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.
- For this reason, Roche supports harmonisation and collaboration activities being undertaken by the Therapeutic Goods Administration (TGA) with regulators in similar jurisdictions.
- Adoption of "overseas" approval is not a simple matter due to differing decisions between jurisdictions and the need for a local context, given differences in medical practice between countries.
- 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 patient assistance programs.

Roche position
Roche considers that the TGA is a robust and high-quality regulatory agency that is actively engaged in harmonisation and collaboration activities with regulators in similar jurisdictions (such as Canada, Switzerland and Singapore) to streamline processes. Roche's recent experience in Australia is that our regulatory submissions are approved by the TGA at roughly the same time or earlier than in the EU[1]. This is supported by a recent international comparison of median approval times, which showed Australia outperformed Europe, on average, in recent years[2]. United States (US) Food and Drug Administration (FDA) approvals can be faster, as there is the ability to "fast track" or prioritise some medicines[3].

Roche recognises that there are areas where TGA processes could be more flexible, especially around priority review for areas of high unmet patient need, or local duplication of processes that are well managed internationally, such as risk management programs or adverse event (side effect) reporting. The Australian pharmaceutical industry has seen an overall loss of flexibility in TGA processes, without a gain in timeliness, as noted by Medicines Australia[4].

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. For this reason, Roche supports the Expert Review of Medicines and Medical Devices Regulation commissioned by the Australian Government in October 2014[5]. "Red tape reduction", when undertaken in a considered way, has the potential to benefit industry, patients, government and the community. In order to ensure that deregulation efforts are effective and do not lead to unintended consequences, Roche supports broad consultation with stakeholders and a partnership between the TGA and industry.

Roche considers that many TGA decisions can be streamlined without the loss of community confidence in the system, with options for consideration including:

- Variation of registration pathways according to risk/benefit and assessment needs, for example application of a "fast track" process for innovative medicines addressing high unmet need, as utilised in the US;
- Automatic recognition of EU medical device registration;
- Elimination of bureaucratic barriers to recognition of EU or US Good Manufacturing Practice (GMP) clearance;
- Removal of requirement for a local Risk Management Plan (RMP) if an EU RMP exists;
- Adverse event reporting to be managed through World Health Organisation (WHO) and sponsor companies rather than with the TGA as an intermediary;
- Increased utilisation of foreign evaluation reports for Australian decisions where available;
- Streamlining regulatory approvals of new indications (approved uses) where medicines have become genericised, e.g. based on decisions in other jurisdictions; and
- Reduction in burden of proof for updates to Product Information (PI).

More significant reforms to the TGA's role, such as automatic adoption of overseas approvals for new medicines, must be approached with caution. Not all companies file applications in both Europe and the US; and where they do, the European Medicines Agency (EMA) and FDA do not always come to the same conclusion. This suggests that there is no uniform "overseas approval" that can be accepted in place of a local assessment of quality, efficacy and safety. Differences in medical practice between countries, such as the standard of care that may be currently available to patients, mean that a local context is critical. Regulatory decisions are rarely "yes/no", but are more commonly a decision to approve with caveats. It is the nature and extent of these caveats, usually

involving the extent of patient population, breadth of indication (approved uses) and other special conditions, which determines the way in which the medicine will be used.

If consideration is given to automatic adoption of an overseas decision, the following issues would need to be addressed:

- Approval for products where different decisions or different approvals are made in the EU and US;
- Approval of subsequent variations to a product initially approved under an automatic adoption pathway;
- Providing options for companies appealing a negative decision in Australia if it was based on adopting a decision from overseas; and
- Determining the application of the Pharmaceutical Benefits Advisory Committee (PBAC) parallel process in the absence of local timelines for registration.

This is a complex area, and Roche supports industry consultation to draw on the significant global regulatory experience of multinational companies to ensure that reform is considered and effective. Roche welcomes the opportunity to continue collaboration with regulators in Australia and globally to ensure that patients receive timely access to medicines that are properly evaluated for safety, quality and efficacy.

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 offers significant scope for process improvement, given the need for multiple reimbursement submissions for many innovative medicines. By reducing delays following regulatory approval, streamlining reimbursement processes could 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 May 2015 and entered into force the same day

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[1] Data on file

[2] Centre for Innovation in Regulatory Science. 2014. "The impact of the changing regulatory environment on the approval of new medicines across six major authorities 2004-2013", R&D Paper 55

[3] Food and Drug Administration (FDA). 2014. "Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review", accessed from http://www.fda.gov/forpatients/approvals/fast/default.htm, 28/04/15

[4] Medicines Australia. 2015. "Submission to the Expert Review of Medicines and Medical Devices Regulation". Canberra

[5] Department of Health. 2014. "Expert Review of Medicines and Medical Devices Regulation", accessed from http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation, 19/01/15