APPENDIX 4

Therapeutic Goods Administration – Urogynaecological mesh chronology

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