Access to medicines via the Pharmaceutical Benefits Scheme

Roche Australia (Pharmaceuticals) policy position

Summary

- Patient access to medicines needs to be at the centre of a sustainable Pharmaceutical Benefits Scheme (PBS).
- Roche supports the use of savings measures for off-patent medicines as long as patients aren't disadvantaged in any way.
- Roche is concerned that despite significant savings since 2007, Australia continues to restrict access to new medicines, taking a narrow approach that undervalues innovation.
- Roche supports continued reform of the PBS to better value new medicines and re-prioritise investment to improve access to medicines for patients.

Background

Access to quality healthcare is a shared responsibility requiring all stakeholders to work together. The Pharmaceutical Benefits Scheme (PBS) has delivered access to medicines to generations of Australians and Roche supports its continued role. In Australia, private health insurance does not have the appropriate mechanisms to subsidise medicines for members and as a result, patients rely heavily on the PBS. Over the last decade, the Government has used savings generated from the off-patent market to create "headroom" for investment in new innovative medicines. The separation of patented and generic medicines into "formularies" is a key component of this approach.

Roche position

Roche's aim is for every person who needs our medicines to be able to benefit from them. Roche believes more can be done to support the needs of Australians for affordable, quality healthcare including access to medicines that is at least in line with other comparable developed economies.

Roche recognises the need for the Australian health system to be financially sustainable, while investing appropriately for a highly-developed country. Roche supports the principle that PBS savings should be achieved where generic competition exists and patient access and outcomes are not compromised, allowing continued investment in new medicines that reflects their value.

Major PBS reforms in 2007, 2010, 2013 and 2015 have generated savings well in excess of $20 billion[1]. However, with PBS expenditure now declining per person[1], it appears that Australia has not taken full advantage of this opportunity to reinvest in the benefits of medicines innovation. Instead we have seen extended listing delays and some products never reimbursed due to the challenging health technology assessment (HTA) process. A 2015 report found that Australia ranked 18th out of 20 Organisation for Economic Cooperation and Development (OECD) countries for access to new

medicines[2].

Roche is concerned that access to medicines is being limited by a focus on cost containment and an expectation that Australia can achieve prices significantly lower than in comparable developed nations. When deciding on the Australian price, Roche assesses the product's value as well as Australia's ability-to-pay, meaning prices requested in Australia are similar to those in economically comparable countries. Yet at times these prices are still not considered cost effective by the Pharmaceutical Benefits Advisory Committee (PBAC) and Australian patients may miss out on timely access to medicines and/or indications available overseas. This is largely a consequence of Australia's narrow approach to assessing value, which may miss such elements as unmet need, science and innovation, patient impact and the impact on health systems and society.

We believe the reimbursement system in Australia needs to reform its approach to valuing medicines to better capture the full benefit of innovative therapies and to sustain an appropriate level of investment in medicines. This would allow Australia to align with the prices negotiated in economically comparable countries and ensure that patient access is not compromised. Benchmarking Australia's prices for both patented and generic medicines to other OECD countries with a similar ability-to-pay may allow Australia to re-prioritise investment towards new, innovative medicines and ensure that it appropriately values medicines across their lifecycle, during and after patent protection. Further savings could be achieved by rapidly matching prices achieved globally for off-patent medicines and increasing the funds available to invest in and properly value new, innovative medicines.

In order to improve timely access, Roche supports a more dynamic approach to HTA through the appropriate use of managed entry schemes for innovative medicines. Under managed entry, an initial subsidy is provided at a price justified by the existing data, pending the submission of more conclusive evidence. Roche notes that the initial price must still reflect the value of the product and be in step with launch prices in other developed markets. The totality of available evidence needs to be considered, and subsequent evidence collection must be fit-for-purpose (i.e. focus on areas of clinical uncertainty). Companies and the PBAC should predefine and agree on clinical outcomes limits to be achieved in real-world practice. If these limits are reached and cost-effectiveness improves or becomes more certain, this should allow for a subsequent increase in price.

Roche proposes that the reimbursement system be reviewed to ensure that it strikes the appropriate balance between fiscal sustainability and reinvestment of savings into delivering access to innovative treatments that improve patient outcomes. Investment in the PBS needs to be sustainable, growing in line with the economic resources of Australia and the needs of an ageing population, and appropriately targeted to where the value for healthcare and the community is greatest.

Further reference

Roche Position on Assessing the Value of Roche Products and Services (Global policy)

This position paper was adopted by the Roche Australia (Pharmaceuticals) Leadership Team on 24 February 2017 and entered into force the same day.

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[1] Medicines Australia. 2016. "Submission to the 2016-17 Federal Government Budget". MA, Canberra

[2] Medicines Australia. 2015. "COMPARE: Comparison of Access and Reimbursement Environments". Edition 1. MA, Canberra