Value of medicines innovation

Roche Australia (Pharmaceuticals) policy position

Summary

- The value of innovative medicines includes a broad range of factors, such as improved health and wellbeing, productivity and carer benefits, healthcare efficiency and addressing unmet needs.
- Roche believes medicines funding needs to be sustainable, should grow in line with the economic resources of Australia and the burden of disease, and be targeted to where the value of medicines is greatest.
- If the system for valuing medicines is too narrowly focused on costs and does not appropriately recognise and reward innovation, Australians will miss out on improved health, wellbeing and productivity.
- Roche supports a review of the Australian reimbursement system to ensure that innovation is appropriately valued, with a level of investment that ensures Australians access a high standard of healthcare.

Background

Roche is among the top research investors worldwide and the top investor in the healthcare sector[1]. The company has an industry-leading pipeline of 70 new molecular entities (products in development)[2], with many potential first-in-class or best-in-class medicines in late-stage clinical testing, which may offer tangible health benefits for patients.

Innovative healthcare companies are expected to explore new fields of science in order to find novel and better medicines, diagnostic products, medical devices and services to address unmet medical needs. In Australia, the National Medicines Policy recognises the necessity of a "consistent and supportive environment for the industry, and appropriate returns for the research and development, manufacture, and supply of medicines"[3].

Stakeholders also expect innovative products and services to be affordable and accessible by patients in an equitable manner. In Australia, the Pharmaceutical Benefits Scheme (PBS) is the primary mechanism by which patients access medicines. Decisions on granting or denying access to innovative medicines via the PBS have profound implications for the lives and well-being of patients, their families and society. They also send signals that influence the direction and location of research and development activities of innovation-focused medical research companies like Roche. Hence to secure ongoing investment and ensure Australians continue to have access to new medical innovation, the value of these products and services must be appropriately assessed, recognised and rewarded.

Roche position

Medicines innovation has many value components including: the health impact of a medicine on patients; the suitability of a treatment for patients with unmet needs; the convenience or efficiency of administering a medicine for health professionals; the reduced burden on carers; the economic gains from improved productivity; the budget savings from replacing inefficient older treatments; and the improved understanding of diseases and medicine targets gained by researchers.

There is important community value in both specific products and a sustainable medicines industry that continuously improves healthcare. In order for research-based companies such as Roche to continue to deliver improved healthcare to Australians, it is important there is adequate investment available to provide access for patients and to encourage industry innovation. This funding 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 the community is greatest.

In allocating health funding, Roche supports an evaluation and comparison of the value and the costs of different healthcare technologies, which may include the use of health technology assessment (HTA) and other decision tools. In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) performs HTA to advise the Government about the value of medicines. HTA has the potential to reward innovation, as is the case in countries such as France and Germany which consider the level of innovation in evaluating new medicines. However, in practice, the operation of the Australian HTA system and the reward for innovation are frequently not aligned.

The PBAC's approach is focused on incremental cost-effectiveness ratios (ICERs), which only consider some aspects of value such as survival and quality of life, and budget impact. As a result, funding decisions on specific medicines are often out-of-step with other developed countries which have a similar ability-to-pay. Important value elements of medicines may be missed, including productivity gains, benefits for carers, improvements in patient compliance and the benefits of treatments in rare diseases where robust clinical trials are challenging to conduct. Sending a signal to companies through HTA and access decisions that these aspects are not valued by payers does a disservice to the Australian community and discourages innovative research. It also presents equity issues for those patients who are unfortunate enough to be diagnosed with a rare disease or a disease where the value is measured in a non-standardised way, such as productivity benefits.

Undervaluing and underinvesting in new medicines comes at a cost to Australia. Medicines that do not meet current PBAC hurdles frequently offer superior and better supported value for money than many areas of public spending that are not subject to this level of scrutiny. Seeking to contain costs by restricting access to new medicines on price and budget grounds represents a "false economy" in many cases. By focusing on budget silos and missing the full value of medicines, Australia may risk underinvesting in medicines that could support the productivity of Australia's

ageing population, which would pose long-term budget challenges.

The place of medicines in therapy (and their value) may evolve over time. Frequently, the first patient population in which a medicine is studied is the hardest in which to demonstrate benefits; often these patients are progressed in their disease and have failed all available treatments. As medicines are used at earlier stages of disease and in other conditions, with evolving real-world evidence through use of registries, their full value becomes apparent[4]. A static approach to evaluating medicines is unlikely to recognise their full benefit to Australia and we may inadequately invest in important treatments as a result.

The value of a medicine also continues beyond patent expiry, when generic and biosimilar competitors drive down the price markedly. In most cases, competition and price reductions occur after 10-12 years on the market, and the lifetime value of the medicine may include many years of improved health benefits at very low cost to payers. Without the initial introduction of a medicine, which depends on the innovator company being able to achieve a return on investment, the full long-term value of the medicine may never be realised.

Roche supports a review of the Australian reimbursement system to ensure that innovation is appropriately valued, with a level of investment that delivers a high standard of healthcare.

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] PWC. 2016. "The Global Innovation 1000", accessed from http://www.strategyand.pwc.com/innovation1000#GlobalKeyFindingsTabs3, 11/11/16

[2] Roche. 2015. "Annual Report 2015 highlights", accessed from http://www.roche.com/investors/reporting/ar15_highlights.htm#2015-highlights, 11/11/16

[3] Department of Health. 2000. "National Medicines Policy", Commonwealth of Australia, Canberra

[4] Abernethy A, Abrahams E *et al.* 2014. "Turning the tide against cancer through sustained medical innovation: The pathway to progress", *Clinical Cancer Research*, 20:1081-1086