Action Plan for Medical Devices - Progress Report Card: December 2022

Strategy 1: Improve how new devices get on to the market in Australia

Complete Underway Yet to commence

TARGET	ACTIVITY DESCRIPTION	April 2020	June 2021	Dec 2022	SUMMARY
Early 2019	Identify options for increasing oversight of the evaluation and market approval process for particular devices.	●	●	●	*Since 2019, 31 public consultations have been undertaken and the outcomes published on TGA's website and dedicated TGA Consultation hub.* *In addition to industry, healthcare professionals and other stakeholder consultations prior to any regulatory reform, TGA has undertaken workshops and conducted webinars on particular topics. Five industry stakeholder workshops were held in 2022 to discuss approaches to handling the transitioning and assessment of medical devices approved under the European Union Medical Devices Directive (MDD) and new applications under the new EU Medical Devices Regulations (MDR). Most medical devices currently included in the ARTG are supported by MDD certification, with ARTG devices requiring transitioning to EU MDR certification by May 2024.* *Reviewing and refining recent regulatory changes to ensure that these are fit for purpose for the Australian environment and to align where possible to other international regulators are ongoing work. Some of this work has been delayed due to delays in the EU. These include reviews on conformity assessment procedures, Essential Principles, In Vitro Diagnostics (IVDs) and the EU MDR.* *TGA conducted a post implementation survey of the 2020 Class I low risk devices reforms in May 2022. Between July 2021 and December 2022 25 pieces of guidance were published. Examples include:* • *Regulatory amendments for First aid kits and SOPP (System or Procedure Packs) to align with requirements under EU regulations, to enhance safety and quality of systems or procedure packs supplied in Australia.* • *Guidance on the regulation of software and apps which meet the legislative definition of a medical device in Australia; updated interpretative guidance in February 2022 after feedback from industry.* • *Guidance and sponsor notification forms for the five reclassified medical devices.* • *Guidance and management of the EU MDR transitions; online notifications forms, FAQs and example scenarios.* • *Updates to guidance for the personalised medical devices sector to support the regulatory framework introduced in 2021. There is continued engagement with the sector and frequently asked questions have been published.* *Industry and other interested stakeholders were invited to comment on TGA proposed fees and charges for the 2022-23 financial year in March 2022 and bilateral meetings with industry were held in the last quarter of 2022.* *Reclassification of spinal implants came into effect in November 2021 and included:* • *more detailed assessment of the manufacturer's quality management systems and assessment of technical documentation related to each device.*
Early 2019	Conduct public stakeholder consultations on proposed regulatory changes and guidance materials.	●	●	●	
Mid 2019	Consult with stakeholders on proposed changes that affect change to industry fees and charges or change the regulatory burden on healthcare professionals of industry.	●	●	●	
Mid 2019	Establish a specialist unit in the TGA to increase capacity in assessing and monitoring digital health.	●	●	●	
End 2019	Draft regulatory changes as agreed by the Government.	●	●	●	
End 2019	Increase the capacity of the TGA medical device review teams.	●	●	●	

					• *conformity assessment documents demonstrating procedures appropriate for their classification.* • *a mandatory audit assessment by the TGA for device inclusion applications, including assessment of clinical evidence.* *10 other regulatory changes in the pre-market and medical devices approval stage, including minor updates to previous amendments, received approvals between July 2021-December 2022.*

Strategy 2: Strengthen monitoring and follow up of devices already in use

TARGET	ACTIVITY DESCRIPTION	April 2020	June 2021	Dec 2022	SUMMARY
Early 2019	Establish a working group with state and territory health departments and the Australian Commission on Safety and Quality in Health Care.	🟢	🟢	🟢	*The TGA regularly meets with state and territory health jurisdictions on a range of matters including COVID rapid antigen tests, personal protection equipment and other regulatory actions of medical devices, to both communicate and receive information.* *A suite of measures has commenced to enhance the post-market adverse event reporting and surveillance of medical devices. These involve strong collaboration and strengthened relationships with end users. The TGA works closely with the Australian Commission on Safety and Quality in Health Care and will collaborate with them to explore ways to implement TGA's October 2021 proposal on the mandatory reporting of adverse events by healthcare facilities. Legislation to mandate reporting by the healthcare facilities was introduced in December 2022.* *The Medical Device Consumer Working Group (MDCWG) was reinvigorated and membership expanded in November 2021, to provide input into a range of TGA's initiatives including improving the reporting of adverse events (including possible use of smartphone apps).* *TGA undertook consultations with consumers and industry workshops on proposed changes surrounding Adverse Event Reporting Exemption Rules in November 2021, March and April 2022. A Medical Device Vigilance Program (MDVP) pilot program is being developed to enable auditing and inspection of medical devices sponsor records and premises to verify compliance with regulatory obligations and improve sponsor awareness of their responsibilities as a sponsor of medical devices. We will update clinical guidelines and will publish more content on real world evidence following the close of the consultation in November 2022.* *The Australian Unique Device Identification database (AusUDID) 'Sandpit' to allow user feedback ahead of voluntary compliance is 'live' on TGA's website. Two early adopter projects have been established with public hospitals. 14 public information webinars have been delivered and two working groups established. The third public consultation paper "Detailed considerations for implementing the proposed Australian medical device UDI regulatory framework" closed in October 2022. Outcomes will be published after a review of the responses is completed. The AusUDID is a major reform that will strengthen patient safety through improving the tracking of medical devices*
Mid 2019	Consult on proposed changes to adverse event reporting requirements and systems and strengthened tracking of devices.	🟠	🟢	🟢	
Mid 2019	Consult publicly on proposed changes that potentially incur a change in fees or charges and/or regulatory burden.	🟠	🟢	🟢	
Mid-late 2019	Consult with consumer groups, healthcare industry representatives on opportunities for collaboration and proposed changes.	⚪	🟢	🟢	
Early 2020	Government to introduce legislation to implement agreed regulatory changes.	⚪	🟠	🟠	

					TGA regularly engages with its stakeholders. There have been 40 presentations since June 2021 at different forums and through webinars and other means. Webinars have been held on Essential Principles-consent for non-compliance of certain medical devices, personalised medical device framework, and the Unique Device Identification system as examples. 3 minor regulatory changes were approved between July 2021-December 2022, and 7 pieces of guidance published.

Strategy 3: Provide more information to patients about the devices they use

TARGET	ACTIVITY DESCRIPTION	April 2020	June 2021	Dec 2022	SUMMARY
Mid 2019	Consult with consumer advocacy, support groups and industry on proposed changes to transparency.				*Guidance regarding requirements for Patient Information Leaflets (PILs) and Patient Information Cards (PICs) was updated in March 2022.* *Five working groups with consumer representation have been established and have been meeting regularly for the past few years. The Breast Implant Expert Working Group (BIEWG), met in May and Oct 2022. Medical Device Consumer Working Group (MDCWG) was re-invigorated and expanded, with a focus on areas of priority for the Action Plan for Medical Devices. The terms of reference and meeting statements are available on the TGA website.* *The Women's Health Product Working Group was established has held meetings in June and October 2022. The group advises the Minister and the TGA on matters relating to the clinical evidence and policy matters relating to the safety, quality and efficacy or performance of medicines and medical devices.* *The Ventilator Expert Working Group (VEWG) meets on a monthly basis to consider information related to sleep apnoea devices, regulatory and manufacturers' actions. The Surgical Mesh Expert Working Group (SMEWG) met twice since it was established in October 2021.* *A number of fact sheets have been published to provide information and assist consumers, healthcare professionals and industry including:* • *Digital Mental Health Fact Sheet to provide information to consumers and stakeholders on what software based medical devices are and how such medical devices are regulated.* • *Breast implant associated cancer (BIA-ALCL): Information for consumers.* • *COVID-19 on purchasing approved rapid antigen test kits/self-tests and COVID-19 self-testing on correct use of these tests.* • *Five questions to ask your health professional before you get a medical implant – a dedicated resource to assist consumers with asking the right questions to ensure they get the right implantable device for them. This has been translated into ten languages and linked to healthdirect.gov.au.* • *General requirements for advertising personalised medical devices to consumers.* • *Medical device cyber security – Consumer information and Medical device cyber security guidance for industry were updated in November 2022.* • *Advertising software factsheets for consumers and health professionals have been developed and will be published.*
Mid 2019	Publish regulatory assessment timeframe.				
Late 2019	Government decision on any changes to regulations required to support publication of additional information on medical devices.				
End 2019	Establish new consumer working groups and publish their Terms of Reference.