Access to medicines under 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, where these do not disadvantage patients, rather than restricting patient access to innovative new therapies.
- However, we are concerned that despite significant savings since 2007, Australia continues to restrict access to new medicines, taking a narrow approach that undervalues innovation.
- We support continued reform of the PBS to better value new medicines and re-prioritise investment to improve access for patients.

Background

Access to quality healthcare is a shared responsibility requiring all stakeholders to work together. Roche's aim is for every person who needs our medicines to be able to benefit from them.

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. 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 position

Roche recognises the need for the Australian health system to be financially sustainable, while investing appropriately for a highly-developed country. For this reason, we support the Government's use of savings generated from the off-patent market to create "headroom" for investment in new innovative medicines that can benefit patients. Roche supports the principle that 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.

We have supported the principles of previous reforms to the PBS on the understanding that these would allow continued investment in innovative medicines. These have included the separation of patented and generic medicines into "formularies" and the use of price disclosure for generic medicines to ensure that the PBS price reflects the impact of competition in the market, without this affecting the price of newer, patented treatments.

Savings since 2007 have been significant and continue to exceed their original estimates, supporting the fiscal bottom line more than any new savings measure in the 2014-15 Budget[1]. The Centre for Strategic Economic Studies has estimated that the 2007 and 2010 PBS Reforms will deliver nearly $18 billion in savings to 2017-18[2], providing a real opportunity to invest in innovative medicines.

However, with PBS expenditure now declining relative to economic growth and inflation[3], it appears that Australia has not taken full advantage of this chance to access the benefits of medicines innovation. Instead we have seen declining success rates for reimbursement submissions and extended listing delays, as well as companies deciding not to submit some medicines for reimbursement in Australia due to the challenging health technology assessment (HTA) process. This is demonstrated by Australia's lagging behind other Organisation for Economic Co-operation and Development (OECD) countries in access to cancer medicines. An international comparison showed Australia only funded 46% of approved indications (i.e. types of cancer and patients) for 10 oncology medicines, compared to 100% in the USA and Sweden, 92% in Germany, 90% in France, and 88% in Italy[4].

Underinvestment in new medicines comes at a cost to Australia. Medicines that do not meet current HTA hurdles may offer superior and better supported value for money than many areas of public spending that are not subject to this level of scrutiny. A total of 52 submissions were awaiting reimbursement as at 1 April 2014, having been either rejected or deferred by the Pharmaceutical Benefits Advisory Committee (PBAC)[5].

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 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.

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. Further savings could be achieved by rapidly matching prices achieved globally, increasing the funds available to

invest in and properly value new, innovative medicines. This is aligned with the PBS principle of considering prices "in reasonably comparable overseas countries"[6].

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.

Pricing policies, such as the current application of sections 99ACB and 99ACD of the *National Health Act 1953*, can discourage innovations that bring meaningful benefits to patients, such as through new presentations that may aid compliance and the quality use of medicines. It is vital that mandatory price reductions do not act as a barrier to such improvements being made available.

Access and the efficiency of the reimbursement system are both threatened by an increase in the number and frequency of "post-market reviews" of medicines already listed on the PBS. While Roche agrees that it may be appropriate to review medicines' value for money from time to time, the post-market reviews to date have been challenging, with inadequate consultation with stakeholders and inconsistent application of processes. Although the process has improved following industry engagement, it continues to impose a heavy red-tape burden on all stakeholders.

These therapeutic area-specific reviews appear to have been primarily focused on reducing the price of patented medicines, which may undermine the validity of the initial HTA. This also creates significant uncertainty for research-based companies, which cannot be certain of gaining a fair return on investment during the period of patent protection. Furthermore, real-world evidence used for the purpose of post-market reviews may introduce clinical uncertainty and should be used cautiously to avoid compromising patient health. Roche considers that the use of post-market reviews should be limited to where the evidence base or clinical practice has changed significantly since listing and proper review is necessary to support patient outcomes.

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 16 January 2015 and entered into force the same day.

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[1] Medicines Partnership of Australia. 2014. "May 2014: The PBS leads Budget 'heavy lifting'", accessed from http://medicinespartnership.com.au/pbs-scorecards/may-2014-the-pbs-leads-budget-heavy-lifting/, 18/09/14

[2] Sweeny K. 2013. "The impact of further PBS reforms: Report to Medicines Australia", Victoria University, Melbourne

[3] Calculated from Department of Health "Portfolio Budget Statement" (multiple years), ABS "National Accounts", "Consumer Price Index"

[4] Cheema PK, Gavura S, Migus M, Godman B, Yeung L and Trudea ME. 2012. "International variability in the reimbursement of cancer drugs by publically funded drug programs", *Curr Oncol*. 19(3): e165–e176

[5] Wonder Drug Consulting. 2014. "Development of Industry Relevant Key Performance Indicators for the Pharmaceutical Benefits Scheme (2010-2013)", Report to Medicines Australia

[6] Department of Health. 2013. "Annual Report 2012-2013", Appendix 2, Commonwealth of Australia, Canberra

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