Action Plan for Medical Devices Progress Report Card: December 2023

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	Dec 2023	SUMMARY
Early 2019	Identify options for increasing oversight of the evaluation and market approval process for particular devices.					*We have undertaken 57 public consultations since the Action Plan was published in 2019. Consultations papers and outcomes can be found on the TGA Consultation hub.* *In 2023, we consulted on the classification rules and regulatory processes for medical devices containing materials of animal, microbial or recombinant origin, use of evidence from comparative overseas regulators for these devices, how we select and conduct audits of medical device applications and the operation and experience of medical device sponsors involved in the Medical Devices Single Audit Program (MDSAP) to better understand and inform our approach to the audits and our regulatory framework.* *We sought views from specific point-of-care manufacturing sectors (oral health professionals, allied health, hospital, and healthcare facility/medical device manufacturing hubs), and held a National Symposium in June 2023 to refine regulation introduced in 2021. Prior to 2021, these devices fell within the definition of custom-made devices and are now regulated as 'personalised medical devices', requiring more regulatory oversight by the TGA.* *We continue to support industry, healthcare professionals and other stakeholders through 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) impacted by the extended timelines. Regulatory changes are in place to extend the transition deadline of the reclassification of certain medical devices to 1 July 2029. The extended timelines for the EU MDR has impacted some of the reforms. These include reviews on conformity assessment procedures, Essential Principles, In Vitro Diagnostics (IVDs) and the EU MDR. Over 25 pieces of guidance were issued. These included:* o *Transitioning to new manufacturer evidence for IVD medical devices* o *Personalised medical devices Guidance for Healthcare Practitioners/Professionals/Providers* o *Personalised Medical Devices Guidance for Dental Health Practitioners* o *Medical devices reforms: priority review pathway* o *Legal supply of COVID-19 test kits* o *Changes to medical device essential principles for nanomaterials* o *Clinical performance requirements and risk mitigation strategies for HIV test* o *Digital mental health sector specific guidance* o *Manufacturers evidence for In-vitro diagnostic medical devices*
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.					

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

TARGET	ACTIVITY DESCRIPTION	April 2020	June 2021	Dec 2022	Dec 2023	SUMMARY
Early 2019	Establish a working group with state and territory health departments and the Australian Commission on Safety and Quality in Health Care.					*We have established a dedicated medical device supply disruption team that meets with state and territory health jurisdictions weekly to monitor and manage signals of potential supply disruption. In addition, we have conducted roundtable discussions with states and territories health departments, the hospital sector and the Australian Commission on Safety and Quality in Health Care on a new legislative requirement, passed by Government in March 2023. This new requirement has made it mandatory for healthcare facilities to report medical devices related adverse events to the TGA, strengthening the monitoring of devices in real world settings. Ongoing consultations will inform the implementation of the new requirement.* *Five post-market reviews of medical devices are currently active. These are:* • *Spinal cord stimulation (SCS) devices* • *Ventilators, CPAP and BiPAP devices* • *HIV nucleic acid tests* • *Home use of foetal dopplers* • *Medical devices containing mercury* *We launched the 12-month Medical Device Vigilance Program pilot program in September 2023, to improve sponsor awareness of their responsibilities and verify compliance with regulatory reporting, information holding and recording requirements.* *The Australian Unique Device Identification database (AusUDID), a major reform that will strengthen patient safety by improving the tracking of medical devices has entered into the Pre-Production in April 2023, with functionalities to include electronic Patient Information Leaflets and electronic Instructions for Use released. Voluntary compliance is expected in 2024.* *The outcomes of the 2022 "Detailed considerations for implementing the proposed Australian medical device UDI regulatory framework" consultation is available on our website.* *Real world evidence, patient reported outcomes and the clinical evidence guidelines were published in February and November 2023 respectively. Our consultation on the Recall Reforms Discussion Paper closed on 13 March 2023 and the outcomes, are available on the TGA Consultation Hub.* *We have undertaken around 100 stakeholder engagements over the year as we continue to implement the medical device reforms and engage to consult or educate on the different reform activities.*
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.					

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

TARGET	ACTIVITY DESCRIPTION	April 2020	June 2021	Dec 2022	Dec 2023	SUMMARY
Mid 2019	Consult with consumer advocacy, support groups and industry on proposed changes to transparency.					*Our expert working groups met regularly over the year. The Ventilator Expert Working Group met twice, the Breast Implant Expert Working Group and the Women's Health Product Working Group (WHPWG) met three times and Medical Devices Consumer Working Group met five times including two out-of-session meetings this year. We have worked with the Medical Devices Consumer Working Group (MDCWG) on our social media campaign to inform consumers about:* o *travelling with medicines and medical devices* o *Five questions to ask your health professional before you get a medical implant (Five questions), and* o *beware of buying medicines and medical devices online* *The MDCWG contributed to the development of:* o *Medical device patient information materials: a fact sheet for health professionals* o *Patient information materials for medical implants: a fact sheet for consumers* o *Factsheet - Advertising software based medical devices to health professionals* o *Factsheet - Advertising software based medical devices to consumers* o *General requirements for advertising personalised medical devices to consumers.* *Consumer briefing have been provided on several topics including:* o *Proposed expansion of electronic instructions for use to consumer goods* o *Proposed transition of Class I assistive technologies and prescription lenses to exempt devices* o *Personalised medical devices and point of care manufacturing* o *Review of sponsor adverse event reporting exemption rules* o *Development of the Unique Device Identification Database* *The WHPWG held meetings in March, July and October 2023 and discussed wide ranging topics from the COVID-19 Vaccination Program in Culturally and Linguistically Diverse (CALD) communities, access to women's health products in Aboriginal and Torres Strait Islander communities, access to therapies for the treatment of breast cancer, endometriosis and oral contraceptives to TGA's framework for repurposing of medicines and improving fertility in polycystic ovary syndrome.* *The BIEWG, is working on a risk management framework for breast implants, which is expected to be published in 2024.*
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.