# Action Plan for Medical Devices - Progress Report Card: April 2020

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

Complete ● Underway ● Yet to commence ●

| TARGET | ACTIVITY DESCRIPTION | STATUS | SUMMARY |
|---|---|---|---|
| Early 2019 | Identify options for increasing oversight of the evaluation and market approval process for particular devices. | ● | *4 out of 6 actions complete, work ongoing* |
| Early 2019 | Conduct public stakeholder consultations on proposed regulatory changes and guidance materials. | ● | *All actions progressed* |
| 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. | ● | *Regulatory changes scheduled to commence in 2020* |
| Mid 2019 | Establish a specialist unit in the TGA to increase capacity in assessing and monitoring digital health. | ● | *Work to increase capacity of review teams continues in 2020* |
| End 2019 | Draft regulatory changes as agreed by the Government. | ● | *18 public consultations held* |
| End 2019 | Increase the capacity of the TGA medical device review teams. | ● | *Regulation changes by Government for certain devices* |

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

| TARGET | ACTIVITY DESCRIPTION | STATUS | SUMMARY |
|---|---|---|---|
| Early 2019 | Establish a working group with state and territory health departments and the Australian Commission on Safety and Quality in Health Care. | ● | *Foundation work complete, is ongoing* |
| Mid 2019 | Consult on proposed changes to adverse event reporting requirements and systems and strengthened tracking of devices. | ● | *Consultation on proposed changes underway* |
| Mid 2019 | Consult publicly on proposed changes that potentially incur a change in fees or charges and/or regulatory burden. | ● | *Consultation with industry scheduled to continue in 2020* |
| Mid-late 2019 | Consult with consumer groups, healthcare industry representatives on opportunities for collaboration and proposed changes. | ● | *New legislation to implement regulatory changes scheduled to commence 2020* |
| Early 2020 | Government to introduce legislation to implement agreed regulatory changes. | ● | *Australian Health Ministers Advisory Council project to improve information sharing* |

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

| TARGET | ACTIVITY DESCRIPTION | STATUS | SUMMARY |
|---|---|---|---|
| Mid 2019 | Consult with consumer advocacy, support groups and industry on proposed changes to transparency. | ● | |
| Mid 2019 | Publish regulatory assessment timeframe. | ● | *Action plan consumer working group established* |
| Late 2019 | Government decision on any changes to regulations required to support publication of additional information on medical devices. | ● | *Consumers providing feedback on specific devices of concern* |
| End 2019 | Establish new consumer working groups and publish their Terms of Reference. | ● | |