Health technology assessment

Roche Australia (Pharmaceuticals) policy position

Summary

- Roche is concerned that health technology assessment (HTA) of new medicines in Australia does not recognise the full value of innovative therapies.
- Roche believes the reimbursement system for medicines in Australia needs to consider fit-for-purpose evaluation of medicines.
- Roche is calling for early engagement and increased citizen, patient, clinician and academic involvement in reimbursement system decision-making, along with incorporation of societal values and costs/benefits beyond the health system.
- Roche believes a greater level of investment in innovative medicines is required to ensure Australians retain access to a healthcare system suitable for a highly developed nation.

Background

Public and private payer decisions on granting or denying access to innovative medicines have profound implications for patients, their families and society. It is important that all parties involved in the process have a clear and consistent view on how innovative medicines should be assessed.

In Australia, health technology assessment (HTA) is undertaken by the Pharmaceutical Benefits Advisory Committee (PBAC) for listing of medicines on the Pharmaceutical Benefits Scheme (PBS) and the Medical Services Advisory Committee (MSAC) for listing of diagnostic tests and medical services on the Medicare Benefits Schedule (MBS).

Roche position

Roche considers that reimbursement decisions for our medicines should be based on scientific assessment of the strength and quality of our clinical evidence. They should reflect the value of innovation, which has many different components and extends to many different stakeholders: in addition to patient health outcomes, this includes improvements in efficiency of healthcare delivery, the productivity and quality of life of patients and carers, avoiding unnecessary treatments and procedures, and improving medicine administration and compliance in treatment.

However, Roche is concerned that the Australian HTA system is not delivering on its objective of timely access to affordable medicines, as set out in the National Medicines Policy[1]. 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]. Not only have success rates for reimbursement submissions diminished in recent years, Roche is aware of companies deciding not to submit some medicines for reimbursement in Australia due to the challenging HTA process.

The assessment process also involves lengthy delays for many of those medicines that are eventually listed, including potential for multiple resubmissions and positive recommendations that increasingly come with conditions that may require extensive negotiation if listing is to occur.

Roche believes the reimbursement system for medicines in Australia needs to consider:

- Fit-for-purpose evaluation of medicines (taking into account budget impact, level of innovation and complexity, rarity of disease, unmet need and clinical benefit);
- Increased citizen, patient, clinician and academic involvement in decision-making, with improved transparency around decision-making and criteria;
- Incorporation of societal values and costs/benefits beyond the health system into the decision-making process; and
- Earlier and increased engagement between all stakeholders to reduce the risk of multiple resubmissions.

The overall process of PBAC assessment could be made more fit-for-purpose, in line with the Government's commitment to reducing "red tape", the recommendations of the 2015 Senate inquiry into cancer medicines access and the regulatory reforms announced in response to the 2015 Medicines and Medical Devices Review. There has been a significant increase in workload for the PBAC in recent years. The complexity of a standard evaluation is reflected in the large cost-recovery fees charged to pharmaceutical companies. However, not all submission types require this comprehensive assessment, such as medicines with limited budget impact or where economic issues are comparatively straight-forward. Conversely, more complex submissions would benefit from greater consideration involving a wide group of stakeholders early in the process.

More and more, Australia stands alone in continuing to apply a "one-size-fits-all" approach to cost-effectiveness methodology, regardless of medicine or therapeutic area. The PBAC typically favours a utilitarian approach to equity, seeking to maximise quality-adjusted life years (QALYs) gained for a given cost, whereas other countries' ethical frameworks suggest giving greater consideration to those in greatest need may result in the fairest outcome.

Local evidence suggests that a "QALY maximisation" approach is not supported by the Australian community where it harms equity[3]. While we understand the PBAC exercises some flexibility in this regard, it is important that the Australian community has a voice in determining what is value for money in HTA. These values can only be derived through a process that allows active participation by citizens and a clear set of decision-making principles reflecting society's preferences, an approach considered in other HTA countries (UK, Canada and The Netherlands).

Roche recommends greater incorporation of societal values and benefits beyond the health system (such as productivity gains and benefits to carers) into the decision-making process. At a time

where Australia faces an ageing population and is focused on ensuring a productive and growing workforce, these elements must be given due consideration. While methodological challenges exist, not capturing productivity gains or losses at all is unlikely to be the right approach[4].

Early industry engagement with the PBAC could help address clinical, technical and methodological issues in advance of a first submission and reduce the likelihood of rejection. Companies would greatly value early multi-stakeholder engagement to identify issues and ensure that submissions present an agreed, appropriate approach and are fit-for-purpose.

Roche is also concerned that the PBAC's approach to selecting medicine comparators for HTA is not consistent and may include treatments that are not appropriate, not registered for a particular relevant indication, or not supported by evidence. There was much discussion during the review of the PBAC Guidelines on how the main comparator should be defined, with an earlier version recommending the lowest cost comparator[5]. While the final revised Guidelines have retained a focus on the most commonly used comparator, PBAC decision making is not always consistent with this principle. Roche is concerned that the use of the lowest cost comparator may significantly impact the ability of companies to list new medicines and indications on the PBS due to pricing constraints.

Roche recommends a review of the Australian reimbursement system to ensure that processes are fit-for-purpose and efficient, innovation is valued, and patients do not miss out on access. In the absence of reform, the Government may undervalue, and therefore not invest in, medicines that offer significant benefits to society. Roche supports the use of savings measures to deliver sustainability without reducing health outcomes. This can be achieved where there is competition in the off-patent market, rather than by limiting access to high-value new therapies.

Further reference

Roche Position on Assessing the Value of Roche Products and Services (Global policy)
Roche Position on Pricing (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] Department of Health. 2000. "National Medicines Policy", Commonwealth of Australia, Canberra
[2] Medicines Australia. 2015. "COMPARE: Comparison of Access and Reimbursement Environments". MA, Canberra
[3] Nord E, Richardson J, Street A, Kuhse H, Singer P. 1995. "Maximising health benefits versus egalitarianism: An Australian survey of health issues". Centre for Health Program Evaluation, Working Paper 45, Melbourne
[4] Drummond M. 1992. "Australian guidelines for cost-effectiveness studies of pharmaceuticals". *PharmacEconomics*. 1(1):61-69
[5] Roche Products Pty Ltd. 2016. Response to public consultation on the PBAC Guidelines Review.