Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

ROCHE SUBMISSION TO SENATE
COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Roche Products Pty Limited
Pharmaceuticals Division, Dee Why

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in-vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry eight years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in research and development, including over AUD 37 million in pharmaceuticals in Australia. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

Roche's pharmaceutical division in Australia employs approximately 350 people who are dedicated to the clinical development, registration, reimbursement, sales, marketing and distribution of innovative pharmaceutical medicines. Australian patients have access to about 40 Roche medicines, and the company is the leading provider of cancer medicines in Australia by sales. For more information, please visit www.roche-australia.com.

MN: 37559507

Recommendation

That the Committee recommend passage of the *Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016* by the Senate.

Introduction

Roche welcomes the opportunity to provide input to the Senate Community Affairs Legislation Committee inquiry into the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016.

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.

Opportunity for reform

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. Roche supports measures to find efficiency gains in the Australian regulatory system, including through seeking to align the TGA with international best practice, harmonisation with other high-quality regulators, and seeking to expedite processes for medicines addressing high unmet patient need.

Roche welcomes the collaborative process that has been undertaken by the Government, including through the Medicines and Medical Devices Review (MMDR) and subsequently. The extensive stakeholder engagement to date can give the Committee confidence that reforms are occurring in a way that ensures that the TGA will remain a world-leading regulator.

Provisions of the Bill

Roche supports the Medicines Australia (MA) submission to this inquiry on behalf of the innovator pharmaceutical industry and recommends the passage of the Bill through the Senate. This submission outlines key issues for the Committee to consider.

The Bill does not dilute, diminish or reduce the TGA's statutory focus on medicines safety, efficacy and quality

Roche supports a robust regulatory system in Australia. Australia has globally recognised standards for the approval of medicines and medical devices and this will continue and be enhanced by the provisions of the Bill. Expedited pathways, which would be permitted under the reformed process, would not lower the bar of safety, efficacy and quality that is relied upon by Australians.

The Bill reflects extensive consultation through the MMDR process

The reforms proposed in the Bill reflect detailed consultation undertaken over the last 28 months, during and following the MMDR[1]. They have wide-ranging support from professional and patient groups and the pharmaceutical industry. Over 100 submissions were received and the review panel held face-to-face meetings with consumer, clinician and industry organisations during the consultation process[2].

The Bill will support more timely access to medicines that Australian patients need

Currently, the standard registration process for prescription medicines is 12-15 months[3]. For patients with life-threatening conditions, this delay can have serious consequences. The reforms outlined in the Bill would retain the standard process for most medicines, but would allow some medicines to be "fast-tracked". These medicines, which would be selected by the TGA based on strict criteria, could be available to patients three months earlier[4]. They would still be subject to the TGA's standards for safety, quality and efficacy and the TGA will also have strict criteria for medicines to "exit" these pathways.

As the Government noted in its interim response to the Senate Community Affairs References Committee inquiry into cancer medicines access, the MMDR implementation is the first step in improving access to lifesaving therapies[5]. A more flexible reimbursement system to follow the reformed TGA process will also be needed to ensure that access is also affordable, equitable and sustainable.

The Bill will align the TGA with the world's best regulatory systems

Roche considers that the TGA is a robust and high-quality regulatory agency. However, there are areas where current TGA processes could be more flexible[6] and aligned with international best practice. The Bill will increase sharing of work and documentation with comparable overseas regulators to streamline assessments. However, the TGA will remain the final decision-maker for Australia and will not be ceding this important function.

Parliament will be able to review the details of subsequent regulations

The referral of the Bill to the Senate Committee correctly identifies that there are additional steps in legislative implementation. The amendments to the Act rightly do not provide specificity on how the reforms will be implemented; they provide the enabling changes to the *Therapeutic Goods Act*. Any changes to the *Therapeutic Goods Regulations* or the TGA's operating processes will be subject to further stakeholder consultation to mitigate against unintended consequences[1]. The Parliament will also have the opportunity to approve or reject any changes to the Regulations.

Roche appreciates the opportunity to highlight these issues and affirms its support for the implementation of the reforms outlined in the Bill.

References

1. Ley S. Second reading speech, Therapeutic Goods Amendment (2016 Measures No.1) Bill 2016, 1 December 2016, Hansard
2. Sansom L, Delaat W, Horvath J. 2015. “Review of Medicines and Medical Devices Regulation: Report on the regulatory framework for medicines and medical devices”. Stage One Report. Australian Government, Canberra.
3. Medicines Australia. 2017. “Supporting better health outcomes for Australia”. Issues Brief 1: Access. MA, Canberra
4. TGA. 2016. “Consultation: Expedited pathways for prescription medicines”. Version 1.0. Australian Government, Canberra
5. Ley S. 2016. Interim Government response to the Senate Community Affairs References Committee. 7 October 2016
6. Medicines Australia. 2015. “Submission to the Expert Review of Medicines and Medical Devices Regulation”. Canberra