Action Plan for Medical Devices - Progress Report Card: June 2021

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

Complete Underway Yet to commence

TARGET	ACTIVITY DESCRIPTION	STATUS Apr 2020	STATUS June 2021	SUMMARY of activities April 2020 to June 2021
Early 2019	Identify options for increasing oversight of the evaluation and market approval process for particular devices.	Complete	Complete	*19 consultation papers and outcomes published. Recent consultations included: Scope of regulated software based products; Australian regulations definition of central nervous system; Regulatory options for medical devices containing nanomaterials; Proposed refinements to the regulation of personalized medical devices* *Low risk (class I) medical device review, completed. Fees and resources to support improved integrity of the process in place. Changes to the Class I medical device and Class 1 IVD device inclusion process requires the manufacturer's Declaration of Conformity to be provided as part of the application process.* *Continued consultation on reforms to align regulation of medical devices with the EU framework, with some refinements occurring.* *Consultation with industry on fees and charges and regulatory burden was undertaken for each proposed change.* *Australian corporations can now apply to operate as an Australian Conformity Assessment Body and issue conformity assessment certification for medical devices under Australian law. Guidance and application form published.* *Changes to the legislation and regulations occurred in June and August 2020 to clarify definitions and change risk classification levels for certain devices and enable the UDI.* *Regulatory changes to allow additional self-testing In Vitro Diagnostic (IVD) devices to be marketed in Australia commenced on 1 October 2020.* *Personalised medical device framework and software based medical devices regulatory changes commenced on 25 February 2021. Webinars, workshops and targeted discussions occurred, including a dedicated Dental Working Group established to support the transition for many custom-made devices to personalised devices.* *24 items of guidance published on our website including: Regulation of Software as a Medical Device; 3-D printing (additive manufacturing) of medical devices; Reclassification of surgical mesh devices; Personalised medical devices (including 3D-printed devices) - Regulatory changes for custom-made medical devices; Advice for health procurement teams about therapeutic goods and medical devices; IVD Self-Tests for seasonal influenza, hepatitis B and C and certain sexually transmitted infections*
Early 2019	Conduct public stakeholder consultations on proposed regulatory changes and guidance materials.	Complete	Complete	
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.	Complete	Complete	
Mid 2019	Establish a specialist unit in the TGA to increase capacity in assessing and monitoring digital health.	Complete	Complete	
End 2019	Draft regulatory changes as agreed by the Government.	Underway	Complete	
End 2019	Increase the capacity of the TGA medical device review teams.	Underway	Complete	

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

TARGET	ACTIVITY DESCRIPTION	STATUS Apr 2020	STATUS June 2021	SUMMARY of activities April 2020 to June 2021
Early 2019	Establish a working group with state and territory health departments and the Australian Commission on Safety and Quality in Health Care.			*Work and close collaboration with state and territory health departments and the Commission occurred on medical devices of concern, recalls and supply shortages including fortnightly teleconferences on COVID-19 related devices such as performance of face masks.* *Unique Device Identification system received funding approval from the Government in the 2020-2021 budget. Stage 1 of the UDI database build commenced in June 2021.* *Consultation papers recently published included: Exploring options for the introduction of an Australian Unique Device Identification (UDI) system and Proposed enhancements to adverse event reporting for medical devices.* *Guidance materials were published such as: New compliance dashboard for post-market medical device reviews and Updates to the electronic application for a Conformity Assessment Certificate.* *Work has commenced on: Potential options for mandatory reporting of medical device adverse events by healthcare facilities; Changes to existing adverse events reporting exemptions and better ways to publish information about suspended or recalled devices and: A pilot for an audit and inspection program of sponsor activities and premises in relation to their post-market obligations.* *In depth review commenced of TGA recall processes, IT systems, supply chain and hospital processes, with a national workshop in November 2020 including state/ territory health departments. The System for Australian Recall Actions (SARA) database was enhanced for data to be downloaded.* *Legislation and regulation changes occurred in June, August and October 2020 to enact changes agreed thus far.*
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	STATUS Apr 2020	STATUS June 2021	SUMMARY of activities April 2020 to June 2021
Mid 2019	Consult with consumer advocacy, support groups and industry on proposed changes to transparency.			*Revised guidance published on Medical device patient information leaflets and implant cards based on feedback from consumers.* *The Consumer Working Group was established comprising 10 consumer representative organisations. The group met four times, with communiques published on the TGA website. The Group developed a publication: 'Five questions to ask your health professional before you get a medical implant' available on the TGA website.* *Consumer focus groups were specifically set up to support regulatory actions for breast implants and mesh, including input into the design and content of our website hubs and information materials.* *Significant updating of materials on our website with a consumer focus for COVID-19 related devices including face masks, disinfectants, and test kits.* *Ongoing collaborative work with consumers to develop consumer friendly information will continue.*
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.