Australian Government

Department of Health

SECRETARY

31 May 2017

Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Committee Secretary

INQUIRY INTO NUMBER OF WOMEN IN AUSTRALIA WHO HAVE HAD TRANSVAGINAL MESH IMPLANTS AND RELATED MATTERS.

Please find attached the Department of Health's submission to the Senate Community Affairs References Committee - Inquiry into number of women in Australia who have had transvaginal mesh implants and related matters. The Therapeutic Goods Administration (TGA) is responsible for regulation of medical devices including urogynaecological meshes, and is part of the Department of Health.

The Department acknowledges the importance of this inquiry and the significant health issues, including chronic, severe and life changing pain and complications, which are being experienced by many women who have had urogynaecological mesh implanted. This submission aims to provide background on these medical devices, in respect of both how they have been and are currently regulated, and the emerging evidence about their use.

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Yours sincerely

Martin Bowles PSM
Secretary

Australian Government
Department of Health

SUBMISSION TO THE SENATE COMMUNITY AFFAIRS REFERENCE COMMITTEE:

INQUIRY INTO THE NUMBER OF WOMEN IN AUSTRALIA WHO HAVE HAD TRANSVAGINAL MESH IMPLANTS AND RELATED MATTERS – 29 MAY 2017

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EXECUTIVE SUMMARY

This submission has been prepared by the Therapeutic Goods Administration (TGA) which is the part of the Commonwealth Department of Health responsible for regulation of medical devices including urogynaecological meshes. This inquiry is important in recognising and investigating the significant health issues, including chronic, severe and life changing pain and complications, which are being experienced by many women who have had urogynaecological mesh implanted. This submission aims to provide background on urogynaecological meshes, in respect of both how they have been and are currently regulated, and the emerging evidence about their use.

Surgical mesh devices were originally developed for the treatment of abdominal hernias. In the late 1990s device manufacturers began supplying the first meshes specifically for application in urogynaecological surgery. In the following decade there was rapid uptake of urogynaecological meshes in Australia and overseas for use in the surgical treatment of stress urinary incontinence, followed by the expansion of surgical mesh treatment of pelvic organ prolapse.

Prior to 2002, there was no separate regulatory framework for medical devices in Australia. Rather, medical devices were regulated using the same approach as medicines and were included in the Australian Register of Therapeutic Goods (ARTG) as either a listed or registered therapeutic device[1].

The current regulatory framework for medical devices that came into force in 2002 is based on *Global Harmonization Taskforce*[2] principles of medical device regulation which also form the basis of the European Union medical device regulations.

In brief, the Australian framework has two pre-market components: (1) manufacturers of all medical devices supplied in Australia must demonstrate compliance with safety and performance requirements, known as Essential Principles, reflected in conformity assessment certification, commensurate with intended purpose and risk classification; (2) high risk classified devices (Class III) undergo further mandatory pre-market assessment prior to inclusion of the device into ARTG. Postmarket monitoring of ARTG included devices is then ongoing.

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[1] Categorisation as 'listed' or 'registered' was based on legislated groupings of products; the level of pre-market assessment by the TGA was also governed by the 'listed' or 'registered' categorization; EU certification and FDA approval of therapeutic devices was also an acceptable basis for listing. The term 'medical device' was introduced in Australia with the introduction of the current regulatory framework under the *Therapeutic Goods Act 1989* and the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations).

[2] The GHTF was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems. This was done with two aims in mind: enhancing patient safety and increasing access to safe, effective and clinically beneficial medical technologies around the world.
A partnership between regulatory authorities and regulated industry, the GHTF was comprised of five Founding Members: European Union, United States, Canada, Australia and Japan. The International Medical Device Regulators Forum (IMDRF) is continuing the work of the GHTF.

Because the majority of medical devices that are supplied in Australia are imported, there have been consistent requests from both external reviews of the Australian system and the local medical device industry asking that foreign regulatory approvals feature more dominantly in the Australian market authorisation process. Successive Governments have supported implementation of this approach, as well as endorsing the regulatory framework of 2002 (including risk classification). Overwhelmingly the recommendations handed down from reviews into the activities of the TGA over the last 15 years, including the 2015-16 Expert Panel Review of Medicines and Medical Device Regulation have stated that the TGA should draw upon the activities of comparable foreign regulatory authorities whilst still maintaining a sovereign and effective regulatory capacity in Australia[3].

Hence for the majority of medical devices (except for devices that contain medicines or tissues or substances of animal, microbiological or recombinant origin), sponsors seeking to supply a device in Australia (including those manufactured in Australia) can provide conformity assessment certification issued to the manufacturer by a European Notified Body to support their application for inclusion of a device in the ARTG.

All regulatory agencies strive to achieve a balance between timely access to promising medical interventions and protecting the safety of patients whilst further research evidence is accumulating over time. In the case of urogynaecological mesh, the first devices were approved in Australia in 1998 and for a number of years afterwards they were portrayed as significant beneficial advances in comparison with other surgical alternatives[4]. It was only in 2006, some eight years later, that the first adverse event was reported to the TGA.

For some devices and surgical procedures it takes many years for the full picture of the benefits and harms to be established. This conundrum has been acknowledged by a number of recent international reviews of the use of urogynaecological meshes[5].

For example, synthetic mid-urethral mesh sling is the standard of care for most healthy women seeking surgical treatment of stress urinary incontinence worldwide. The favourable benefit to risk balance at population level for this use is supported by clinical evidence developed over the past two decades. Delaying access to a medicine or a medical device for use in clinical practice in Australia for eight or more years after they have become available in Europe or the United States to see if adverse events occur would not be considered reasonable and certainly not in the interests of patients.

Unfortunately, there are some examples of both medicines and medical devices for which the health outcome advantages observed earlier in the lifecycle of a product do not subsequently translate into enduring health benefits for some or all of the originally

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[3] Australian Government Responses: 'Review of Medicines and Medical Devices Regulation', May 2016. 'Review of Health Technology Assessment in Australia. 2010. Commonwealth of Australia publication. McEwan J. 2007. 'A History of Therapeutic Goods Regulation in Australia.

[4] For example: http://www.smh.com.au/national/advance-aids-prolapse-recovery-20091006-glh5.html

[5] Mowat, A.E., Maher, C. February 2017. *Transvaginal mesh: let's not repeat the mistakes of the past*. ANZJOG, V57; http://onlinelibrary.wiley.com/doi/10.1111/ajo.12597/full; Maher C, Haya N. *The transvaginal mesh decade*. Expert Reviews in Obstetrics and Gynaecology (2013) 8(5):485-92.

intended population for use of the product. In some instances, the benefit to risk balance can become unfavourable over time, for all or some of the uses of that product, or in some or all patient groups. This is where the evidence is now pointing in the case of urogynaecological meshes for transvaginal use in pelvic organ prolapse.

The actions taken by the TGA to date with respect to urogynaecological meshes fall into two categories: greater stringency of pre-market assessment, and postmarket reviews.

Since early 2014 all new applications for ARTG inclusion for urogynaecological mesh devices, including Class IIb devices, are selected for a supplementary application audit of their conformity assessment certification. The audit includes assessment of the supporting clinical evidence over and above the conformity assessments already carried out by a European Notified Body. This underlines the greater stringency of assessment for these products by Australia currently compared with the EU.

The first Australian postmarket activity was in response to the 2008 US-FDA safety alert regarding the use of urogynaecological meshes. At that time the TGA took the US-FDA information and domestic reports of adverse events to an expert committee for consideration[6]. The expert committee considered international developments relating to urogynaecological mesh and the domestic reports of adverse events and recommended that the TGA continue monitoring domestic adverse event reports and - if there was increase in the pattern of reports - undertake investigation and further review of meshes.

In 2010 the TGA undertook a review in response to a report that removal of mesh was not able to be safely performed because it was difficult to be visualised by surgeons once implanted. Broader review and consultation actually found that most meshes were coloured or had radio-opaque markers included within the mesh, so that visualisation should be straightforward. Therefore, no further regulatory action was taken at that time.

To further consider the available clinical evidence in 2012, the TGA commenced a more comprehensive review of the available literature relating to urogynaecological meshes[7]. A Working Group was also established to provide independent expert advice to the TGA on matters related to the safety and performance of urogynaecological mesh[8].

Both these reviews highlighted the importance of appropriate patient selection, surgeon training and experience and the need for informed patient consent.

The 2013 TGA postmarket review was much larger. It assessed the supporting clinical evidence for the approximately 100 devices then included in 42 entries of the ARTG. Sponsors cancelled 14 entries during the review process. The TGA cancelled a further 8

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[6] *Medical Device Incident Review Committee (MDIRC)* meeting, 17 November 2008. The role of the statutory MDIRC was to advise and make recommendations to the Minister for Health and the Therapeutic Goods Administration (TGA) on the safety, risk assessment, risk management and performance of medical devices supplied in Australia. The *Advisory Committee on Medical Devices (ACMD)* now fulfils this function.

[7] TGA Publication: *Post Market Review of Urogynaecological Graft Devices Version 1.0*, August 2013.

[8] The Urogynaecological Devices Working Group (UDWG) provided advice to the TGA in relation to urogynaecological meshes on 27 August 2013 and 22 October 2013.

entries for non-compliance with the Essential Principles (that set out the regulatory requirements for safety and performance) and 1 entry for non-payment of fees. A further five entries have been cancelled since the end of the review by sponsors or alternatively those entries no longer support mesh products use in urogynaecological procedures for treatment of stress urinary incontinence or pelvic organ prolapse. Fourteen (14) entries currently remain on the ARTG covering 29 mesh devices for urogynaecological procedures.

For all devices that were reviewed by the TGA and remain included in the ARTG, three additional conditions of inclusion have been added:

- Annual reporting of all device sales, adverse events in Australia and overseas and complaints for at least 5 consecutive years;
- Sponsors must report all Australian adverse events related to these devices to the TGA with no exemptions permitted;
- Restricting supply of future devices under each ARTG entry without prior evidence review and approval by the TGA[9].

Additional warnings and risks have also been added to the Instruction-For-Use (IFU) documentation for each product. This documentation is essential for communicating known risks to surgeons and assists in the informed consent process.

There has been one Australian manufactured Class IIb urogynaecological mesh device supplied in Australia. The device was included in the ARTG in 2006 and was cancelled by the TGA in 2014 due to lack of evidence of compliance with the Essential Principles for safety and performance. The sponsor (TFS Surgical) has appealed this TGA decision to the Administrative Appeals Tribunal (AAT) and the case is currently pending.

As the evidence available for urogynaecological mesh is continuing to evolve, the TGA is actively considering the latest information, together with the existing body of evidence, with a view to taking further regulatory actions. In addition, given that the Australian regulatory system is harmonised with the European regulations, and that in May 2017 the EU has approved the up-classification of all surgical mesh products to the highest risk category, it is envisaged that similar changes might be proposed in Australia in the coming months.

All proposals for revising parts of the regulatory framework to align with European changes require public consultation and the careful consideration of government to approve regulatory amendments. Regulatory changes can only be implemented on approval by the Executive Council (of Ministers, chaired by the Governor General), based on a recommendation by the Health Minister. As per the usual procedure, any changes to the Therapeutic Goods Act that may be required to align with the new EU regulatory framework would have to be passed by both houses of the Australian parliament.

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[9] Under the Therapeutic Goods Act, a 'kind of medical device' must generally be included in the ARTG prior to supply in Australia. For high risk devices, a 'kind of device' is a fairly narrow grouping restricted to a single Unique Product Identifier (UPI), typically covering design variations of a single device such as devices with different length, width, shape, etc. For lower classifications, a 'kind of medical device' is a broader concept and covers a range of similar products which have the same sponsor, manufacturer, risk classification, and are described by the term of the same Global Medical Device Nomenclature (GMDN) code. For example, a single ARTG entry may cover a range of different models or brands of similar devices.

The TGA, the Australian Commission on Safety and Quality in Health Care (ACSQHC), and relevant specialist medical colleges are also working together and taking complementary approaches to develop best practice safety and clinical care, and medical device regulations that support such practice. The role of the ACSQHC is to lead and coordinate national improvements in the safety and quality of health care, working in partnership with patients, clinicians, and healthcare organisations. The TGA will continue to require through pre-market assessment and audit, and postmarket monitoring, that the industry sponsors and manufacturers of these devices comply with their regulatory obligations. The ACSQHC's priority is for the development of guidance for consumers, clinicians and health services on the use, complications and removal of urogynaecological mesh products for the treatment of pelvic organ prolapse and stress urinary incontinence. The TGA and the ACSQHC have co-funded consultations with patients who have been affected negatively by certain mesh devices, leading clinicians and their clinical societies about possible ways forward. The ACSQHC has convened a Reference Group to develop guidance for appropriate patient selection, surgical training for insertion and removal of the device, supporting consumers through improved information and decision support tools, and approaches for development of integrated data collection mechanisms. The TGA has taken part in meetings of this Reference Group.

Broader regulatory reforms are also commencing through the implementation of the Government agreed recommendations made by the 2016 Expert Panel Review of Medicines and Medical Devices Regulation.

Several of the reform measures aim to enhance postmarket surveillance and improve the integration of pre- and postmarket activities. These include:

- System improvements and enhancements to enable greater collection of adverse events information to enable streamlined reporting of adverse events to the TGA, as well as improve data analytics through linking with other data (such as MBS item numbers);
- Improvements to the capability to undertake signal detection, drawing from adverse events information, monitoring international evidence and literature, and working with overseas regulators.

Once the necessary legislation is in place, the implementation of the reforms is expected to take place over the next 12 to 18 months[10].

[10] The Expert Panel also recommended development of registries for all high risk implantable devices as part of a more comprehensive postmarket monitoring scheme. The Government deferred overall implementation of this recommendation until further consultation with stakeholders has been done to adequately assess the risks and benefits of establishing registries, and to determine appropriate mechanisms to enable access to data. Nevertheless, the Government has continued its funding support for the development of two new registries for implantable devices - the Cardiac Devices Registry and the Australian Breast Device Registry for a further year. This budget measure will align with the completion of a national clinical quality registry policy and funding framework being developed by the Department of Health.

GLOSSARY

ARTG	*Australian Register of Therapeutic Goods - medical devices obtain market authorisation in Australia by inclusion in the ARTG. Unless specifically exempt or excluded, all medical devices must be included in the ARTG prior to supply in Australia.*
Application for ARTG Audit (application audit)	*The audit of applications for ARTG inclusion may involve a desk top review of various information relevant to the device (subject of the application) such as the labelling, instructions for use, technical and advertising materials for the device, clinical evidence, risk management documentation for the device, reports from the EU Notified Bodies, or TGA microbiology assessment.*
Conformity Assessment	*Conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device complies with the Essential Principles and conforms to the requirements of the relevant legislation.*
Conformity Assessment Procedure	*How a manufacturer demonstrates that they have met the Essential Principles and legislative requirements for particular medical devices*
Conformity Assessment Certification	*The certification issued by a regulatory body (or designated third party Conformity Assessment Body) to demonstrate that a manufacturer has been assessed and has the appropriate systems in place to manufacture their devices.*
Design Examination Certification	*A particular kind of conformity assessment certificate that is issued to the highest risk class of device (Class III) once that device has been assessed and found to comply with the Essential Principles and legislative requirements.*
Essential Principles	*The Essential Principles set out the requirements relating to the safety and performance characteristics of medical devices. For a medical device to be supplied in Australia, it must be demonstrated that the relevant Essential Principles have been met.*
EU Notified Body	*EU Notified Bodies are commercial entities that have been designated (by European Union national regulatory authorities) to issue conformity assessment certification according to the European Union medical devices legislation.*
GHTF	*The Global Harmonization Task Force (GHTF) was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems. It was a partnership between regulatory authorities and regulated industry. The GHTF was comprised of five founding Members: European Union, United States, Canada, Australia and Japan. The work of the GHTF now continues under the International Medical Device Regulators Forum (IMDRF)*

Market Authorisation or Market Approval	*In the context of Australian medical device regulation, Market Authorisation or Market Approval is obtained by a sponsor of a device once the TGA includes the device in Australian Register of Therapeutic Goods (ARTG). ARTG inclusion requires that the manufacturer of the device holds appropriate conformity assessment certification. Once a device is included in the ARTG it is able to be legally supplied in Australia.*
Mesh Exposure or Erosion	*Mesh exposure or erosion is a possible complication of prolapse or incontinence surgery where mesh is used. The mesh can become exposed through the vaginal wall, and/or come into contact with the pelvic organs, such as the bladder, the urethra, or the bowel.*
Native Tissue Repair - NTR	*Native Tissue Repair refers to surgical repair of pelvic organ prolapse or stress urinary incontinence that utilises only the patient's own local tissue. The weakened area may be reinforced with stiches and nearby tissue and it is the surgical method used to repair prolapse or incontinence when not using a surgical mesh.*
POP	*Pelvic Organ Prolapse (POP) is where the lower pelvic organs - bladder, uterus or bowel - have prolapsed, or moved down, into the vagina or anus. The most common cause is pregnancy, labour and childbirth. POP is a common condition, and up to 50 per cent of women who have been through childbirth will have some prolapse present.*
RANZCOG	*Royal Australian and New Zealand College of Obstetricians and Gynaecologists*
Sponsor	*A sponsor is the person or company who takes legal responsibility for supplying a medical device in Australia.*
Surgical mesh	*Surgical mesh is a medical device that is used to provide additional support to weakened or damaged tissue.*
SUI	*Stress Urinary Incontinence (SUI) is the leaking of urine during activities such as coughing, lifting and playing sport. The causes of SUI are similar to POP. SUI affects about one third of women of childbearing age.*
TGA	*Therapeutic Goods Administration is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.* *Medical devices in Australia are regulated under the Therapeutic Goods Act 1989, and the Therapeutic Goods (Medical Device) Regulations 2002*
Transvaginal - TV	*Transvaginal means 'through the vagina'. In the context of urogynaecological mesh, transvaginal refers to the mesh being surgically introduced through the vagina (as opposed to through the abdomen).*

Urogynaecological mesh	*Urogynaecological mesh refers to implantable medical devices that are used in the surgical treatment of urogynaecological disorders such as pelvic organ prolapse or stress urinary incontinence. There are various mesh types and various surgical methods that are used in surgical treatment of POP and SUI.*
US-FDA	*United States Food and Drug Administration. The medicines and medical device regulatory authority in the USA.*

UROGYNAECOLOGICAL ANATOMY AND SURGICAL MESH

Pelvic organs in women include the bladder, uterus and rectum and are held up from above by tissues called 'fascia' and 'ligaments' and they are supported from below by the pelvic floor muscles. If any of the supporting structures are stretched or damaged, as can occur with long term coughing/straining, obesity, pregnancy or childbirth and menopause, then the pelvic organ/s can bulge and sag down into the vagina. This is known as pelvic organ prolapse (POP)[11]. Pelvic organ prolapse (POP) is a common condition, and up to 50% of women who have given birth will have some prolapse present.

POP can be asymptomatic, with women unaware of the condition, or symptomatic. Symptoms relating to POP are varied and can range in severity, often including one or more of: back and pelvic pain, vaginal pressure, vaginal discomfort, urinary incontinence or urinary obstruction, bowel incontinence or other bowel dysfunction, bleeding or unusual vaginal discharge, pain during exercise, and pain during sex. Troublesome POP symptoms can be managed conservatively with pelvic floor exercises, diet and lifestyle changes, or vaginal pessaries (silicone devices that are inserted into the vagina to support the pelvic organs).

Each woman is affected by prolapse differently. The symptoms of POP can impact on normal everyday life and can also have significant negative health, social and psychological outcomes if left untreated. Conservative management is the first line option for any woman with POP, but surgery is an option for women who have symptomatic prolapse and have not been unable to achieve relief through conservative management.

Stress Urinary Incontinence (SUI) is where there is accidental or involuntary loss of urine from the bladder, usually during activities that increase pressure within the abdomen and push down on the bladder, for example, exercise or laughing. Contributing factors can be long term cough, long term constipation, obesity, pregnancy, childbirth and menopause[12]. Statistics vary with populations, age and how the severity of the incontinence is assessed. Bothersome stress urinary incontinence has been reported in 15% of women aged 25-84[13].

As with POP, symptoms can be mild, moderate or severe and can significantly affect quality of life. SUI can be managed non-surgically through bladder training, strengthening of the pelvic floor, weight loss, medication, incontinence pessaries (devices inserted into the vagina to support the bladder), absorbent pads, or the use of a catheter. If the symptoms of SUI do not resolve or are severe then surgery can be considered.

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[11] Continence Foundation of Australia. Pelvic floor muscles. Information accessed from: https://www.continence.org.au/pages/prolapse.html (31/3/2017).

[12] Continence Foundation of Australia. Pelvic floor muscles. Information accessed from: https://www.continence.org.au/pages/what-is-incontinence.html (31/3/2017).

[13] Lukacz ES et al. *Evaluation of women with urinary incontinence*. UpToDate. Last updated Dec 2016. Accessed from: https://www.uptodate.com/contents/evaluation-of-women-with-urinary-incontinence (3/4/17).

Surgical treatment options for POP and SUI

There are a variety of surgical operations that can be chosen to treat SUI. In the late 1990s open colposuspension was the main operation provided for SUI. Colposuspension involves making an incision in the lower abdomen, lifting up the neck of the bladder, and stitching it in this lifted position. Urogynaecological mesh (also called tape) procedures were introduced in late 1990s and became more common than colposuspension. This is because midurethral mesh slings have the same rate of relief of SUI symptoms as colposuspension (about 80 per cent), but with quicker recovery time and fewer adverse events such as de-novo urinary urgency. The operation using a midurethral synthetic mesh sling involves inserting it through a small vaginal incision and placing half way down the tube carrying urine from the bladder (urethra) to provide support when abdominal pressure is increased, and then exit through the abdomen[14].

Today, synthetic mid-urethral mesh sling is the standard of care for most healthy women seeking surgical treatment of SUI worldwide. The favourable benefit to risk balance at population level for use in SUI is supported by clinical evidence developed over the past two decades[15]. It has most recently been confirmed by a population-based cohort study of 16,660 women in Scotland covering a period from 1997-2016. The study concluded that this procedure is effective and safe in comparison with colposuspension, with fewer immediate and similar late complication rates up to 5 years later[16].

POP surgery can be done through incisions in the abdomen (transabdominal) or through the vagina (transvaginal). There are different compartments of the vagina affected in POP: anterior/cystocele (bladder bulging into vagina), posterior/rectocele (rectum bulging into vagina) or apical/vaginal vault (uterus descending into vagina).

The choice of surgical approach depends on the type of prolapse and individual patient characteristics. Repair of the weakened tissue can be done utilising the patient's own tissue (native tissue repair) and/or using surgical synthetic mesh or biological grafts. A benefit of native tissue repair is that no foreign materials (such as surgical mesh) are introduced, so there is no risk of 'foreign body' response[17]. However, there is the risk of donor site complications such as infection, or not having enough tissue available to adequately repair the prolapse.

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[14] Jelovsek JE et al. *Surgical management of stress urinary incontinence in women: Choosing a type of midurethral sling.* Last updated Feb 2017. Accessed from: https://www.uptodate.com/contents/surgical-management-of-stress-urinary-incontinence-in-women-choosing-a-primary-surgical procedure?source=search_result&search=mid%20urethral%20sling&selectedTitle=3~150#H30.

[15] Scottish Government publication: Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women Final Report March 2017.

Ford AA, Rogerson L, Cody JD, Ogah J. *Mid-urethral sling operations for stress urinary incontinence in women.* Cochrane Database of Systematic Reviews 2015, Issue 7. Art. No.: CD006375.

[16] Morling JR et al. *Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997-2016: a population-based cohort study*. Lancet 2017; 389:629-40.

[17] A 'host' or 'foreign body' response is the way an individual's body and immune system reacts to a foreign body, for example, a mesh device that is implanted.

For isolated anterior or posterior prolapse, guidelines from professional bodies do not recommend the use of mesh in the transvaginal repair of prolapse (anterior and posterior colporrhaphy without mesh)[18]. For apical prolapse (either isolated or with anterior or posterior prolapse), repair via abdominal sacral colpopexy (with permanent synthetic mesh) is the first-line option[19]. A reasonable first-line alternative is a transvaginal procedure without mesh (vaginalcolporraphy, sacrospinous or prespinous ligament suspension)[20].

Surgical mesh

Surgical mesh is a medical device that is used to provide additional support to weakened or damaged tissue. Surgical mesh was developed for the repair of abdominal hernia (a weakening in the abdominal wall). The first mesh product specifically for SUI was approved by the US-FDA in 1996, and for POP in 2002. The TGA approved the first urogynaecological meshes for supply in Australia in 1998.

There is a variety of mesh types available on the market. The most commonly used mesh in prolapse and incontinence surgery is permanent (non absorbable) synthetic mesh made of polypropylene[21]. Recently, lightweight permanent synthetic polypropylene meshes have been marketed. Whilst in theory these newer lightweight meshes might have fewer adverse events than older meshes, this is yet to be confirmed in clinical studies.

Absorbable synthetic meshes that gradually resorb into the body after having provided initial structural support have been manufactured, although none are approved in Australia. Another less commonly used option is a biological graft.

Urogynaecological mesh usage in Australia

The Department of Health holds a number of different sources of information that can be used to understand the number of women who have received urogynaecological mesh in Australia.

The sources of information that have been examined include:

1. Supply records from Australian sponsors of urogynaecological meshes
2. The Medicare Benefit Schedule (MBS) codes relating to POP and SUI procedures
3. The number of episodes of prostheses utilisation from the Prostheses List.

There is no single definitive source of information for the number of urogynaecological meshes that have been implanted into women in Australia.

There are a number of MBS items for pelvic organ prolapse and stress urinary incontinence surgeries conducted in private clinical practice. Currently, the item descriptors for these procedures specify that techniques “with or without mesh” can be employed. As such, the

[18] RANZCOG 2016 Statement. Polypropylene vaginal mesh implants for vaginal prolapse C-Gyn 20

[19] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Brown J. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD012376

[20] RANZCOG 2016 Statement. Polypropylene vaginal mesh implants for vaginal prolapse C-Gyn 20

[21] A polymer used in a variety of surgical, medical, and non-medical applications.

descriptors are not defined in a way that allows an accurate determination of the number of procedures where surgical mesh was used, or the type of mesh used (whether biological or synthetic).

Whilst an approximation of the average number of services for pelvic organ prolapse and female stress urinary incontinence could be provided, it is not currently possible to further interrogate the Medicare data or to separate out the procedures that employed mesh from those that did not.

The Prostheses List is the list of surgically implanted prostheses, human tissue items and other medical devices that private health insurers must pay benefits for when they are provided to a patient with appropriate health insurance cover and there is a MBS item for the procedure. There are a number of urogynaecological meshes listed on the Prostheses List. Prostheses List utilisation data, however, only gives an indication of the number of transvaginal meshes used in the private sector.

Prostheses List information and Medicare data together provide an incomplete picture of the number of mesh surgeries in Australia as procedures performed in public hospitals for public patients do not attract Medicare benefits.

The MBS Review Taskforce is currently undertaking a program of work across the entire MBS to ensure it is contemporary, reflects up-to-date clinical practice and allows for the provision of health services that improve health outcomes. As part of the MBS Review, a number of Clinical Committees and Working Groups are undertaking clinical reviews of individual MBS items.

The Gynaecology Clinical Committee of the MBS Review Taskforce is currently reviewing MBS items for the use of biological and permanent mesh, and other gynaecology related items. The provision of services for the removal of mesh is also being considered as part of this review.

The Gynaecology Clinical Committee of the MBS Review Taskforce recently reviewed these procedures and its draft recommendations include:

1. revising MBS item number so that mesh and non- mesh surgery is distinguished to enable better data collection
2. restrict use of mesh to patients who are undergoing revision surgery (i.e. primary operative repairs have failed to relieve symptoms)
3. introduce specific MBS items for mesh removal.

These recommendations will undergo public consultation during 2017, before the Taskforce make its final recommendations to Government.

In the meantime, the supply numbers provided by the Australian sponsors of urogynaecological mesh devices could be considered the best indicator we have of the extent of their use. The current medical device regulations require that sponsors hold

supply records for 10 years for urogynaecological meshes[22]. However, many industry sponsors have records of supply reaching further back in time. From this information it is calculated that since 1998 there has been about:

- 31, 805 meshes intended for pelvic organ prolapse procedures supplied in Australia
- 106, 512 meshes intended for use in stress urinary incontinence procedures supplied in Australia
- 12, 144 meshes with intended use for SUI or POP procedures supplied in Australia

It must be noted that supply numbers for meshes does not equate to the number of women receiving urogynaecological mesh because not all meshes supplied have been implanted. Also, more than one mesh may be used in a single surgical procedure, particularly for POP procedures.

The number of women in Australia who have had transvaginal mesh implants (Terms of Reference 1(a)): There is no single definitive data source for the number of women who have had an urogynaecological mesh implant in Australia. The TGA has obtained supply information from the sponsors that sold these devices in Australia. It is estimated that around 151,000 urogynaecological mesh devices have been supplied in Australia since 1998. This does not equal the number of women who have received mesh implants because not all supplied meshes are implanted, and surgeons may elect to use more than one mesh in a single surgical procedure.

The safety signal for urogynaecological mesh devices was relatively slow to emerge. Although the first device was approved in Australia in 1998, the first adverse event relating to an urogynaecological mesh was received by the TGA in 2006. Between 2006 and October 2012, the TGA received 63 adverse events for all urogynaecological meshes[23]. By 2014 the most frequently reported adverse events were pain and erosion.

The number of women in Australia who have had transvaginal mesh implants who have experienced adverse side effects (Terms of Reference 1(b): As of 29 May 2017, the TGA has received a total of 226 (covering 249 patients) adverse event reports relating to implantation of urogynaecological meshes (some reports cover adverse events from more than one patient). It is highly likely that the number of women experiencing adverse events from implantation of urogynaecological meshes is more but no accurate figures are available

[22] The distribution record retention period requirement is based on the risk classification and usage of a device. Class III devices and Class IIb implantable devices are required to supply distribution records for a 10 year period when requested under Regulation 8.1 of the Therapeutic Goods (Medical Devices) Regulations 2002.

[23] TGA statement - Behind the news, urogynaecological surgical mesh implants – statement provided to the 7.30 Report (ABC) by the TGA, 15 October 2012

The number of women in Australia who have made attempts to have the mesh removed in Australia or elsewhere (Terms of Reference 1(c)): The TGA does not regulate clinical practice and current MBS descriptors do not permit an estimation of MBS services for the removal of the mesh. Out of the total of 243 women for whom the TGA holds an adverse event report, 90 have reported undergoing a procedure to remove the mesh device. Four of the women reported that their mesh removal surgery occurred in the USA. One report states that partial mesh removal surgery was performed in Australia with more mesh to be surgically removed in the USA[24].

In Australia, and the overwhelming majority of OECD countries, only sponsors and manufacturers have mandatory reporting obligations for device adverse events[25]. Adverse event reporting to the TGA is thus voluntary for surgeons, other healthcare professionals, and patients. The TGA has implemented a program[26] to raise the profile and encourage spontaneous reporting of all adverse events related to medical devices by health care professionals. Additionally and specific to urogynaecological meshes, the TGA released on 2 August 2016 a web statement encouraging patients to report adverse events. This statement was also shared with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists with a request that it would also be disseminated to its members.

In 2012 the TGA introduced a web-based form for consumer reporting of adverse events for medical devices, and also publicised its existence with consumer groups and encouraged them to report. However, we recognise that the current adverse events reporting mechanism is not sufficiently user friendly for consumers. We are working with ACSQHC to develop ways to facilitate the reporting of incidents by consumers and health professionals with a view to receiving a more comprehensive picture of adverse events for a medical device.

CLINICAL PRACTICE

The TGA has no regulatory powers with respect to the clinical practice of medical practitioners.

The Australian framework for regulation of medical practitioners and the services they provide is complex, with different responsibilities for each of the Commonwealth, state and territory governments, professional organisations, independent statutory bodies and public and private hospitals.

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[24] TGA postmarket information.

[25] Regulation 5.7 of the Therapeutic Goods (Medical Devices) Regulations 2002.

[26] The TGA *insite* program was established to enhance relationships with health professionals at the various levels of governance within state and territory government health departments, individual public hospitals, area health networks and the private health sector. The program was piloted in the Canberra hospital and is now operating in areas of Sydney.

Quality of clinical practice is principally a matter of professional judgment by the individual medical practitioner, assisted by codes of conduct, and guidelines and policies issued by the profession. Individual medical colleges are responsible for the determination and maintenance of standards for their respective disciplines and for the training and education of medical specialists in that discipline. The credentialing of surgeons is a hospital responsibility.

Information provided to women prior to surgery about possible complications and side effects (Terms of Reference 2): Under the *Therapeutic Goods Act 1989* the TGA has no regulatory role with respect to clinical practice. In November 2016 the Royal Australian and New Zealand College of Obstetricians and Gynaecologists published a statement detailing the paramount importance of informed patient consent for prolapse surgical treatment involving urogynaecological mesh[27]. This statement advised that the informed patient consent process should be wide ranging and should cover issues such as: alternatives to surgical management, surgical alternatives to mesh procedures, the limited clinical data available for mesh products, and comprehensive discussion around potential mesh complications and the difficulty in treating these complications.

The ACSQHC's priority is for the development of guidance for consumers, clinicians and health services on the use, complications and removal of urogynaecological mesh products for the treatment of pelvic organ prolapse and stress urinary incontinence. The ACSQHC has convened a Reference Group to develop guidance for appropriate patient selection, surgical training for insertion and removal of the device, supporting consumers through improved information and decision support tools, and approaches for development of integrated data collection mechanisms. TGA has been an active participant in meetings with ACSQHC and of the reference group.

Information provided to doctors for urogynaecological meshes (Terms of Reference 3): Under the *Therapeutic Goods Act 1989* the TGA's remit includes regulatory oversight of the information that industry sponsors must provide for all medical devices – termed the 'instructions-for-use'. As part of a postmarket review, the TGA requested the recall for product correction of urogynaecological meshes on the ARTG. The manufacturers were required to release updated instructions-for-use to include additional advice on appropriate patient selection and more explicit information regarding possible complications. This is described further under the response to *Terms of Reference 6*.

[27] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. College Statement C-Gyn 20. *Polypropylene Vaginal Mesh Implants for Vaginal Prolapse*. Current November 2016

Financial or other incentives provided to medical practitioners (Terms of Reference 4): The TGA is not aware of any reports of surgeons receiving financial or other incentives to promote the use of urogynaecological mesh devices.

SURGICAL MESH COMPLICATIONS

As mentioned previously, the safety signal for urogynaecological mesh devices was relatively slow to emerge. Although the first device was approved in Australia in 1998, the first adverse event relating to an urogynaecological mesh was received by the TGA in 2006.

For a number of years key clinical and surgical leaders emphasised the advantages of surgical procedures with these kinds of devices in comparison with existing surgical techniques especially for the treatment of SUI. The synthetic mid-urethral mesh sling remains the standard of care for most healthy women seeking surgical treatment of SUI worldwide on the grounds of demonstrated favourable benefit to risk balance at population level. Regulators such as the TGA assess risk-benefit of medicines and devices at the population level i.e. for intended use in particular populations.

The types and incidence of health problems experienced by women with transvaginal mesh implants and the impact these health problems have had on women's lives (Terms of Reference 5): All surgical operations can potentially have complications. Mesh complications can cause a range of symptoms that are experienced by the patient including physical, social and emotional impacts.

Adverse events that have been identified over time in the medical literature to be associated with the use of urogynaecological mesh are listed as follows: punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel (these may require surgical repair); transitory local irritation at the wound site; a 'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation); mesh extrusion, exposure, or erosion into the vagina or other structures or organs; infection; over-correction (too much tension applied to the mesh tape) may cause temporary or permanent lower urinary tract obstruction; acute and/or chronic pain; voiding dysfunction; pain during intercourse; neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area; recurrence of incontinence; bleeding including haemorrhage, or haematoma; seroma; urge incontinence; urinary frequency; urinary retention; adhesion formation; atypical vaginal discharge; exposed mesh may cause pain or discomfort to the patient's partner during intercourse; mesh migration; allergic reaction; abscess; swelling around the wound site; recurrent prolapse; contracture; scarring; excessive contraction or shrinkage of the tissue surrounding the mesh; vaginal scarring, tightening and/or shortening; constipation/defecation dysfunction; granulation tissue formation.

A concerning complication of mesh surgery is chronic, severe and life changing pain. This serious adverse event was brought to the attention of regulators and doctors through reports from affected women. These individual reports have been critical in helping the medical community obtain a fuller clinical understanding of urogynaecological surgical mesh outcomes. However, case reports, such as these, do not typically allow calculation of the size of the risk. Put another way, the size of the risk for severe chronic disabling pain, following a mesh operation, cannot be estimated with the data currently available. Better knowledge of the true frequency of adverse events would greatly inform decision making around the balance of risks and harms for all therapeutic goods, including urogynaecological meshes.

Another complication of mesh is 'exposure'. This is where mesh can be seen or felt in the vaginal wall. In some cases this is associated with pain or infection, in which case it is sometimes called 'erosion'. Not all, of the women who have chronic severe pain, also have exposure or erosion.

The risk of exposure depends on the nature of surgical operation. When the operation is done through the abdomen for pelvic organ prolapse, the risk of exposure is less than 1 per cent[28]. When the surgical operation is done through the vagina for pelvic organ prolapse, the risk of exposure has been estimated in some studies to be 10 per cent[29]. In contrast, for the other urogynaecological operation where mesh is used—mid urethral sling procedures for stress urinary incontinence—the risk of exposure is less than 2 per cent[30].

Besides mesh exposure and chronic life-changing, severe pain, other complications include those that occur during the operation (for example, accidental perforation of the bladder) and those that occur immediately after the operation (for example, bleeding, infection).

The need for a repeat operation, because the first operation did not work, could also be considered a complication. A repeat operation puts women at extra risk because all operations potentially have complications. Some women develop de novo stress urinary incontinence after a mesh operation for prolapse. This might also require an additional operation, which could have complications.

It is not uncommon for medical technologies, both medicines and medical devices that the health outcome advantages observed earlier in the lifecycle of a product do not subsequently translate into enduring health benefits. In some instances, the benefit to risk balance can become unfavourable overtime, for all or some of the uses of a product and/or

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[28] Nygaard IE, McCreery R, Brubaker L, et al. *Abdominal sacrocolpopexy: a comprehensive review*. Obstetric Gynecology 2004; 104:805.

[29] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. *Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse*. Cochrane Database of Systematic Reviews 2016, Issue 2. Art. No.: CD012079. DOI: 10.1002/14651858.CD012079

[30] Ford AA, Rogerson L, Cody JD, Ogah J. *Mid-urethral sling operations for stress urinary incontinence in women*. Cochrane Database of Systematic Reviews 2015. Issue 7. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub3.

in all or some patient populations. This underpins the importance of strong postmarket monitoring in therapeutic goods regulation.

In 2016, the latest update of the Cochrane systematic review of clinical publications of evidence on use of mesh for pelvic organ prolapse was published[31]. It concluded that permanent synthetic vaginal mesh for prolapse might be useful for particular individual women, who might be willing to accept the risks. Such women might include those with a large prolapse (which is particularly debilitating for the activities of daily living) or those who had previous surgery, which had failed. However, there was limited information as to the benefits and risks for such individual women. The review stated that more research was needed.

In January 2017, the results of the 'PROSPECT' trial were published[32]. This trial compared various types of mesh to native tissue repair for pelvic organ prolapse. The trial participants were women who were having their first surgical repair for pelvic organ prolapse. Rates of successful treatment of the prolapse did not differ between women in the permanent synthetic mesh group versus women in the native tissue repair group. This result is different from previous studies of permanent synthetic mesh versus native tissue repair, which reported higher rates of success with permanent synthetic mesh versus native tissue repair[33].

The large PROSPECT trial has demonstrated that there is no treatment benefit in using a mesh device over native tissue repair in women undergoing initial surgical treatment for prolapse when inserted trans-vaginally. Further, this trial concluded that the use of mesh introduces the potential for mesh-related complications that are not present in native tissue repair surgery.

The TGA is actively considering this recent clinical information, along with the existing body of evidence, with a view to taking further regulatory action for urogynaecological mesh devices. We have been involved in regular meetings with the ACSQHC and relevant healthcare and surgical bodies who are also considering this recent evidence with a view to updating relevant surgical and treatment guidelines. This is described further under the response to *Terms of Reference 6*.

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[31] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. *Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse*. Cochrane Database of Systematic Reviews 2016, Issue 2. Art. No.: CD012079. DOI: 10.1002/14651858.CD012079.

[32] Glazener, Cathryn MA et al. 2016. *Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT).* The Lancet, Volume 389 , Issue 10067 , 381 – 392.

[33] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. *Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse*. Cochrane Database of Systematic Reviews 2016, Issue 2. Art. No.: CD012079. DOI: 10.1002/14651858.CD012079.

REGULATORY FRAMEWORK FOR MEDICAL DEVICES IN AUSTRALIA

Evolution of device regulation in Australia

The regulatory oversight of medical devices has evolved over time in response to technological innovation. Devices that are common today largely came about through a period of rapid technological expansion in the devices sector in the 1980s and 1990s. As with many complex sectors, the level of regulatory oversight has increased over time as product knowledge has increased and with the increases in average human lifespans and widening of healthcare services, many devices are implanted for longer periods of time than even a couple of decades ago.

As medical devices have become a mainstay of contemporary health systems globally, there has been a concerted effort from leading regulatory agencies to find ways of achieving greater uniformity between their national medical device regulatory systems. This significant undertaking was formalised in the 1990s with the establishment of the *Global Harmonization Task Force (GHTF)*. The work of the GHTF now continues under the *International Medical Device Regulators Forum* (IMDRF)[34]. Australia's current medical device regulatory framework came into force in 2002 and is founded on the GHTF principles of regulation as is the European Union's medical device regulations (although the EU adopted elements of the GHTF approach to medical regulation earlier than Australia).

Prior to 2002, there was no separate regulatory framework for medical devices in Australia. Rather, medical devices were termed 'therapeutic devices' and they were regulated using the same approach as medicines under the *Therapeutic Goods Act 1989* and were included in the ARTG as either a listed or registered therapeutic device. Categorisation as 'listed' or 'registered' was based on legislated groupings of products. The level of pre-market assessment by the TGA was governed by the 'listed' or 'registered' categorisation. EU certification and FDA approval of therapeutic devices was also an acceptable basis for listing.

Mesh products that contained human tissue or tissues of animal origin were registered therapeutic devices whereas under the law at that time, all other mesh products were listed therapeutic devices.

The term 'medical device' was introduced in Australia as part of the current regulatory framework under the *Therapeutic Goods Act 1989* and the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations). The role of the TGA in administering this legislation is to consider the safety and performance of medical devices.

Because the majority of medical devices supplied in Australia are imported, there have been consistent requests from both external reviews of the Australian system and the local

[34] www.imdrf.org

medical devices industry asking that foreign regulatory approvals feature more dominantly in the Australian market authorisation process.

Successive Governments have supported the implementation of this approach as well as endorsing the regulatory framework of 2002. Overwhelmingly the recommendations handed down from reviews into the activities of the TGA over the last 15 years, including the 2015-16 Expert Panel Review of Medicines and Medical Device Regulation have stated that the TGA should draw upon the activities of comparable foreign regulatory authorities whilst still maintaining a sovereign and effective regulatory capacity in Australia[35].

Current model of device regulation in Australia

The existing regulatory frameworks operating in the EU and Australia are closely aligned; in fact many requirements are identical. This regulatory alignment, along with the calls to avoid duplication of overseas regulatory activities, means that the Australian market authorisation process relies significantly on the regulatory assessment work undertaken in the EU.

However two points of difference are the mandatory requirement for entry in the ARTG (after receiving appropriate conformity assessment certification) before legal supply of a medical device in Australia, and the additional requirement for mandatory application audits by the TGA for high risk devices (see below). The EU does not have a comparable register of products. Rather legal supply of a medical device can occur after the manufacturer of the device has received appropriate conformity assessment certification from a designated EU Notified Body – often referred to as a 'CE Mark'.

The Australian medical device framework spans the life cycle of a medical device. Two foundational principles of the regulatory framework are:

1. The Essential Principles – which relate to the safety and performance characteristics of medical devices; and
2. A risk-based classification system which determines the level of regulatory oversight.

Manufacturers must be able to demonstrate compliance with the Essential Principles for all medical devices supplied in Australia. The level of regulatory oversight that is then applied to a device is dependent on its intended use and risk classification.

This means that manufacturers can self-declare compliance with the Essential Principles for devices of the lowest risk-classification (for example, a sticking plaster), while for the higher risk classes of devices (for example, a lung ventilator or a pacemaker) a manufacturer's claims of compliance are assessed before providing market authorisation.

[35] Australian Government Responses: 'Review of Medicines and Medical Devices Regulation', May 2016; 'Review of Health Technology Assessment in Australia'. 2010. Commonwealth of Australia publication; McEwan J. 2007. 'A History of Therapeutic Goods Regulation in Australia'.

The Therapeutic Goods Administration's role in investigating the suitability of the implants for use in Australia (Terms of Reference 6(a)):

The TGA is responsible for the regulation of medical devices in Australia which can be broken down into three main parts:

1. Premarket assessment: Conformity assessment and conformity assessment certification
2. Market authorisation: Inclusion in the Australian Register of Therapeutic Goods (ARTG)
3. Postmarket monitoring: Continuing compliance with all regulatory, safety and performance requirements and standards.

Premarket assessment - conformity assessment and certification

Conformity assessment procedures[36] are used by a manufacturer to demonstrate that their medical device conforms to the Essential Principles. Conformity assessment procedures look at things like quality management systems for the design and manufacture of the device, and for the evidence of safety and performance of the device itself, which includes supporting clinical evidence.

For moderate risk and high risk devices, the manufacturer must seek certification from an independent body to demonstrate that the appropriate conformity assessment procedure has been applied – this is called conformity assessment certification. Under the current legislation, manufacturers can obtain conformity assessment certification from either the TGA or from an EU Notified Body.[37,38]

Market authorisation – inclusion of medical devices in the ARTG

Once conformity assessment certification is obtained from the TGA or an EU Notified Body, a sponsor can apply to include the medical device in the ARTG[39]. A sponsor is the person or company who takes legal responsibility for supplying a medical device in Australia and is usually an Australian importer of overseas manufactured medical devices.

The below table describes the conformity assessment certification that is required for the various risk classes of devices in order to obtain market authorisation.

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[36] Conformity assessment procedures are outlined in Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002.

[37] In Australia the TGA is the only body that can issue conformity assessment certificates – though this may change as a result of the Government-agreed-to recommendations of the *Expert Review of Medicines and Medical Device Regulation*.

[38] In the EU, the national regulatory authorities designate commercial entities, called *Notified Bodies*, to issue conformity assessment certification. These certificates are issued under the European Directive 93/42/EEC on Medical Devices or Directive 90/385/EEC on Active Implantable Devices.

[39] Under the Act, a 'kind of medical device' must generally be included in the ARTG prior to supply in Australia. For high risk devices, a 'kind of device' is a fairly narrow grouping restricted to a single Unique Product Identifier (UPI), typically covering design variations of a single device such as devices with different length, width, shape, etc. For lower classifications, a 'kind of medical device' is a broader concept and covers a range of similar products which have the same sponsor, manufacturer, risk classification, and are described by the term of the same Global Medical Device Nomenclature (GMDN) code. For example, a single ARTG entry may cover a range of different models or brands of similar devices.

Table 1 – Risk classes of devices and their conformity assessment certification requirements

Risk Class of Device	Conformity assessment certification needed for Australian market authorisation (ARTG inclusion)
Class I (low risk)	Self-declaration
Class IIa (moderate risk)	TGA conformity assessment certificate, or EU Notified Body certificate of European conformity
Class IIb (moderate risk)	TGA conformity assessment certificate, or EU Notified Body certificate of European conformity
Class III (high risk)	TGA conformity assessment certificates (including design examination), or EU Notified Body certificates of European conformity (including design examination) supplemented by a mandatory TGA application audit

The import dominant nature of the Australian medical devices sector means that the majority of devices supplied in Australia are supported by conformity assessment certification issued by EU Notified Bodies[40].

If a sponsor seeks market authorisation for a device using conformity assessment certification other than that issued by the TGA then the Regulations prescribe whether the TGA must undertake further pre- market assessment of the device prior to inclusion in the ARTG. The Regulations dictate that all high-risk devices (Class III) will undergo a supplementary mandatory TGA application audit prior to market authorisation decision, which includes assessment of the supporting clinical evidence. The Regulations also prescribe mandatory ARTG application audits for a small subset of lower risk (Class IIa or IIb) devices[41].

The TGA can also initiate non-mandatory audits of documentation that supports any application for ARTG inclusion regardless of risk classification. In the calendar year, 2016, about 6% of applications for class IIb medical devices were selected by the TGA for a supplementary non-mandatory audit over and above the certification issued by EU Notified Bodies.

[40] More than 95% of ARTG entries are supported by conformity assessment certification issued by EU Notified Bodies.

[41] Under Regulation 5.3 (Therapeutic Goods (Medical Devices) Regulations 2002), some devices require a mandatory TGA application audit if the sponsor is seeking Australian market authorisation using conformity assessment certification other than that issued by the TGA These devices include barrier contraceptives, implantable contraceptive devices, implantable intraocular lenses, intra-ocular visco-elastic fluid, and all Class III devices.

In the case of urogynaecological mesh, the devices of biological nature are classified as Class III, whilst the majority of urogynaecological mesh devices are currently classified as Class IIb[42]. Nevertheless, as a direct consequence of learnings from the postmarket reviews that the TGA commenced in 2013, the TGA has imposed further regulatory scrutiny of all urogynaecological mesh by mandating that all ARTG applications for these devices undergo a supplementary audit, including review of the supporting clinical evidence, during the premarket authorisation assessment.

Postmarket – continuing compliance

Maintenance of conformity assessment

Once a device is available for supply, manufacturers are required to continue to monitor the safety and performance of their devices. The information generated from adverse event reports and complaints, newly identified risks, published literature, any updated or new clinical investigations, significant regulatory actions and formal surveillance activities such as registries could be used by the manufacturer to ensure continued compliance with the Essential Principles.

TGA postmarket activities

Postmarket monitoring by the TGA is carried out to ensure the ongoing regulatory compliance and safety of medical devices supplied to the Australian market. TGA activities include:

- risk assessment and investigation of medical device adverse event and complaint reports
- targeted postmarket reviews
- conducting inspections of manufacturers' quality management systems and technical documentation
- imposing specific requirements for manufacturers and sponsors to report, within specified timeframes, adverse incidents involving their medical devices.

The sponsor of a medical device has ongoing responsibilities once a device has been included in the ARTG. These statutory responsibilities include that the sponsor must report to the TGA: adverse events, overseas regulatory actions, and the results of investigations undertaken by the manufacturer that result in corrective actions. The sponsor must also maintain distribution records.

All adverse event reports or complaints received by the TGA are analysed according to a risk matrix stratified by frequency and severity of reports. TGA investigations can result in product recovery (recalls); hazard and safety alerts; recalls for product correction by a manufacturer; surveillance inspections of manufacturing sites; and/or suspension or cancellation of market authorisation.

[42] Implantable meshes that contain medicines or biological materials are classified as Class III.

UROGYNAECOLOGICAL MESH IN AUSTRALIA

Urogynaecological mesh market authorisation in Australia

The first urogynaecological meshes was approved for supply in Australia in 1998[43].

Since then, a total of 70 entries for urogynaecological meshes have been included in the ARTG, nine of which precede the introduction of the current Medical Device Regulations (2002) under the *Therapeutic Goods Act 1989*.

As described previously, prior to 2002 categorisation as a 'listed' or 'registered' therapeutic device was based on legislated groupings of products. EU certification and FDA approval of therapeutic devices was also an acceptable basis for listing. Mesh products that contained human tissue or tissues of animal origin were registered therapeutic devices whereas all other mesh products were listed therapeutic devices.

Since 2002, 61 ARTG entries - covering 134 urogynaecological meshes - have been authorised for supply in Australia (note that under the Act, a single ARTG entry can cover multiple devices depending on their risk classification[44]). All these devices have undergone conformity assessment against safety and performance requirements and have received certification from either an EU-Notified Body or from the TGA. The majority of urogynaecological meshes used EU Notified Body-issued conformity assessment certification[45].

The TGA or the EU Notified Body, as part of conformity assessment, will assess a sample of the manufacturer's Class IIb products on a rotating basis in order to confirm compliance and issue certification to the manufacturer. Manufacturers of Class III devices require a more comprehensive assessment. This is called design examination, where each individual device is assessed and certified by the TGA or the EU Notified Body.

Since 2014, all ARTG inclusion applications for urogynaecological mesh devices, regardless of risk classification, that seek market authorisation in Australia based on EU conformity assessment certification, undergo a supplementary application audit carried out by the TGA. This additional scrutiny includes the review, among other things, of the clinical

[43] TGA historical records of ARTG inclusion information: Protegen Sling, sponsor - Boston Scientific Pty Ltd; manufactured by Boston Scientific Medi-Tech/Steris Isomedex Services was included in the ARTG 21/04/1998 and removed from the ARTG 28/02/2002; Vesica Sling Kit with Protegen, sponsor - Boston Scientific Pty Ltd; manufactured by Boston Scientific Medi-Tech/Steris Isomedex Services was included in the ARTG 1/05/1998 and removed from the ARTG 13/01/2003; TVT (TENSION-FREE VAGINAL TAPE), sponsor - Johnson & Johnson Medical Pty Ltd, manufactured by Medscand Medical AB was included in the ARTG 21/07/1998 and removed from the ARTG 11/10/2001.

[44] New products which are devices of the same 'kind' may be supplied under an appropriate existing ARTG entry without further clearance by, or notification to, the TGA (unless required under conditions of ARTG inclusion, or when information entered on the ARTG in relation to the device should be corrected). However, any new device which fits within the 'kind' must meet the requirements of the conformity assessment procedures implemented by the manufacturer in relation to that kind of device (and in line with the risk of the device will be assessed or monitored via the ongoing certification by either TGA or a European notified body.

[45] ARTG records as at 30 April 2017 and TGA administrative records.

evidence provided by the sponsor to support the safety and performance claims of that device.

Australian regulatory review of urogynaecological meshes

In the decade that followed the initial market approvals for urogynaecological meshes there was rapid uptake in the surgical use of these devices internationally. At the time many clinicians thought that surgery with mesh devices could revolutionise the management of pelvic organ prolapse in the same manner as sub-urethral tapes had revolutionised continence surgery[46].

Adverse event reports in the first decade of widespread mesh usage were attributed to insufficient surgical training in the correct placement of the meshes.

In response, a number of national regulatory authorities released statements warning of the potential safety complications arising from urogynaecological mesh and emphasising the need for specialised surgical training, appropriate patient selection, and the paramount importance of informed consent (see Attachment 1 for details).

In 2008 the US-FDA released the first safety alert regarding the use of urogynaecological meshes. The TGA took the US-FDA information and domestic reports of adverse events to an expert committee for consideration[47]. The expert committee considered international developments relating to urogynaecological mesh and the domestic reports of adverse events and recommended that the TGA continue monitoring domestic adverse event reports and advised that if there was increase in the pattern of reports, the TGA should investigate and further review meshes.

In 2010 the TGA undertook a review of a specific urogynaecological mesh issue in response to a report that removal of mesh was not able to be safely performed because it was difficult to visualise the mesh by surgeons once implanted. Broader review and consultation actually found that most meshes were coloured or had radio-opaque markers included within the mesh, so that visualisation should be straightforward. Therefore no further regulatory action was taken at that time.

In 2011, the US-FDA published information advising that, in the USA, adverse events relating to urogynaecological mesh were more common than initially anticipated. In particular, the US-FDA saw a significant increase in the number of adverse event reports, with 2,784 adverse events being reported between 2008 and 2010 for urogynaecological mesh procedures[48].

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[46] Maher C, Haya N. *The transvaginal mesh decade*. Expert Review in Obstetric Gynecology (2013) 8(5):485-92.

[47] *Medical Device Incident Review Committee (MDIRC)* meeting, 17 November 2008. The role of this statutory committee was to advise and make recommendations to the Minister for Health and the TGA on the safety, risk assessment, risk management and performance of medical devices supplied in Australia. The *Advisory Committee on Medical Devices (ACMD)* now fulfils this function.

[48] FDA Publication: *Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse*, July 2011.

To further consider the available clinical evidence in 2012 the TGA commenced a more comprehensive review of the available literature relating to urogynaecological meshes[49]. A Working Group was also established to provide independent expert advice to the TGA on matters related to the safety and performance of urogynaecological mesh[50].

In 2013 the TGA commenced a review to assess whether all urogynaecological meshes available at that time in Australia (approximately 100 devices then included in 42 entries of the ARTG) were fully compliant with the regulatory requirements. The review focused on the manufacturers' postmarket clinical evidence about the use of the mesh device, risk assessment, risk mitigation strategies, and the information supplied to the surgeon with the device.

Several manufacturers – when instructed to provide this postmarket information – cancelled the ARTG inclusions for their devices. The remaining manufacturers had their evidence assessed by the TGA. As a result of this assessment, the TGA cancelled a further 8 ARTG inclusions for non-compliance with the regulations and 1 ARTG inclusion for non-payment of fees.

A further five entries have been cancelled since the end of the review by sponsors or alternatively, those entries no longer support mesh products use in urogynaecological procedures for treatment of SUI or POP. Today, 29 urogynaecological meshes remain available for supply in Australia under 14 ARTG entries[51].

Furthermore, as part of the review process, the TGA examined the instructions-for-use (IFUs) for each device. As a consequence, the manufacturers were required to release updated instructions-for-use to include additional advice on appropriate patient selection and more explicit information regarding possible complications.

International regulatory position

There is a constant challenge facing regulators in balancing the protection of consumers without undue restriction on access to innovative technologies[52].

The medical device regulations are evolving to better handle technology developments and the push from industry, and often clinicians and patient groups for early access to promising innovative devices and, on the other hand, the need for confirmatory evidence of safety and performance which may take a long time to gather in order to provide certainty.

Internationally, there are moves to strengthen the regulatory requirements and regulatory oversight for many medium and high risk medical devices. This shift is occurring in response to the ever increasing use and complexity of medical devices and also because

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[49] TGA Publication: *Post Market Review of Urogynaecological Graft Devices Version 1.0,* August 2013.

[50] The Urogynaecological Devices Working Group (UDWG) provided advice to the TGA in relation to urogynaecological meshes on 27 August 2013 and 22 October 2013.

[51] ARTG information as at 30 April 2017.

[52] OECD (2017), *New Health Technologies: Managing Access, Value and Sustainability*, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264266438-en.

of a number of international events that have highlighted the need for greater oversight of device manufacturers under all shared responsibility regulatory models.

Specifically for urogynaecological mesh devices, Health Canada has not banned the supply of these devices, but is currently undertaking a review into the clinical evidence which may lead to regulatory changes.

No European regulatory authority has cancelled the supply of these devices to date. The Scottish Independent Review of 2017[53] also did not result in preventing the use of these devices for all urogynaecological procedures.

The EU Parliament has recently agreed to a new set of medical device regulations to be applied in all EU member nations[54]. These new regulations have increased the pre- and postmarket requirements with which the device manufacturers and EU Notified Bodies must comply. The incoming EU regulations – which came into force in May 2017, with a 3 year transition period – classify all implantable meshes as Class III (the highest risk class).

In the United States, the US-FDA requested in 2012 that additional postmarket surveillance studies be undertaken by manufacturers of urogynaecological meshes[55]. The US-FDA has not actively cancelled market approvals for urogynaecological meshes but, it is understood that a significant number of mesh manufacturers withdrew their mesh products from the USA market, rather than undertake the postmarket studies requested by the US-FDA. The US-FDA has also reclassified urogynaecological mesh used for transvaginal insertion in the surgical treatment of POP as Class III.

The Therapeutic Goods Administration's role in ongoing monitoring of the suitability of the implants (Terms of Reference 6(b)): The TGA monitors urogynaecological mesh products in the postmarket setting using information from a number of sources including: domestic and international adverse event reports, published literature, international regulatory actions, statements from relevant professional colleges, and advice from established expert working groups and advisory committees. In 2013 the TGA undertook a comprehensive regulatory review of all urogynaecological meshes available for supply in Australia. This review resulted in a significant reduction in the number of urogynaecological meshes available for supply in Australia and changes to the conditions of registrations for those devices that remained on the market.

As a result of the TGA's ongoing postmarket review activities 29 urogynaecological meshes are still remaining available for supply in Australia under 14 ARTG entries.

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[53] *The Scottish Independent Review of the Use, Safety and Efficacy of transvaginal mesh implants in the treatment of stress urinary continence and pelvic organ prolapse in women*; Final Report March 2017.

[54] http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision_en, accessed 4 May 2017.

[55] USA legislation 'Section 522' gives the FDA the authority to require postmarket surveillance studies from manufacturers of class II and class III devices (note the USA uses a different classification system to that used in Australia). The FDA ordered manufacturers to undertake these '522' surveillance studies in 2012.

The TGA continues to monitor urogynaecological meshes and requires manufacturers to do the same. Manufacturers that do not comply with their regulatory obligations will have their market authorisation cancelled. The TGA is also continuing to appraise the latest research with a view to taking appropriate regulatory action. Given that the Australian regulatory system is harmonised with the European regulations, and that in May 2017 the EU has approved the up-classification of all surgical mesh products to the highest risk category, it is envisaged that similar changes might be proposed in Australia.

The Therapeutic Goods Administration's knowledge of women suffering with health problems after having transvaginal mesh implant (Terms of Reference 6(c): As of 29 May 2017 the TGA has received a total of 226 (covering 249 patients) adverse event reports relating to implantation of urogynaecological mesh devices.

Adverse event reporting to the TGA is voluntary for surgeons, other healthcare professionals, and patients. The TGA has implemented, for a number of years, a specific program[56] to raise the profile and encourage spontaneous reporting of adverse events by health care professionals.

TGA officers met with representatives of a patient support group in early 2016 and discussed their concerns about the safety and performance of these devices. As a result, the TGA released, on 2 August 2016, a web statement encouraging patients to report adverse events. This statement was also shared with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists with a request that it would also be disseminated to its members.

The TGA is also working with the ACSQHC to make the current reporting system more user friendly for consumers and health professionals with a view to receiving a more comprehensive picture of adverse events for medical devices. This work takes place within the broader reform measures arising from the Government accepted recommendations made by the 2016 Expert Panel Review of Medicines and Medical Devices Regulation. Several of the reform measures aim to enhance postmarket surveillance and improve the integration of pre- and postmarket activities. These include: System improvements and enhancements to enable greater collection of adverse events information to enable streamlined reporting of adverse events to the TGA, as well as improve data analytics through linking with other data (such as MBS item numbers); and improvements to the capability to undertake signal detection, drawing from adverse events information, monitoring international evidence and literature, and working with overseas regulators.

[56] The TGA *insite* program was established to enhance relationships with health professionals at the various levels of governance within state and territory government health departments, individual public hospitals, area health networks and the private health sector. The program was piloted in the Canberra hospital and is now operating in areas of Sydney.

Options available to women to have transvaginal mesh removed (Terms of Reference 7): When urogynaecological mesh complications occur they can be managed conservatively or surgically. The *Therapeutic Goods Act 1989* does not allow the TGA to regulate clinical practice.

The TGA, the ACSQHC and relevant specialist medical colleges are taking complementary approaches to develop best practice safety and clinical care, and medical device regulations that support such practice. The TGA will continue to ensure through premarket assessment and audit, and postmarket monitoring that the industry sponsors and manufacturers of these devices comply with their regulatory obligations. The ACSQHC's priority is for the development of guidance for consumers, clinicians and health services on the use, complications and removal of urogynaecological mesh products for the treatment of pelvic organ prolapse and stress urinary incontinence.

The TGA and the ACSQHC have co-funded consultations with patients affected negatively by certain mesh devices, leading clinicians and their clinical societies about possible ways forward. The ACSQHC has convened a Reference Group to develop guidance for appropriate patient selection, surgical training for insertion and removal of the device, supporting consumers through improved information and decision support tools, and approaches for development of integrated data collection mechanisms. TGA has been an active participant in meetings with ACSQHC and of the reference group.

ATTACHMENT 1 – UROGYNAECOLOGICAL MESH CHRONOLOGY

Year	Details	Domestic/Foreign
1996	First urogynaecological meshes approved for supply in the USA	USA
1998	First urogynaecological meshes approved for supply in Australia	Australia
2006	The first adverse event relating to a urogynaecological mesh was received by the TGA.	Australia
2008	The US-FDA issues a Safety Communication recommending that surgeons should undertake specialized further training and should notify patients that mesh is permanent, complications can occur, and cannot always be resolved with further surgery.	USA
2008	TGA investigates Australian adverse event reports for urogynaecological meshes and consults an expert panel. It is agreed that the TGA will continue to monitor mesh reports and emerging clinical evidence.	Australia
2008	The TGA and NZ Medsafe seek advice from the Medical Device Incident Review Committee. The committee emphasises the need for informed patient consent and surgeon training when using such devices.	Australia New Zealand
2009	US-FDA releases statement: a literature review demonstrates conflicting information on the success rates for transvaginal mesh placement and further investigation is required.	USA
2010	Health Canada releases a notice to hospitals informing healthcare professionals of the complications associated with urogynaecological mesh.	Canada
2010	The TGA undertakes a targeted postmarket review of specific urogynaecological meshes in response to a report that meshes difficult to visualise once implanted. Broader review and consultation finds that most meshes are coloured or have radiopaque markers included within the mesh.	Australia
2011	FDA releases an updated communication advising that adverse events a no longer considered rare, there is no compelling evidence of greater success with mesh in posterior compartment, and some evidence of greater	USA

	efficacy in anterior compartment. All patients should be advised that long term data on safety of mesh is limited and alternatives to mesh should be discussed.	
2012	US-FDA issues orders for manufacturers to conduct postmarket surveillance for meshes - “522 studies”	USA
2012	The TGA publishes a web article *Concerns with urogynaecological surgical mesh implants*	Australia
2012	The TGA commences a comprehensive postmarket review of published literature for urogynaecological meshes	Australia
2013	The Australian Department of Health establishes a Urogynaecological Devices Working Group to consider the available clinical evidence and to contribute to the postmarket review activities being undertaken by the TGA	Australia
2013	The TGA commences a broad review of all urogynaecological meshes available for supply in Australia.	Australia
2014	Health Canada issues an updated notice to hospitals and patients advising that Health Canada continues to receive reports of complications, including some serious and life-altering events.	Canada
2014	Scottish Cabinet Secretary for Health and Wellbeing appeals to NHS Scotland to suspend transvaginal mesh procedures pending the outcome of an independent review.	Scotland
2014	The MHRA releases a statement that there is no regulatory justification for removing surgical mesh from use in UK hospitals.	UK
2014	The TGA reports on the postmarket review into all urogynaecological meshes available for supply in Australia and there is a significant reduction in the number of urogynaecological meshes available on the Australian market.	Australia
2015	New Zealand report into the safety of surgical mesh is published	New Zealand
2015	Scottish independent review into urogynaecological mesh – interim report is published	Scotland
2015	NHS England Releases the Mesh Working Group Interim Report.	UK
2015	European Commission (SCENIHR 2015) report into the safety of urogynaecological meshes suggests limiting mesh surgical procedures wherever possible, certification systems for surgeons, and appropriate patient selection and	EU

	counselling.	
2016	The FDA reclassifies urogynaecological POP mesh as Class III – a high risk device. Manufacturers are given 30 months to provide updated evidence. The reclassification does not apply to all implantable meshes.	USA
2016	The NZ House of Representatives Health Committee releases a report which includes a recommendation for the establishment of a centralized surgical registry. RANZCOG releases a response welcoming the report and the recommendation that meshes remain available as a surgical option.	NZ Australia
2016	The Australian Pelvic Mesh Support Group meets with Ministerial Advisors and senior Department of Health officers. This meeting includes discussion on how to encourage patient adverse event reporting in Australia.	Australia
2016	The TGA publishes a web article urging the reporting of adverse events relating to urogynaecological surgical mesh	Australia
2016	Health Canada considers powers to require mandatory reporting of adverse events by healthcare institutions – Vanessa's Law.	Canada
2016	RANZCOG publishes a statement advising that transvaginal mesh is not recommended as the first line of treatment for any vaginal prolapse. Surgeons should consider clinical trial recruitment for use of any new mesh types.	Australia NZ
2016	A Cochrane Review is released comparing mesh to native tissue repair for POP and reports that while permanent mesh has some advantages over native tissue, there are also disadvantages in its routine use.	International
2016	The Lancet publishes a Scottish multi-centre trial into urogynaecological mesh (PROSPECT study). This study finds no benefit in using mesh for surgical treatment of POP in comparison to traditional surgical methods. TGA is considering taking appropriate regulatory action.	Scotland
2017	The EU confirms regulatory reclassification of all surgical mesh to Class III and Australia proposes to commence the regulatory process to reclassify all surgical meshes as Class III (the USA the reclassification of meshes which occurred in 2016 is limited to urogynaecological mesh used in POP).	Australia EU
2017	Scottish independent review into urogynaecological mesh – final report published	Scotland

ATTACHMENT 2 – REGULATION OF CLASS IIB VERSUS CLASS III MEDICAL DEVICES

Most surgical meshes are currently Class IIb medical devices (moderate to high risk). At present, only meshes containing medicines or biological materials are classified as Class III (high risk). The classification system for medical devices underpins the risk-based approach used by the independent conformity assessment body to assess the conformity assessment procedure applied by a manufacturer. The outcome of the independent assessment of the manufacturer's application of a conformity assessment procedure is communicated through certification issued by the conformity assessment body.

For Class III medical devices conformity assessment includes:

- **Full Quality Management System (QMS):** Manufacturers must have a QMS that controls the manufacturing process. This QMS must specify how the manufacturer will control the design of, the testing and validation of, the transfer to production of, production of, and finally the supply of, and then monitoring of the device. The conformity assessment body will review this QMS and this review will involve an onsite inspection of the manufacturer's sites.
- **Design Examination:** The conformity assessment body will assess the manufacturer's individual medical devices for conformity to the Essential Principles and other regulatory requirements. This assessment is done in addition to the onsite inspection. It includes examination of issues such as clinical performance, risk management, engineering, biomaterials, toxicology, microbiology (the specifics of what is assessed vary based on the device).

For Class IIb medical devices conformity assessment includes:

- **Full Quality Management System (QMS):** Assessment of the manufacturer's QMS with an onsite inspection (as above, same as for Class III device manufacturers).
- **Technical documentation review**: The conformity assessment body will review a sample of the manufacturer's technical documentation to determine compliance with the Essential Principles and other regulatory requirements. The conformity assessment body samples from the various device 'families'. 'Families' refers to the various applications or technologies of the devices of that manufacturer (for example, surgical meshes, lung ventilators, cardiac stents, etc.). This sampling review can occur during the onsite inspection of the manufacturer's QMS, and can also occur separate from the onsite inspection as part of the conformity assessment body's ongoing program of review for the manufacturer. For Class IIb devices the design of individual devices is not examined in depth by the independent conformity assessment body.

ATTACHMENT 3 – CURRENT UROGYNAECOLOGICAL MESH DEVICES ON THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (ARTG)

Boston Scientific Pty Ltd – 4 ARTG entries

ARTG 174878 Class III included 2010 **Manufactured by Boston Scientific Corporation (previously TEI Biosciences Inc)**	
1 Product	**Intended Purpose**
Xenform Tissue Repair Matrix (UPN M0068302450) (UPN M0068302470) (UPN M0068302410) (UPN M0068302430)	Intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of colon, rectal, urethral, and vaginal prolapse; reconstruction of the pelvic floor; and procedures such as sacrocolposuspension and urethral sling.
ARTG 150342 Class IIb included 2008 **Manufactured by Boston Scientific Corporation**	
4 Products	**Intended Purpose**
PFR Kit Uphold LITE Vaginal Supp System (UPN M0068317170)	POP (transvaginal) - The Uphold Vaginal Support Systems are indicated for tissue reinforcement in women with pelvic organ prolapse, for the transvaginal repair of anterior and apical vaginal wall prolapse.
PFR Kit Pinnacle range PFR Kit - Pinnacle, Anterior Apical (UPN M0068317050) PFR Kit- Pinnacle, Posterior (UPN M0068317100) PFR Kit Pinnacle LITE Anterior /Apical (UPN M0068317140) PFR Kit Pinnacle LITE Posterior (UPN M0068317150)	POP (transvaginal) - The Pinnacle Pelvic Floor Repair Kits are indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor in vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.
Uphold range Uphold Vaginal Support System (UPN M0068317080) Uphold (TM) LITE w/ Capio SLIM (UPN M0068318170)	POP(transvaginal) - The Uphold Vaginal Support Systems are indicated for tissue reinforcement in women with pelvic organ prolapse, for the transvaginal repair of anterior and apical vaginal wall prolapse.
Upsylon Y-Mesh Kit (UPN	POP (abdominal) - Upsylon Mesh is intended for use as a bridging material for sacrocolposuspension / sacrocolpopexy

M0068318220)	(laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.
ARTG 104326 Class IIb included 2004 **Manufactured by Boston Scientific Corporation**	
4 Products	**Intended Purpose**
Advantage Single Handle Kit (UPN M0068502000) Advantage Fit – single (UPN M0068502110) Advantage Fit - 5 pack (UPN M0068502111)	SUI (transvaginal) - The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
Lynx Suprapubic Mid-Urethral Sling Sys. (UPN M0068503000) Lynx Suprapubic Sling Syst 5-Pack (UPN M0068503001)	SUI - The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
Obtryx Curved Single System Device (UPN M0068504000) Obtryx Halo Single System Device (UPN M0068505000) Obtryx Halo System 5-Pack (UPN M0068505001) Obtryx II, Halo, Single unit (UPN M0068505110) Obtryx II, Halo, 5 pack (UPN M0068505111)	SUI (transobturator) - The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
Solyx; SIS System, Single (UPN M0068507000)	SUI (transvaginal) - The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
ARTG 246992 Class IIb included 2015 **Manufactured by Boston Scientific Corporation**	
1 Product	**Intended Purpose**
Pinnacle Posterior Lite (UPN M0068318150)	The Pelvic Floor Repair (PFR) Kit is indicated for tissue reinforcement in women with pelvic organ prolapse, for the transvaginal repair of posterior vaginal vault prolapse.

Johnson & Johnson Medical Pty Ltd – 2 ARTG entries

ARTG 165075 Class IIb included 2009 **Manufactured by Ethicon LLC**	
2 Products	**Intended Purpose**
Gynemesh PS Prolene (GPSL)	POP (abdominal) - GYNECARE GYNEMESH is indicated for use as a bridging material for apical vaginal and uterine prolapse where surgical treatment (laparotomy or laparoscopic approach) is warranted.
Gynemesh PSXL Mesh (GPSXL3)	GYNECARE GYNEMESH is indicated for use as a bridging material for apical vaginal and uterine prolapse where surgical treatment (laparotomy or laparoscopic approach) is warranted.
ARTG 99193 Class IIb included 2004 **Manufactured by Ethicon SARL**	
5 Products	**Intended Purpose**
Gynecare TVT W/Abdominal (810041A)	SUI(transvaginal) - The GYNECARE TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT introducer, rigid catheter guide and GYNECARE TVT abdominal guides and couplers are available separately and intended to facilitate the placement of the GYNECARE TVT device.
Gynecare TVT Device (810041B)	SUI - The GYNECARE TVT Device is intended to be used as a pubourethral sling for treatment of Stress Urinary Incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT Introducer and Rigid Catheter Guide are available separately and are intended to facilitate the placement of the GYNECARE TVT Device.
Gynecare TVT Obturator (810081),	SUI(transobturator) – The GYNECARE TVT Obturator device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
TVT Exact Retropubic System (TVTRL)	SUI (transvaginal) - The GYNECARE TVT EXACT™ Continence System is intended to be used as a pubourethral sling for treatment of female Stress Urinary Incontinence, resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT Rigid Catheter Guide is available separately and is intended to facilitate the placement of the

	GYNECARE TVT EXACT™ Continence System.
TVT ABBREVO (TVTOML)	SUI (transvaginal) - The GYNECARE TVT ABBREVO™ Continence System is intended for use in women as a suburethral sling for the treatment of SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Coloplast – 4 ARTG entries

ARTG 190172 Class IIb included 2011 **Manufactured by Coloplast AS**	
2 Products	**Intended Purpose**
Restorelle M 15x10cm (501320) Restorelle XL 30x30cm (501330) Restorelle L 24x8cm (501440) Restorelle Y 24x4cm (501420) Restorelle Y-XL 27x4cm (501430)	POP (Abdominal) - Restorelle L, M, XL, Y, Y-XL are indicated for use as a bridging material for sacrocolposuspension / sacrocolpopexy (i.e., abdominal placement via laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.
Restorelle Direct Fix Anterior (501450) Restorelle Direct Fix Posterior (501460)	POP (transvaginal) - Restorelle DirectFix is indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor in vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or a bridging material for the fascial defects.
ARTG 190173 Class IIb included 2011 **Manufactured by Coloplast AS**	
1 Product	**Intended Purpose**
Altis Single Incision Sling (519650)	SUI (transvaginal) - The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).
ARTG 160738 Class IIb included 2009 **Manufactured by Coloplast AS**	
2 Products	**Intended Purpose**
Aris kit with Aris mesh (UR3105)	SUI (transobturator) - Aris is an implantable, suburethral, support tape indicated for the surgical treatment of all types of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Supris kit with Aris mesh (519562)	SUI(transvaginal) -The Supris Retropubic Kit consists of the Supris implantable suburethral support sling and disposable introducers for placement using a “top-down” or “bottom-up” retropubic surgical approach. The Supris sling and introducers are indicated for the surgical treatment of female stress urinary incontinence (SUI), resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
ARTG 157074 Class IIb included 2008 **Manufactured by Abiss**	
1 Product	**Intended Purpose**
Aris (UR3101)	POP (transvaginal) - Novasilk is a permanent, implantable support mesh for the surgical treatment of all types of pelvic organ prolapse, both for tissue reinforcement and stabilization where surgical treatment is indicated.

Sponsor William A Cook Australia Pty Ltd – 2 ARTG entries

ARTG 186657 Class III included 2011 **Manufactured by Cook Biotech Incorporation**	
1 Product	**Intended Purpose**
Biodesign Posterior Pelvic Floor Graft - Multi-purpose surgical mesh, collagen (J-PF-POST-AU)	POP (transvaginal) -Cook® Biodesign® Anterior and Posterior Pelvic Floor Grafts are used for soft tissue repair of pelvic floor defects such as: cystocele, rectocele, enterocele, sacrocolpopexy, and/or intra-operative bladder neck suspension. The graft is supplied sterile and intended for one-time use.
ARTG 153049 Class III included 2008 **Manufactured by Cook Biotech Incorporation**	
1 Product	**Intended Purpose**
Biodesign Anterior Pelvic Floor Graft - Multi-purpose surgical mesh, collagen (J-PF-ANT-AU) Biodesign Anterior Pelvic Floor Graft - Multi-purpose surgical mesh, collagen (J-PF-ANT-SSL-AU)	POP (transavaginal) - Cook® Biodesign® Anterior and Posterior Pelvic Floor Grafts are used for soft tissue repair of pelvic floor defects such as: cystocele, rectocele, enterocele, sacrocolpopexy, and/or intra-operative bladder neck suspension. The graft is supplied sterile and intended for one-time use.

Endotherapeutics Pty Ltd – 2 ARTG entries

ARTG 174659 Class IIb included 2010 **Manufactured by Promedon SA**	
1 Product	**Intended Purpose**
Ophira Minisling (KIT-OT-01)	SUI (transvaginal) -The Ophira sling is intended to be used for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
ARTG 118082 Class IIb included 2005 **Manufactured by Promedon SA**	
3 Products	**Intended Purpose**
Safyre T	SUI(transobturator) - Safyre T is a kit for the treatment of stress urinary incontinence grades II and III
Safyre T Plus	SUI(transobturator) - Safyre T plus is a kit for the treatment of stress urinary incontinence grades II and III
Safyre VS	SUI(transvaginal) - Safyre VS is a kit for the treatment of stress urinary incontinence grades II and III