

Health technology assessment

Roche Australia (Pharmaceuticals) Policy Position

Summary

- Roche is concerned that health technology assessment (HTA) in Australia of new medicines 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;
 - Increased citizen, patient, clinician and academic involvement in decision-making;
 - Incorporation of societal values and costs/benefits beyond the health system; and
 - Earlier and increased engagement between all stakeholders.
- This should be accompanied by a level of investment in innovative medicines that ensures Australians retain access to a healthcare standard 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 outcomes (both length and quality of life), this includes improvements in efficiency of health care delivery, 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 Policy¹. For example, Australia lags behind other Organisation for Economic Co-operation and Development (OECD) countries in terms of access to oncology medicines. An international comparison of 10 oncology medicines in 2012 showed Australia only funded 46% of the approved indications (i.e. types of

cancer and patients) for these medicines, compared to 100% in the USA and Sweden, 92% in Germany, 90% in France, and 88% in Italy². 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. In addition, sponsor companies can only engage with the PBAC to understand technical issues once a submission has been rejected.

Targeted therapies that use companion diagnostic tests (“co-dependent technologies”) are key to delivering on the promise of personalised medicine, maximising the benefits of treatment and minimising side-effects. Unfortunately, the process for assessing these technologies is even more complex, with the time to access a targeted therapy at least twice that for a medicine that does not require a genetic test³. While the Government’s HTA Review in 2009⁴ initiated significant activity integrating assessment of medicines and diagnostics, the process remains complex and unpredictable.

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.

The overall process of PBAC assessment could be made more fit-for-purpose, in line with the Government’s commitment to reducing “red tape”. There has been a significant increase in workload for the PBAC, with meetings now extended from three to four days. The complexity of a standard evaluation is reflected in the large cost-recovery fees charged to sponsor 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.

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. Although not explicit, Roche

experience suggests that an acceptable incremental cost-effectiveness ratio (ICER) range for the PBAC is \$45,000-\$60,000/quality-adjusted life year (QALY), declining if any clinical, economic or financial uncertainty exists. The World Health Organisation proposes that between one to three times GDP per capita is cost effective⁵. Australia's GDP per capita suggests that ICERs in the range of \$46,631⁶-\$139,893 per QALY should be acceptable.

The PBAC also typically favours a utilitarian approach to equity, seeking to maximise the 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 equity⁷. 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. These decision-making frameworks have been 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 approach⁸.

Fundamentally, Roche considers that the PBAC methodology should be less focused on negotiating on price, and return to its original role of robust consideration of the incremental value of a treatment relative to its costs. Comments by people associated with the PBAC about sponsor companies' "ambit claims" in relation to pricing reflect a tactical approach focused on cost reduction rather than fair valuation.

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, nor supported by evidence. The PBAC Guidelines consider the appropriate comparator is the most commonly used medicine in Australian clinical practice. However, quality evidence may be limited for off-label use and listings, and comparisons outside of a registered label

may not represent quality use of medicine. Clear guidance from the Department of Health and consistent, transparent PBAC decision making are required.

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 16 January 2015 and entered into force the same day.

¹ Department of Health. 2000. "National Medicines Policy", Commonwealth of Australia, Canberra

² 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*. Jun 2012; 19(3): e165–e176.

³ Medicines Australia. 2014. "Submission to the National Commission of Audit November 2013", Canberra

⁴ Department of Health. 2009. "Review of health technology assessment in Australia", Commonwealth of Australia, Canberra

⁵ World Health Organisation. "Cost-effectiveness thresholds", accessed http://www.who.int/choice/costs/CER_thresholds/en/, 18/09/14

⁶ Department of Foreign Affairs and Trade. 2014. "Australia", accessed from <https://www.dfat.gov.au/geo/fs/aust.pdf>, 17/11/14

⁷ 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

⁸ Drummond M. 1992. "Australian guidelines for cost-effectiveness studies of pharmaceuticals". *PharmacEconomics*. 1(1):61-69