

Pricing

Roche Australia (Pharmaceuticals) Policy Position

Summary

- The prices of Roche medicines reflect the value that innovation delivers to patients, their families and societies, and a sustainable return on the high-risk investments Roche makes in developing therapies for unmet needs.
- As we operate in a globalised economy, Roche follows a global pricing band set by our parent company for economically-comparable countries.
- The Australian system for valuing medicines needs to be reformed to better capture the full benefit of innovative therapies when assessing their prices and to ensure that patient access is not compromised.
- Benchmarking Australia's prices for both patented and generic medicines to countries with a similar ability-to-pay may give the Government confidence in knowing Australia is getting a fair deal, and allow investment to be prioritised to innovative medicines that improve patient outcomes.

Background

At Roche, our primary contribution is to invent and develop medicines that significantly improve people's lives. Our aim is for every person who needs our medicines to be able to benefit from them. The prices of Roche medicines reflect the value the innovation delivers to patients, their families and societies as well as the inherent risks in research and development required to sustain vital innovation and to continue to fulfil unmet patient needs in the future.

The development process for a new medicine is highly risky; only a small portion of early-stage research makes it into clinical trials involving patients, and of those, only one in five results in an approved medicine¹. To develop one medicine, it is estimated to cost over USD 1.4 billion (AUD 1.6 billion)². Pricing of those medicines that make it to market must take into account the costs of research "failures" and allow investment for future success.

Roche position

As an innovation-driven global healthcare leader, Roche relies on a transparent, open and consistent assessment and decision-making process of third party payers when considering the value of our innovative medicines.

We believe value has many components and it extends to many different stakeholders: in addition to patient outcomes (both length and quality of life), this includes improvements in efficiency of

health care delivery, avoiding unnecessary treatments and procedures, and improving drug administration and compliance in treatment.

When deciding on the Australian price, Roche assesses the viability of a price that reflects the ability-to-pay of the Australian payer (generally the Government) for a specific medicine. Since Roche sells medicines globally, prices in different markets are interdependent, due to external reference pricing and parallel trade. While differences in health technology assessment (HTA) methodology and decision criteria may change payers' "willingness-to-pay", many governments and insurers will typically seek to achieve the best price available in similarly developed markets. This restricts the ability of a company like Roche to grant price concessions exclusively to payers that apply different HTA methodologies but are otherwise economically comparable. Roche Australia operates within a global pricing band set by the parent company and has very limited ability to price below this band.

On the one hand, this ensures that prices requested for medicines in Australia on the Pharmaceutical Benefits Scheme (PBS) are in line with those requested and reimbursed in comparable developed countries such as in Western Europe. However, at times prices requested in Australia are not considered cost effective by local HTA decision-makers. As a result, several medicines and/or their indications (uses) may not be currently available to Australian patients but may be available to patients in economically-comparable countries. This is largely a consequence of the narrower approach to assessing the value of innovative medicines and a lower "willingness-to-pay" in Australia.

In some cases, in order to meet the requirements of the Australian Pharmaceutical Benefits Advisory Committee (PBAC), a confidential pricing agreement is used to allow some limited flexibility within the global pricing band. While Roche welcomes pricing transparency at an aggregate level to demonstrate the level of cost savings afforded to the Government through these discounts, pricing flexibility would not be possible in the presence of complete price transparency at the individual product level.

Roche notes that concerns about increasing prices of innovative medicines in Australia are not supported by evidence. The average PBS price paid for oncology medicines has declined in the last two years³, in comparison to an overall health inflation rate of more than four percent per annum and consumer price inflation of two percent⁴. Confidential rebates may lower prices further.

Roche believes the reimbursement system in Australia needs to reform its approach to valuing medicines to better capture the full benefit of innovative therapies. The Australian HTA system must be increasingly flexible, taking account of the value of medicines to patients, carers, clinicians and society, as well as the evolving value of a medicine over its lifecycle, and adopting a willingness-

to-pay in line with other developed countries. This would allow Australia to align with the prices negotiated in economically comparable countries and ensure that patient access is not compromised by undervaluing medicines.

Benchmarking Australia's prices for both patented and generic medicines to other Organisation for Economic Co-operation and Development (OECD) countries with a similar ability-to-pay may give the Government confidence in knowing Australia is getting a fair deal, and allow resources to be directed towards investing in new, innovative medicines that improve patient outcomes.

Further reference

Roche Position on Pricing (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.

¹ Medicines Australia. 2011. "Innovation for the Health of the Nation", Occasional Paper Series No. 2, Canberra

² Tufts Centre for the Study of Drug Development. 2014. "Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion" accessed from http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study, 27/11/14, converted at rate of 0.85 USD = 1 AUD

³ Calculated from PBS Expenditure Statistics for ATC group "Antineoplastic and immunomodulating agents", accessed from <http://www.pbs.gov.au/info/browse/statistics#Expenditure>, 16/09/14

⁴ Australian Bureau of Statistics. 2014. "6401.0 - Consumer Price Index, Australia, Jun 2014", accessed from <http://www.abs.gov.au/ausstats/abs@.nsf/mf/6401.0>, 16/09/14