regulatory response to the evidence available regarding the risks associated with transvaginal mesh devices.

5.29 The committee is concerned at the length of time afforded to manufacturers of devices that are currently listed on the ARTG to provide a reclassification application. The committee considers that compliance with the new requirements ought to be achievable in a shorter timeframe. At the same time, the committee notes that the significance of the up-classification of surgical mesh devices, for the regulation of transvaginal mesh devices currently listed on the ARTG must be seen in the context of other measures announced in December 2017 and January 2018.

5.30 The committee welcomes the requirements to increase the level of information available to consumers regarding medical devices. The committee considers that these requirements will go some way to addressing some of the key concerns identified in this inquiry. In particular, a patient implant card should ensure that all patients know exactly which device has been implanted and this should in turn assist them, and their medical practitioners, should they need to seek advice or treatment in relation to possible complications. The card should also make it easier for patients to monitor any developments in relation to the safety of the particular device they have received.

Postmarket review and monitoring

5.31 The TGA advised the committee that it continually monitors international developments in the use and regulation of devices. Since the introduction of mesh devices in Australia in 1998, the TGA has undertaken three post-market reviews: in

21 Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017, Explanatory Statement, p. 4.

22 Explanatory Statement, pp. 4-5.

2008; 2010 and a major review in 2013. The Department's submission provides a chronology that places the actions of the TGA in the context of regulatory responses internationally up to the release of the Scottish Independent Review of Transvaginal Mesh Implants on 27 March 2017.²³ This chronology is included at Appendix 1 to this report.

5.32 In late 2017 the TGA took steps to remove certain urogynaecological mesh devices used in the treatment of pelvic organ prolapse (POP) and single incision mini-slings used in the treatment of stress urinary incontinence (SUI) from the ARTG.

5.33 On 17 January 2018, the TGA announced that it had amended the information that must be provided to consumers in relation to adverse events associated with urogynaecological mesh implants.

Removal of transvaginal mesh products

5.34 On 30 November 2017, the TGA announced that it had decided to remove transvaginal mesh devices solely used for the treatment of POP from the ARTG.²⁴ In making this announcement, the TGA advised that, following a review of the latest international studies and the clinical evidence for each product, it was of the belief that the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks the devices pose to patients.²⁵

5.35 The committee notes that the Australian Commission on Safety and Quality in Health Care (ACSQHC) had reached a similar conclusion in September 2017. Professor Debora Picone advised the committee that the ACSQHC had reached the view that transvaginal mesh implants for the treatment of POP should be used only in a research context due to the uncertainty surrounding long term effects and risks of complications.²⁶

5.36 The decision includes single incision mini-slings which are used in the treatment of SUI, as distinct from mid-urethral slings. The TGA noted that there was a lack of adequate scientific evidence for it to be satisfied that the benefits of these devices outweigh the risks to patients.²⁷

5.37 The committee notes that special arrangements will enable medical practitioners to access unapproved devices either through the Special Access Scheme,

23 Department, *Submission 19, Attachment 1*, pp. 32-34.

24 Department of Health, Therapeutic Goods Administration, 'TGA undertakes regulatory actions after review into urogynaecological surgical mesh implants', *Media release*, 30 November 2017; Adjunct Professor Skerritt, *Committee Hansard*, 6 February 2018, p. 2.

25 Department of Health, Therapeutic Goods Administration, *TGA actions after review into urogynaecological surgical mesh implants*, 22 December 2017, <https://www.tga.gov.au/node/768243> (accessed 23 March 2018).

26 Adjunct Professor Debora Picone, Chief Executive Officer, Australian Commission on Safety and Quality in Health Care, *Committee Hansard*, 19 September 2017, p. 7.

27 Department of Health, Therapeutic Goods Administration, *TGA actions after review into urogynaecological surgical mesh implants*, 22 December 2017.

by becoming an Authorised Prescriber or for the purposes of clinical trials. Professor Skerritt explained:

So it's not an outright ban. Access to cancelled devices is still possible through a special access scheme—through authorised prescriber clinical trials schemes. But all of these schemes require additional oversight by an ethics committee and/or a medical expert, who will look at the individual case for using that product. It won't be, 'Just grab something off the shelf that happens to be available in the hospital.'²⁸

5.38 Professor Skerritt emphasised to the committee that this latest regulatory action is the outcome of a process that has been evolving over several years as evidence has emerged:

As the evidence evolved, we then assessed the clinical evidence. We then went out to the companies. We gave them time to answer, 'Show us your evidence as to why you believe the benefit risk is still appropriate.' A number of companies said, 'We don't have it,' and they withdrew the products, and we withdrew some of their other products.²⁹

5.39 The TGA noted that there have been suggestions that the TGA should restrict access to mesh devices to certain individual medical practitioners with particular high-level skills. The TGA explained that it has no legal authority to apply such a restriction, but that consideration of credentialing is being undertaken by the ASQHC.

Some people have suggested that we should, as TGA, only allow particular individual expert surgeons to use those particular products. We have no powers under our legislation to restrict particular devices to particular individual medical practitioners with particular high-level skills.³⁰

Increased information requirements for urogynaecological mesh implants.

5.40 On 17 January 2018, the TGA announced that as a result of further post-market review of urogynaecological mesh implants, it had required sponsors of mid-urethral sling implants used in the treatment of SUI, to include information about certain adverse events, such as severe chronic pain, groin pain and bladder perforation, in the device instructions for use of the product. Ms Platona advised the committee that two sponsors had chosen to update the information and a third sponsor—Johnson & Johnson—elected to withdraw its devices from the market.³¹

5.41 Ms Platona confirmed that there are now seven entries on the ARTG for urogynaecological mesh and 14 devices remaining.³²

28 *Committee Hansard*, 6 February 2018, p. 3.

29 *Committee Hansard*, 6 February 2018, p. 2.

30 Adjunct Professor John Skerritt, *Committee Hansard*, 6 February 2018, pp. 2-3.

31 *Committee Hansard*, 6 February 2018, p. 3.

32 *Committee Hansard*, 6 February 2018, p. 3.

Committee view

5.42 The committee welcomes the TGA's decision to remove transvaginal mesh products solely used for transvaginal POP procedures from the ARTG. The committee also welcomes the removal of single incision mini-slings. The committee remains concerned about the continued listing of MUS. Notwithstanding evidence provided to the committee regarding the apparent safety of MUS devices, the committee is concerned by the personal accounts it received from women who have experienced severe complications following transvaginal mesh procedures employing MUS.

5.43 The committee notes the changed requirements regarding the type of information to be provided in the Instructions for Use for each device. However, the committee is concerned that such information may not be readily accessible to consumers, in particular, to enable them to make an informed decision about such devices. These concerns are considered under the committee's findings on informed consent.

5.44 The committee accepts that the assessment and approval of medical devices is a continuous process of review and that regulatory responses to emerging issues need to be carefully considered and evidence based. However, the committee considers that criticisms of the lag in the regulatory response to emerging evidence of complications in relation to transvaginal mesh products are justified.

Capturing and recording data

5.45 A key concern to the committee is that there is no clear indication of how many women have received transvaginal mesh implants in Australia or how many women have experienced complications. Not only is there no single source of data on the use of transvaginal mesh implants, but each of the potential sources of data available is subject to significant limitations.

5.46 The ability to collect and analyse data is central to an effective and efficient health care system. The committee considers that the ability of regulators and the medical profession to arrive at evidence based responses to concerns relating to medical procedures involving implantable devices is greatly impeded without access to accurate and timely data about the use of such devices in Australia. The committee considers that there is an urgent need to improve existing reporting systems and examine options for greater complementarity between data sets.

Reporting adverse events

5.47 The committee is particularly concerned about the lack of reliable data available to inform the TGA's post-market monitoring activities. In Chapter 3, the committee noted its concern at the level of underreporting of adverse events involving transvaginal mesh implants and noted the significance of this for post-market monitoring by the TGA and individual device sponsors. The committee is particularly concerned that underreporting of adverse events associated with transvaginal mesh products has provided a false indication of the safety of such devices and contributed to delays in responding to the issues identified. The committee is deeply concerned that this has resulted in more women suffering complications.

5.48 The committee considers that accurate and timely reporting of adverse events is fundamental to a robust post-market monitoring scheme. This in turn has flow on benefits for effective and timely regulation of the use of medical devices. The committee is concerned that failures in the current adverse reporting system have contributed to delays in the identification of complications associated with the use of transvaginal mesh products.

5.49 As previously discussed, while adverse event reporting is mandatory for device sponsors, it is voluntary for medical practitioners. In Chapter 3, the committee noted that, to a significant degree, device sponsors are reliant on reporting from medical practitioners and patients to identify adverse events. The committee also expressed concern that there was some potential for inconsistency in the reporting of adverse events and concluded that clear criteria should be available to guide the reporting of adverse events.

5.50 Evidence to the committee indicates that many women who have been implanted with transvaginal mesh devices were not aware that they could report the complications they were experiencing to the TGA or to the device manufacturer. The committee notes that discussion in the media of complications associated with mesh devices, together with the activities of the Australian Pelvic Mesh Support Group, and to some extent this inquiry, may have contributed to an increased awareness of adverse reporting among women who have received mesh implants. However, many women who have attempted to report adverse events have told the committee that they have found the process difficult.

5.51 Many women have experienced difficulty gaining access to their medical records. The committee considers that the introduction of patient implant cards will assist in this regard in the future. However, the committee is concerned that there is a large cohort of women who have experienced complications following transvaginal mesh implants who should be encouraged to report these complications to the TGA. Many of these women will require assistance to access their health records. The committee considers that these women should not be required to pay to access their medical records.

5.52 In its 2011 inquiry into the regulatory standards for the approval of medical devices in Australia, this committee recommended that the TGA put in place mechanisms to educate and encourage doctors to report adverse incidents associated with medical devices. The committee also recommended that consideration be given to the introduction of mandatory reporting of adverse events by medical practitioners.

5.53 The committee notes that the TGA has periodically published media releases on its website encouraging both patients and medical practitioners to report adverse events. The TGA has also met with patient groups and provides alerts through RSS and Twitter to patient groups, individual doctors and medical colleges. However, the TGA is not funded to undertake large-scale consumer/community information

programs. In this regard, it relies upon partnerships with clinical and consumer groups.³³

5.54 The committee notes that the TGA is committed to examining the scope within its budget and within its legal mandate to stimulate reporting by patients and doctors.³⁴ The committee notes that the TGA does not have a legal basis to mandate doctors to report adverse events.³⁵

Recommendation 1

5.55 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;**

Recommendation 2

5.56 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.

Establishment of a national register of medical devices

5.57 As noted previously, the committee is concerned that it is not possible to accurately identify the number of women who have received transvaginal mesh implants. The committee considers that an understanding of the true scale of the risk posed by transvaginal mesh devices, or any implantable medical device, is fundamental to tailoring an effective regulatory response.

5.58 The committee notes that there is widespread support for the establishment of a national register of medical devices. Medical practitioners and professional colleges emphasised the importance of capturing and evaluating longitudinal data to facilitate the evaluation of the safety and efficacy of medical devices. As noted in Chapter 3, many of the women who wrote to the committee could not understand why there was not already a register of medical devices.

33 Adjunct Professor John Skerritt, *Committee Hansard*, 3 August 2017, p. 47.

34 Adjunct Professor John Skerritt, *Committee Hansard*, 6 February 2018, p. 6.

35 Dr Tim Greenaway, *Committee Hansard*, 6 February 2018, p. 7.

5.59 The committee notes that some medical specialists and colleges have been maintaining their own registers or databases. While there is no doubt that there is merit and value in this, the committee considers that the issues identified in this inquiry demonstrate a clear need for a national database.

5.60 Professor Stephen Robson, President of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists summarised the arguments for a national register by stating:

One of the key issues identified has been the need for a register of women who have had mesh surgery. It's likely that other implantables in the future will be subject to question and concern, and I call on the government to establish a national implantables register. Many Australians have or will have different implants—joints, mesh, other implants—and, rather than having multiple different registries, there should be a single, appropriately funded and independently run national register of implantables. It could be funded by the manufacturers of implants and it should be integral to the e-health records system in Australia. The next phase of implants in Australia will be genetic implants, and it's imperative that a national register is embedded in health care in this country before that phase arrives.³⁶

5.61 The significance of a national device register was identified by the Review of Medicines and Medical Devices Regulation (MMDR Review). The MMDR Review noted that the timely and effective post-market monitoring of medical devices is an essential element of an effective regulatory system.³⁷ It stated that device registries play an important role in post-market monitoring as they can provide detailed information about patients, procedures and devices not routinely collected through other means.³⁸

5.62 Recommendation 22 of the MMDR Review recommended the establishment of a registry for all high-risk implantable devices, noting that the Australian regulatory body should continue to collaborate with overseas medical device regulators to actively share registry data, with a view to facilitating timely identification of emerging safety concerns.³⁹

5.63 The Government deferred consideration of this recommendation on the ground that establishing and maintaining registries requires careful consideration of

36 *Committee Hansard*, 19 September 2017, p. 20.

37 MMDR Review, *Report on the regulatory framework for medicines and medical devices*, March 2015, p. 126.

38 MMDR Review, *Report on the regulatory framework for medicines and medical devices*, March 2015, p. 127.

39 MMDR Review, *Report on the regulatory framework for medicines and medical devices*, March 2015, p. 129.

the range of registries managed by a variety of organisations and how they could be sustainably managed and funded in the future.⁴⁰

5.64 The Department and the Medical Technology Association of Australia (MTAA) noted that any consideration of how an implantable devices registry would be funded, should recognise that such a registry would have benefits across the health system including to hospitals, patients and device manufacturers.⁴¹

5.65 The committee recognises that there are important considerations in the establishment of a database, not least of all the cost of establishing and maintaining it. The committee notes that registers have been established under interim arrangements for certain devices. The committee also notes advice received during the inquiry that work is currently underway to consider the appropriate approach to the establishment of a register or registers.

Recommendation 3

5.66 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.

Improving the accuracy of other data sources

5.67 In Chapter 3 the committee noted a range of potential sources of data that could be used to gain an informed understanding of complications arising from the use of transvaginal mesh devices and procedures. These include the claim data held by private health insurance companies, Prostheses list data, hospital records and databases maintained by medical professional colleges. In each case the committee noted some important limitations on these data sets.

5.68 In particular, the committee noted evidence that suggested the Medicare Benefits Schedule (MBS) codes relating to surgical procedures for POP and SUI are a potential source of valuable data about the use of medical devices. However, these codes are procedure based and do not distinguish between procedures using a mesh device or native tissue and is of limited assistance in identifying the number of women who have attempted to have mesh devices removed, either partially or fully.

40 Department of Health, *Australian Government Response to the Review of Medicines and Medical Devices Regulation*, 15 September 2016, p. 21, <http://www.health.gov.au/internet/main/publishing.nsf/Content/MMD-govresp> (accessed 20 March 2018).

41 Adjunct Professor John Skerritt, *Committee Hansard*, 3 August 2017, p. 54; Mr Ian Burgess, Chief Executive Office, Medical Technology Association of Australia, *Committee Hansard*, 18 September 2017, pp. 38, 47; Adjunct Professor John Skerritt, *Committee Hansard*, 6 February 2018, p. 5.

5.69 While the committee understands that the MBS is primarily a mechanism for providing a subsidy for listed services, the committee considers that there is benefit in revising the codes allocated to surgical procedures for the treatment of POP and SUI to improve the accuracy of the data collected.

5.70 The committee notes that the Gynaecology Clinical Committee of the MBS Review Taskforce has reviewed MBS items for the use of biological and permanent mesh, together with other gynaecology related items, and has recommended:

- revising MBS item numbers so that mesh and non-mesh surgery can be distinguished to enable better data collection;
- restricting the use of mesh to patients who are undergoing revision surgery (i.e. primary operative repairs have failed to relieve symptoms); and
- introducing specific MBS items for mesh removal.

5.71 The committee was advised that these recommendations would undergo public consultation during 2017, before the MBS Taskforce makes its final recommendations to government. The committee notes that it has been six months since the MBS Taskforce endorsed the release of a report by the Gynaecology Clinical Committee for public consultation on 20 September 2017.⁴² The Gynaecology Clinical Committee's report has not been released to date.

Recommendation 4

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

5.73 The committee considers that improved coding and reporting of procedures for implantable devices has the potential to contribute valuable information to the post-market monitoring of all medical devices. Further, the integration of existing data sets has the ability to contribute to a more complete understanding of the level and seriousness of complications with medicines and medical devices as they arise.

5.74 The committee notes that the MMDR Review recommended the establishment of a more comprehensive post-market monitoring scheme for medicines and medical devices. It recommended better integration of available datasets to support the analysis of data from the Pharmaceutical Benefits Scheme, the Medicare Benefits Scheme, eHealth records, hospital records and device and other relevant registries and datasets.⁴³

42 Release of the report for public consultation was endorsed by the MBS Taskforce at its meeting on 20 September 2017. See: Department of Health, *MBS Review Taskforce meeting outcomes, 20 September 2017*, <http://www.health.gov.au/internet/main/publishing.nsf/Content/MBSR-outcomes-20september2017> (accessed 22 March 2018).

43 MMDR Review, *Report on the regulatory framework for medicines and medical devices*, March 2015, p. 160.

5.75 The government accepted this recommendation, noting the development of a more comprehensive post-market monitoring scheme will enhance consumer protection and complement existing post-market monitoring processes.⁴⁴

5.76 The committee received evidence during the inquiry that as part of its work on the development of clinical guidance, the ACSQHC is also considering appropriate recording of the details of products that are implanted, either through administrative data collections, such as the MBS and clinical coding of hospital separations, clinical registries or electronic records such as My Health Record.⁴⁵

Recommendation 5

5.77 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.

Improved clinical practice

5.78 The committee notes the evidence from medical practitioners throughout the inquiry acknowledging the need to improve the standard of care provided to women with POP and SUI. In particular, the committee notes the acknowledgement that there have been circumstances where the doctor-patient relationship has not supported women through their treatment for POP and SUI as it should and cases where the medical profession has not dealt with women correctly.⁴⁶

Informed consent

5.79 The committee is deeply concerned by the evidence received regarding the information provided to women to enable them to provide their informed consent to a transvaginal mesh procedure. The committee is particularly concerned that, despite the availability of detailed guidance and patient information leaflets produced by specialist colleges and societies, many women appear to have received little or no information to assist them to make a decision or provide their informed consent. The committee is dismayed by reports that some women were not advised that a transvaginal mesh implant was being used as part of their treatment.

5.80 The committee notes the comprehensive and systematic consent processes outlined by sub-specialist urology and gynaecology units and considers that these provide a useful model for other practitioners.

44 Department of Health, *Australian Government Response to the Review of Medicines and Medical Devices Regulation*, 15 September 2016, p. 24, <http://www.health.gov.au/internet/main/publishing.nsf/Content/MMD-govresp> (accessed 20 March 2018).

45 ACSQHC, *Submission 46*, p. 4.

46 See, for example: Dr Gary Swift, President, National Association of Specialist Obstetricians and Gynaecologists (NASOG), *Committee Hansard*, 3 August 2017, p. 29; Dr Caroline Dowling, Urologist, Urological Society of Australia and New Zealand, *Committee Hansard*, 3 August 2017, p. 27; Dr Michelle Atherton, *Committee Hansard*, 25 August 2018, p. 30.

5.81 The committee notes the evidence received that an effective consent process must involve a dialogue between the medical practitioner and the patient and must be tailored to the need of the individual patient. As a minimum this dialogue should:

- outline the full details of the proposed treatment;
- 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.

5.82 The committee notes that the ACSQHC is currently finalising resources that should assist women to inform themselves about procedures recommended to them. The resources will provide explanations of the symptoms of POP and SUI together with the range of treatment options available. The committee notes that these resources have been developed following extensive consultation with women affected by complications of transvaginal mesh.⁴⁷

5.83 The committee is interested to see how women will be directed to these resources. The committee is mindful that many people experience difficulty locating information on websites. The committee believes that helplines established by state and territory governments (discussed further below) should ensure that they direct women affected by transvaginal mesh to these resources.

5.84 The committee supports the development and publication of information resources by the ACSQHC for women experiencing POP or SUI and notes that these resources will support the process of informed consent between a patient and their medical practitioner.

5.85 However, the committee notes evidence to the inquiry about the inconsistent and at times cursory manner in which consent has been obtained from patients undergoing transvaginal mesh procedures. The committee is deeply concerned by reports that some medical professionals have not provided patients with detailed guidance and patient information leaflets. The committee is particularly concerned by the evidence of the APMSG that guidance prepared by RANZCOG has not been used to guide the process of informed consent in many cases.

5.86 Therefore, the committee considers that, in addition to patient information resources, the ACSQHC should develop guidance material on effective informed consent.

47 ACSQHC Update, additional information received 6 February 2018, p. [1].

Recommendation 6

5.87 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.

Care pathways for POP and SUI

5.88 In addition to patient information resources, the committee notes that the ACSQHC is also developing care pathways for POP and SUI to describe the clinical consideration to be made when assessing women with POP and SUI. The ACSQHC told the committee:

The pathways provide clinicians with an evidence-based approach to first line management, specialised surgical and non-surgical care and the types of medical specialists who may be involved in providing care.⁴⁸

5.89 The ACSQHC told the committee that the surgical pathways being developed will use a traffic light approach to help identify options for surgical treatments based on the strength of evidence and patient outcomes for each type of procedure.

5.90 The ACSQHC's guidance on care pathways is intended to improve the provision of appropriate, safe care through the standardisation of care processes, to enable patients to receive 'the sequence of evidence-based assessment and treatment actions that will deliver the best outcomes.'⁴⁹

5.91 In its submission the ACSQHC states that in developing this guidance, it has drawn on the most recent evidence and clinical advice, including statements issued by RANZCOG, the Urogynaecological Society of Australasia and the United Kingdom National Institute for Health and Care Excellence. The ACSQHC has also considered an international consensus pathway on treatment of POP developed by the International Consultation on Incontinence Surgical Management Prolapse Committee.⁵⁰

48 ACSQHC, Update, additional information received 6 February 2018, p. [2].

49 ACSQHC, *Submission 46*, p. 4.

50 *Submission 46*, p. 4.

5.92 Consideration has also been given to the role played by General Practitioners (GPs) in the assessment of women with POP and SUI, as well as their role in caring for women following transvaginal mesh procedures. In its submission, the ACSQHC recognises the important role accessible information on care pathways for POP and SUI can play in raising the awareness of GPs of the complications that may be associated with transvaginal mesh procedures, available referral pathways and management of symptoms. This work is being undertaken in partnership with Primary Health Networks and the Royal Australian College of General Practitioners.⁵¹

5.93 The committee notes that interactive web versions of the pathways are being developed and that this should allow easier access for clinicians reviewing treatment options and also in explaining various care pathways to women seeking treatment.⁵²

5.94 The committee notes that professional colleges and specialist societies have an important role to play in the continuing professional development of specialist doctors and in providing guidance on effective practice in their specialty. RANZCOG explained their role to the committee:

Once doctors have specialist qualifications, it is our role to monitor their continuing professional development activities, but it's also our role to guide practice and provide guidance to the profession: guidance as the appropriate ways to manage clinical conditions in women's health and standards for professional behaviour.⁵³

5.95 The committee considers that resources of the type described by the ACSQHC have the potential to greatly improve the standard of information available to both patients and medical practitioners and looks forward to reviewing these resources once they have been released.

5.96 The committee notes that final approval processes for the care pathways resource are underway and that the ACSQHC is also developing a care pathway for the removal of transvaginal mesh following complications.⁵⁴

Recommendation 7

5.97 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.

51 ACSQHC, *Submission 46*, pp. 4-5.

52 ACSQHC Update, additional information received 6 February 2018, p. [2].

53 Professor Stephen Robson, *Committee Hansard*, 19 September 2018, p. 19.

54 ACSQHC Update, additional information received 6 February 2018, p. [2].

Recommendation 8

5.98 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.

Appropriate governance for the introduction of new devices and procedures

5.99 The committee received a range of evidence regarding the governance that should be applied to the use of new devices. Some witnesses to the inquiry have suggested that new devices should be used in restricted circumstances initially.

5.100 The committee understands that there are already well-accepted governance procedures available through ethics approval committees that medical practitioners could use to ensure the timely and safe introduction of new devices and procedures. The committee was told that ethics approval committees ensure that the use of the device or procedure is subject to an appropriate model of oversight, supports informed consent and provides for appropriate follow up with patients post- surgery.⁵⁵

5.101 Evidence has also been received proposing that transvaginal mesh procedures should be restricted to medical practitioners who are highly skilled in such procedures.

Training and credentialing of senior medical practitioners

5.102 In Chapter 4, the committee noted concerns regarding the knowledge and skill of surgeons practicing transvaginal mesh procedures. Based on the evidence of personal accounts received from individual women, the committee considers that there is a need to improve the awareness of medical practitioners, especially General Practitioners, of symptoms associated with surgical mesh devices. There is also a clear need to improve the communication skills of some medical practitioners to ensure that they are communicating effectively with, and listening to patients.

5.103 The committee understands that registered medical practitioners must ensure they comply with Continuing Professional Development requirements set by the Medical Board and medical practitioners with specialist registration must continue to meet the requirements set out by their relevant college.

5.104 RANZCOG advised the committee that it had been providing guidance and advising caution regarding transvaginal mesh surgery to its member for a decade.⁵⁶ The committee heard similar evidence from a number of professional colleges and

55 Associate Professor Maher, *Committee Hansard*, 19 September 2017, pp. 29-30.

56 Professor Stephen Robson, *Committee Hansard*, 19 September 2017, p. 19.

societies regarding their role in the provision of training and information to their members.⁵⁷

5.105 The committee is therefore concerned by reports that transvaginal mesh has been used as a first response treatment, without considering alternative treatment options, indicating to the committee that transvaginal mesh has been overused by some medical professionals.

5.106 Evidence to the committee indicates that there is a need to review the current training models to ensure that the skill levels of medical practitioners to diagnose and treat POP and SUI meet minimum quality standards.

5.107 In particular, the committee notes evidence that procedures involving transvaginal mesh devices should only be performed by surgeons who can demonstrate that they have the requisite skills, in settings where their performance can be audited and complication rates can be recorded. For example, RANZCOG stated that there is evidence which indicates more highly skilled surgeons with big caseloads tend to have fewer complications. RANZCOG told the committee that this is true for any surgical procedure, not just transvaginal mesh devices.⁵⁸

5.108 The committee received evidence that some surgeons have been keeping their own personal data bases to enable them to review their own complications rates.⁵⁹ The committee received evidence that, based on such analysis, some surgeons no longer use transvaginal mesh devices in the treatment of their patients.⁶⁰ The committee notes that some specialist surgical units have a practice of holding regular multidisciplinary meetings to discuss all planned surgery, complimented by regular surgical audits and use this to inform their practice.⁶¹

5.109 Specialist colleges and associations told the committee that there was merit in reviewing how surgeons are trained and accredited.⁶² RANZCOG told the committee that it considers that a formal mechanism is required to ensure that training in new surgical techniques occurred. Professor Robson told the committee:

it's become clear to us that there is the need for a formal mechanism to ensure that training in new surgical techniques should be undertaken by experienced surgeons with an ongoing audit of the cases that they do—

57 See, for example: Urogynaecological Society of Australasia, *Submission 32*; Urological Society of Australia and New Zealand, *Submission 42*; NASOG, *Submission 49*; Australasian Gynaecological Endoscopy and Surgery Society Limited, *Submission 18*.

58 Associate Professor Jason Abbott, President, Australasian Gynaecological Endoscopy and Surgery Society, *Committee Hansard*, 18 September 2017, p. 30.

59 *Committee Hansard*, 18 September 2017, p. 30.

60 *Confidential Submission 153*.

61 Monash Health, *Submission 47*, p. [2].

62 See, for example: Professor Picone, *Committee Hansard*, 3 August 2017, pp. 40-41; Dr Jenny King, Chair, UroGynaecological Society of Australasia, *Committee Hansard*, 18 September 2017, pp. 16, 23; Professor Stephen Robson, *Committee Hansard*, 19 September 2017, pp. 19-20.

certainly during their training period. We have been recommending this, again, but we don't have any actual power to enforce our own recommendations. I believe there's an opportunity to include these sorts of mechanisms and pathways as part of revalidation, and this could be an ongoing project we'd be happy to work with the Medical Board of Australia in realising.⁶³

5.110 ACSQHC advised the committee that it considers there is potential to apply credentialing to other health professions and indicated that this would form a key part of the resources being developed to support improved care to women requiring treatment for mesh complications and mesh removal surgery.⁶⁴

5.111 The committee notes that the ACSQHC has developed guidance for the credentialing and training of senior medical practitioners who implant transvaginal mesh for the treatment of POP and SUI and also for the removal of transvaginal mesh.⁶⁵ The credentialing guidance has been developed in consultation with the Royal Australasian College of Surgeons, RANZCOG, the Urological Society of Australia and New Zealand, the Transvaginal Mesh Reference Group and state and territory health departments.⁶⁶

5.112 The guidance will set out the experience and qualifications that senior medical practitioners need to be credentialed to implant and remove mesh for treatment of POP and SUI. It includes recommendations on:

- device specific training;
- requirements for maintaining skills;
- monitoring and reporting patient outcomes;
- the type of specialty support services hospitals should have if they offer implantation and removal of transvaginal mesh; and
- the requirement for post-operative follow-up.⁶⁷

5.113 The ACSQHC advised that states and territories will use the guidance in their local credentialing processes and that it would be working to promote the use of the guidance for credentialing across private hospitals.⁶⁸

63 *Committee Hansard*, 19 September 2017, pp. 19-20.

64 *Submission 46*, p. 6.

65 ACSQHC Update, additional information received 6 February 2018, p. [2].

66 ACSQHC, *Submission 46*, p. 6.

67 ACSQHC Update, additional information received 6 February 2018, p. [2].

68 ACSQHC Update, additional information received 6 February 2018, p. [2].

Recommendation 9

5.114 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.

5.115 The committee acknowledges that the changes by the TGA to restrict the use of transvaginal mesh for POP means that transvaginal mesh will in effect only be available under a special access scheme and will limit the ability of medical professionals to utilise transvaginal mesh for the treatment of POP except in certain circumstances.

5.116 At the same time, the committee is deeply concerned by the personal accounts of women expressing their lack of faith in medical professionals following their experience with transvaginal mesh. The committee heard that women trusted their doctor to fully inform them of the risks and benefits of transvaginal mesh, alternative treatment options, and to be adequately skilled to perform the transvaginal mesh procedure and identify complications arising from the procedure. For many women this trust has now been lost.

5.117 The committee believes that professional medical colleges and specialist societies should demonstrate leadership in this area by implementing governance arrangements which limit the use of all transvaginal mesh to skilled specialists. The committee believes this would go some way to restoring the faith in medical professionals of women who have suffered from transvaginal mesh related complications.

Recommendation 10

5.118 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.**

Auditing transvaginal mesh procedures

5.119 The committee has received a great deal of evidence emphasising the important distinctions between treatment of POP and SUI and the important differences between transvaginal mesh devices. Medical practitioners have

encouraged the committee to note the differences in complication rates between different procedures and different devices.

5.120 The committee notes that the personal accounts it has received cover a very wide range of procedures and devices. These personal accounts underscore the importance of gaining a much closer understanding of the factors that may contribute to either success or severe failure in individual cases. The committee has heard variously that complications can be attributed to the device, the procedure or the patient or a combination of these.

5.121 While noting the number of studies and trials drawn to its attention throughout this inquiry, the committee considers that there is a pressing need to undertake an audit of all available sources of data in Australia to gain a more complete understanding of the use of transvaginal mesh procedures and the incidence and nature of complications associated with different types of devices and procedures. The committee considers it is important that such an audit should endeavour to capture information on the impact of transvaginal mesh procedures on the quality of life of the women who have received them.

5.122 The committee is all too aware that the currently available sources of data make this a challenging task, however, the committee considers that without an appropriately expert review of this nature, Australia risks repeating mistakes made in the introduction of transvaginal mesh products in the introduction of future devices.

Recommendation 11

5.123 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.

The role of device manufacturers in promoting the use of transvaginal mesh implants

5.124 The committee heard a range of evidence regarding the interactions between device manufacturers or sponsors and medical practitioners. Such concerns ranged from questions over the presence of sponsor representatives in the surgical theatre to the possibility of financial inducements to medical practitioners to use specific products.⁶⁹

5.125 The Health Consumers Councils across Australia (HCC) expressed concern that such incentives could lead to unsafe treatment practices. The HCC submission stated that Health Consumers Councils have been informed that there are clinical variations with a higher number of mesh procedures performed in certain states. The

69 See, for example: Public Health Association Australia, *Submission 20*, p. 5; TFS Surgical, *Submission 22*; Johnson & Johnson Medical Pty Ltd, *Submission 23*; pp. 14-15; Associate Professor Christopher Maher, *Submission 154*, p. [13].

HCC was not able to substantiate this claim, but submitted that such concerns warrant further investigation.⁷⁰

5.126 The Australian Pelvic Mesh Support Group (APMSG) drew the committee's attention to urogynaecological conventions sponsored by device manufacturers where the programs have included 'mesh' updates. The APMSG questioned the reason for this involvement, noting that many surgeons seemed to be unaware of the severe complications posed by urogynaecological mesh devices.⁷¹

5.127 The committee has been assured that the majority of medical practitioners have been motivated only by a desire to provide relief to women suffering with POP and SUI. Medical practitioners explained the importance of receiving training and guidance in the use of new devices and of the role played by surgeons the provision of such training.

5.128 Specialist medical colleges assured the committee that there are appropriate governance systems in place to guard against unprofessional relationships between device manufacturers and medical practitioners. RANZCOG advised the committee that the vast majority of surgeons do not have any financial incentive to use particular transvaginal mesh products. The committee notes that any doctors who do have a financial relationship with a company are expected to declare any interest as recommended by the Code of Conduct for Doctors in Australia⁷².

5.129 Representatives of device manufacturers assured the committee they have acted ethically and responsibly in the research, development and supply of medical devices. Each emphasised the care and compassion they feel for patients who have experienced adverse side effects as a result of devices they manufacture and affirmed their commitment to support and help patients.⁷³

5.130 The MTAA advised the committee that its members are bound by a Code of Practice (code) to promote ethical interactions with healthcare providers. The aim of the code is to ensure that healthcare providers are not influenced in their decision making around the use of medical devices through financial or other inducements.⁷⁴

5.131 The code requires that:

- any supplier expenditure on education events be reasonable and set in an appropriate context;

70 *Submission 21*, p. 8.

71 *Submission 130*, pp. 5-6.

72 Medical Board of Australia, *Good Medical Practice: A code of conduct for doctors in Australia*, March 2014, <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx> (accessed 23 March 2018).

73 Mr Gavin Fox-Smith, Managing Director, Johnson & Johnson Medical Devices, *Committee Hansard*, 18 September 2017, p. 36; Mr Pat Callanan, Business Unit Director Australia and New Zealand, Urology and Pelvic Health, Boston Scientific, *Committee Hansard*, 18 September 2017, p. 37.

74 MTAA, *Submission 40*, p. 4.

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- supplier financial contribution to conferences should be reasonable and proportionate to the educational content of the of the event; and
 - gifts to be restricted to those that are of educational value and very small value.⁷⁵

5.132 Compliance with the code is monitored and Mr Ian Burgess told the committee that there is a self-regulatory and disciplinary process for non-compliance that can result in the imposition of fines.⁷⁶

5.133 The committee understands the symbiotic nature of the relationship between device manufacturers and medical practitioners but, while it notes the codes of conduct that each sector has in place to guard against unprofessionalism, it is concerned by some of the evidence it has received. In particular, evidence that medical practitioners have proposed transvaginal mesh products as a 'quick fix' or preventative option for minor symptoms of POP and SUI or been overenthusiastic in their embrace of this new technology is troubling.

5.134 In its inquiry into the regulatory standards for the approval of medical devices in Australia, the committee recommended that then Department of Health and Ageing undertake work to address the issue of inducements paid by pharmaceutical companies and medical device manufacturers to doctors and teaching hospitals.⁷⁷

5.135 In its response to the report, the Government agreed with the recommendation in principle, but noted 'that a legislative framework for ethical conduct of industry in the promotion of therapeutic goods to healthcare professions is not warranted in the Australian context at this time. The Government committed to working with industry to support stronger self-regulation, better communication and shared systems for complaints reporting.

Recommendation 12

5.136 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.

Addressing the needs of women living with mesh related complications

5.137 The committee is very mindful of the need to ensure adequate and readily accessible support is available for all women who have received transvaginal mesh implants and those who may be considering such surgery in the future. In particular,

75 MTA, *Submission 40*, p. 4.

76 *Committee Hansard*, 18 September 2017, p. 45.

77 Senate Community Affairs References Committee, *The regulatory standards for the approval of medical devices in Australia*, 22 November 2011, p. 106.

the committee understands the importance of ensuring treatment and support is available for all women currently living with mesh related complications.

5.138 The committee notes evidence that emphasises the need for standardised, multidisciplinary, holistic care to support women in their rehabilitation.⁷⁸ In particular, the committee notes the importance of specialist pain management in the treatment of complications following transvaginal mesh surgery. The committee recognises concerns that the current resources and supports available to women may be inadequate to address their needs.

5.139 The ASQHC advised the committee that each state and territory is reviewing the provision of services for the use and removal of transvaginal mesh, and some have developed specific information resources and support services, including dedicated telephone information and referral services and improved coordination and designation of services to promote more coordinated access services.⁷⁹

5.140 The ASQHC advised that the service model framework it is developing regarding the optimal service for removal of mesh will also draw together information on the services available in each jurisdiction.⁸⁰

5.141 In the meantime, the committee notes that a number of states and territories are implementing support services to respond to the needs of women living with mesh related complications. The services differ between states and are in various stages of implementation, but give an indication of the types of services under consideration.

Western Australia

5.142 In September 2017, the Western Australian Minister for Health announced the:

- Establishment of a confidential free contact line to provide a link to expertise and clinical services and help determine how many women in WA have mesh-related symptoms; and
- Establishment of a mesh register to prospectively record the use of pelvic and abdominal mesh.⁸¹

5.143 The Western Australian Government's Healthy WA website provides information on pelvic mesh, possible complications and symptoms; and treatment for these. The website advises that the King Edward Memorial Hospital (KEMH) is planning to commence a mesh complication service (Mesh Clinic) run by Urogynaecologists with a dedicated multidisciplinary team. The website advises that

78 Kim, *Committee Hansard*, 3 August 2017, pp. 3-4.

79 ACSQHC Update, additional information received 6 February 2018, p. [3].

80 ACSQHC Update, additional information received 6 February 2018, p. [3].

81 Government of Western Australia, The Hon Roger Cook, Deputy Premier, Minister for Health, Mental Health, 'New Phone line to help WA women affected by mesh implants', *Media release*, 8 September 2017, <https://www.mediastatements.wa.gov.au/Pages/McGowan/2017/09/New-phone-line-to-help-WA-women-affected-by-mesh-implants.aspx> (accessed 1 February 2018).

KEMH will be seeking consumer input, including from the APMSG, in establishing this clinic.⁸²

Victoria

5.144 The Victorian Minister for Health made an announcement on 19 December advising:

- the establishment of the Victorian mesh information and help line; and
- the availability of specialist programs to assist women with complications following mesh procedures.⁸³

5.145 The Victorian Government has provided further information regarding the use of transvaginal mesh, possible complications, alternative treatment options and the availability of support services on its Better Health Channel website.⁸⁴

New South Wales

5.146 At the committee's Sydney hearing, Dr Kerry Chant, Chief Health Officer, NSW Ministry of Health (NSW Health), described work that it was undertaking in consultation with specialist urogynaecologists and the State's five public sector specialist clinics to address the needs of women who have sustained injuries following transvaginal mesh procedures. This work comprised steps to ensure that mesh-injured women are supported by a multidisciplinary team, led by a urogynaecologist and incorporating effective pain management. This work is being complemented by the development of information resources to support informed consent and guidance for general practitioners to enable them to provide appropriate care. NSW Health is liaising with the ACSQHC in developing these resources.⁸⁵

5.147 Dr Marianne Gale told the committee that NSW Health is considering the need to ensure device information is appropriately captured and the development of stronger guidance about the need to record implanted devices on the discharge summary for each patient.⁸⁶ NSW Health also advised that it supported strengthening adverse reporting requirements.⁸⁷

82 Western Australian Department of Health, Healthy WA health information for Western Australians, *Pelvic Mesh*, http://healthywa.wa.gov.au/Articles/N_R/Pelvic-mesh (accessed 1 February 2018).

83 Victorian Minister for Health, The Hon Jill Hennessy, 'Transvaginal Mesh Support for Victorian Women', *Media release*, 19 December 2017, <https://www.premier.vic.gov.au/transvaginal-mesh-support-for-victorian-women/> (accessed 1 February 2018).

84 Victorian State Government, Better Health Channel, *Transvaginal mesh*, <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/Transvaginal-mesh> (accessed 1 February 2018).

85 Dr Kerry Chant, *Committee Hansard*, 18 September 2017, p. 53.

86 Dr Marianne Gale, Medical Adviser, Office of the Chief Health Officer, New South Wales Ministry of Health, *Committee Hansard*, 18 September 2017, p. 54.

87 Dr Kerry Chant, *Committee Hansard*, 18 September 2017, p. 53.

5.148 In December 2017, the NSW Government released a safety notice advising:

- Patients seeking access to medical records should be assisted and where health information sought relates to continued treatment and/or future management, no charge should be raised.
- Patients presenting with symptoms following transvaginal mesh procedures should be provided with information sheets and supported to access multidisciplinary specialist services for the assessment and management of complications.
- Mesh removal should only be considered at specialist centres with the appropriate multidisciplinary model in place, including a qualified urogynaecologist as the lead, and comprehensive diagnostic procedures in place, including someone experienced in performing and interpreting pelvic floor ultrasound.
- Supporting disciplines to include: pain services; pelvic floor physiotherapists and psychology. Urology and colorectal units should be available for consultation.
- The location of specialist multidisciplinary services with an experienced urogynaecologist.
- Guidance on reporting adverse events to the TGA and incidents, near-misses or complaints to the Incident Information Management System.⁸⁸

Australian Capital Territory

5.149 On 9 January 2018, the ACT Health announced that it is directly contacting all women who have been identified as having undergone transvaginal mesh procedures at Canberra Hospital and Health Services within the past 10 years to notify them of the issues and the options available to them if they are concerned. A dedicated phone service and email address has also been established.⁸⁹

Committee view

5.150 The committee considers that the support and referral services being established by the states and territories go some way to providing an appropriate level of care for women suffering from mesh related complications. The committee encourages states and territories to continue to work with the ACSQHC and women affected by transvaginal mesh in the implementation of services.

Recommendation 13

5.151 The committee recommends that State and Territory governments continue to work with the Australian Commission on Safety and Quality in

88 NSW Government, Safety Notice 015/17, *Transvaginal mesh implants for Pelvic Organ (Vaginal Prolapse)*, 20 December 2017, <http://www.health.nsw.gov.au/sabs/Pages/default.aspx> (accessed 17 January 2018).

89 ACT Government, ACT Health, *Transvaginal Mesh*, 9 January 2018, <http://www.health.act.gov.au/node/8925> (accessed 9 February 2018).

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.**

Concluding comments

5.152 The committee wishes to say to the women who have given us evidence that it has heard them. It understands the different perspectives that have been brought to this inquiry. The committee hopes that the findings and recommendations that it has made as a result of this inquiry serve women well by improving regulatory processes and care pathways such that they are robust, evidence based, clinically sound and focused on good patient outcomes.

5.153 The committee thanks all women for their courage in coming forward to provide their very personal accounts to the inquiry.

Senator Rachel Siewert

Chair

