The reforms to the regulation of medical devices will provide earlier access to new medical devices for Australian consumers and health professionals, and potentially reduce costs for industry, by:

- increasing flexibility in pre-market assessment processes, including establishing a process for expedited approval in certain circumstances;
- enabling the establishment of commercial bodies in Australia designated to undertake medical device assessments; and
- increasing the use of assessments from comparable overseas regulators.

The proposed reforms will also enhance post-market surveillance and improve the integration of pre- and post-market activities. In addition, a support service to assist Small and Medium sized Enterprises to navigate regulatory processes will be established, along with improved regulatory guidance information.

The TGA will continue to undertake conformity assessment (Pathway 1A) for inclusion of medical devices, including products containing a medicine or biological substance, providing flexibility for applicants.

The current most-commonly used approach to market authorisation in Australia where a device is issued with a CE mark following assessment by a European notified body, will continue as an option for sponsors to utilise (Pathway 2A). Mandatory application audits will continue for Class III and Active Implantable Medical Devices using this pathway, and application audits for certain Class II devices will continue to ensure an appropriate level of safety of medical devices supplied in Australia. It is anticipated, that as Europe continues its improvements to medical device regulation, confidence in selected European notified bodies will increase over the next few years and fewer TGA audits will be required.

In addition, three new pathways by which sponsors can seek TGA approval for inclusion of medical devices in the Australian Register of Therapeutic Goods (ARTG) will be available:

- Conformity assessment completed by a TGA-designated commercial body in Australia. These bodies could be an Australian affiliate of a European notified body, or a separate organisation (Pathway 1).
- Using an overseas marketing approval for the device in circumstances where the device has been:
  - Assessed by a body that has been designated to undertake conformity assessments by a comparable overseas designating authority (Pathway 2A);
  - Or approved by a comparable overseas regulator (Pathway 2B).
- Expedited approval for novel medical devices in certain circumstances (Pathway 3).

**Conformity assessment completed by a TGA-designated commercial body in Australia (Pathway 1)**

The TGA will develop a model similar to that in the EU whereby there could be multiple bodies, designated by the TGA, that are able to undertake conformity assessment certification within Australia. Medical devices certified by these bodies would not undergo application audit by the TGA when applying for inclusion in the ARTG. These designated bodies could potentially be designated to undertake conformity assessments for all classes of devices or for certain devices only.

These designated bodies would need to be located within Australia and would be assessing against Australian requirements, irrespective of whether the organisation was an Australian branch of a European notified body or an independent organisation. Development of this pathway will require the establishment of standards for technical and clinical competence and governance (including management of conflict of interest) which such bodies would need to meet in order to be designated. These standards will be developed in consultation with health care consumers, health professionals and industry.
The removal of the need for an application audit could mean a potential saving for industry of 6 months and earlier access for consumers.

**Utilisation of overseas conformity assessments or overseas approvals (Pathways 2A + 2B)**

This pathway includes the existing process whereby TGA accepts conformity assessment undertaken by a body designated by a comparable overseas designating authority, and uses this assessment to determine whether the device should be included on the ARTG. Currently, application audits are used to mitigate the risk of conformity assessments conducted by EU notified bodies. A concerted investment will be undertaken to build confidence in notified bodies that are commonly relied on for Australian marketing approval, with a view to the TGA over time recognising certification without the need for the current system of application audits.

In addition, the potential for more straightforward inclusion of a device that has been approved by a comparable overseas regulator will be explored. This would potentially allow for a streamlined application procedure for medical devices authorised by regulators such as those in the USA or Canada.

Benefits of these pathways include:

- Potential for faster access to market for industry and therefore earlier access for consumers – potentially six months sooner where an application audit is no longer required.
- Flexibility of alternative pathways for industry for inclusion of devices in the ARTG.
- Potential to remove the application audit process if the management of risk is appropriately shifted to the designation process.

**Expedited approval process for certain novel medical devices (Pathway 3)**

This pathway involves an expedited assessment of certain medical devices that are identified as ‘novel’. The TGA will develop criteria for what constitutes a ‘novel’ medical device, in consultation with consumers, health practitioners and industry.

Devices considered for expedited inclusion on the ARTG under an expedited assessment process will still be required to meet all relevant Essential Principles, and it is anticipated that this pathway will only be available for products which demonstrate the potential to address unmet medical needs for life-threatening or irreversibly debilitating diseases or conditions, and demonstrate a significant advance over those products already included in the ARTG. It is anticipated that most devices for which an expedited approval pathway is appropriate will be higher risk medical devices and IVDs. The decision on whether to accept a particular product for assessment into an expedited pathway will be made by TGA, and in practice will involve putting such products to the ‘front of the assessment queue’.

It is anticipated that applications may be able to be made for either:

- A priority conformity assessment to be undertaken by the TGA or by a body designated by the TGA (Pathway 1), and for the expedited assessment of the subsequent application for inclusion of the device in the ARTG; or
- For priority consideration of the manufacturer’s evidence supplied in conjunction with an overseas assessment (Pathway 2A + 2B), and for the expedited assessment of the subsequent application for inclusion of the device in the ARTG.

In some cases, TGA may apply particular conditions on the inclusion, such as requiring certain data to be collected post-market and reported to TGA at regular intervals. Benefits of Pathway 3 include faster patient access to medical devices capable of addressing unmet clinical need.