

Regulatory assessment of prescription medicines Roche Australia (Pharmaceuticals) Policy Position

Summary

- Roche supports ongoing consideration of opportunities to reduce “red tape” in pre-market regulatory requirements where it impacts on patients, the community and industry.
- Roche supports activities to streamline the Therapeutic Goods Administration (TGA) processes, arising from the Medicines and Medical Devices Review.
- Roche considers that the Australian reimbursement process also offers significant scope for process improvement, to reduce access delays following regulatory approval.

Background

The Therapeutic Goods Administration (TGA) regulates medicines through assessment for initial marketing authorisation, post-market monitoring and enforcement of medicine and manufacturing standards. It is in the community’s interest that regulatory decisions are timely and appropriate and that it can have confidence in them. Roche supports the TGA’s important role in assessing the efficacy, safety and quality of medicines in Australia.

Roche’s aim is for every person who needs our medicines to be able to benefit from them. So it is important that the pharmaceutical industry and the TGA work together to ensure that medicines are assessed in a timely way and made available to patients at the earliest opportunity. In Australia, Roche files dossiers for regulatory approval roughly at the same time as in the European Union (EU), based upon similar requirements. Roche additionally seeks to make investigative medicines available to patients prior to marketing authorisation through clinical trials and medicines assistance programs.

Roche position

It is important for the TGA to remain fit-for-purpose and internationally competitive, to ensure that Australian patients are protected by a robust system but do not experience delayed access. A best-practice regulator will work to ensure that its processes do not impose unnecessary delays in access and are focused on core activities that ensure safety, efficacy and quality of medicines for patients. Roche supports the TGA’s ongoing harmonisation and collaboration activities with regulators in similar jurisdictions (such as Canada, Switzerland and Singapore).

Roche welcomes the regulatory reform process arising from the Government’s Medicines and Medical Devices Review (MMDR), particularly the new priority and provisional approval processes. The extensive stakeholder engagement conducted as part of the reforms has been appreciated, as it is critical to ensuring that changes are occurring in a way that ensures that the TGA will remain a

world-leading regulator. As further legislative and regulatory amendments are developed, Roche expects that this collaborative, consultative approach will continue.

Roche supports ongoing consideration of opportunities to reduce “red tape” where it impacts on patients, the community and industry. In particular, Roche considers that the Australian reimbursement process through the Pharmaceutical Benefits Advisory Committee (PBAC) offers significant scope for process improvement, given the need for multiple reimbursement submissions for many innovative medicines. While companies have the opportunity to make “parallel” submissions for registration and reimbursement, there is also misalignment in timelines for documentation, cut-offs and meeting dates. As a result of fixed evaluation cycles, small differences in timing of regulatory and reimbursement processes can lead to much larger impacts on availability to patients.

Roche supports consideration of a future regulation policy that includes:

- continued red-tape reduction;
- further optimisation of internal processes for TGA and PBAC; and
- optimisation of these processes with respect to each other

Reducing delays prior to and following regulatory approval can be expected to have a significant benefit for patients who are awaiting access.

This position paper was adopted by the Roche Australia (Pharmaceuticals) Leadership Team on 15 September 2017 and entered into force the same day