

# REVIEW OF MEDICINES AND MEDICAL DEVICES

## Terms of Reference

### Background

1. Australia has, by a number of different measures (life expectancy, survival with cardiovascular disease, survival with a range of cancers), amongst the best health outcomes of the OECD countries.
2. The regulatory framework of the Therapeutic Goods Administration (TGA) provides an important protection to the Australian community ensuring only safe and effective medicines and medical devices are granted authority to be marketed and/or exported.
3. The TGA also performs crucial post-market roles including the regulation of advertising for therapeutic products and the monitoring of adverse events to ensure the ongoing safety of therapeutic products.
4. A safe and effective regulatory framework for medicines and medical devices should balance safety and market access priorities to the benefit of patients and industry and align with the government's commitment to increase productivity and competitiveness.
5. It is timely to review the regulatory framework and processes under which the TGA operates, to identify opportunities to improve its operations. This will ensure the TGA is able to operate effectively and efficiently in comparison with high quality international regulators, in respect of regulatory imposts such as timeframes and costs to industry, while also maintaining appropriate public health and safety protections.

### Scope of the Review

6. The Review will benchmark TGA regulatory arrangements against trusted international authorities.
7. The Review will make recommendations and related implementation information to:
  - a. Ensure there is an appropriate balance between risk and benefit in the regulation of prescription, over-the-counter, complementary medicines and medical devices, as well as access for individuals to unapproved medicines and medical devices;
  - b. Simplify and streamline the approval processes undertaken by TGA. This will include recommendations on:
    - i. fast tracking approvals processes for medicines and medical devices;
    - ii. opportunities for working together with trusted regulators in other jurisdictions, including the potential for work-sharing assessments for products marketed in multiple countries; and
    - iii. exploring how risk assessments, standards and determinations of trusted regulators can be used more extensively by Australian regulators when approving the supply of medicines and medical devices.

- c. Ensure regulatory arrangements are sufficiently flexible to accommodate developments in medicines and medical devices, including exploring opportunities to streamline approvals that cross regulatory categories;
  - d. Improve the processes that assist industry, researchers and consumers to navigate the regulatory system for medicines and medical devices;
  - e. Support work underway on medical device reforms and clinical trial approval arrangements in Australia; and
  - f. Any other matters that the review committee regards as important and relevant to the safe and efficient supply of effective medicines and medical devices to the Australian people.
8. The Review will not make recommendations in relation to:
- a. Any aspect of the Pharmaceutical Benefits Scheme;
  - b. Work by the Department of Health on the reimbursement systems, including reimbursement and or subsidy of medicine and medical devices;
  - c. National Health and Medical Research Council arrangements relating to research and development; or
  - d. Work currently underway by the Department of Health and the Department of Industry on ethics processes for clinical trials.
9. The Review report will be provided to the Minister for Health, copied to the Prime Minister, the Assistant Minister for Health, and the Parliamentary Secretary to the Prime Minister responsible for deregulation, by 31 March 2015.