

Cancer medicines

Roche Australia (Pharmaceuticals) Policy Position

Summary

- Challenges in the assessment and reimbursement of innovative cancer medicines are delaying access to advances in treatment and creating inequalities between patients.
- These issues can be attributed to a “one-size-fits-all” approach to assessing the value of medicines and risk-averse management of uncertainty.
- The Pharmaceutical Benefits Scheme (PBS) requires urgent review to ensure the system is “fit-for-purpose”, aligned with community values and efficiently engages all stakeholders early on in the process, to avoid the delays of multiple submissions.
- Roche does not advocate that cancer treatments should inherently be held to different standards than other specialty medicines. Nevertheless, as cancer is frequently life-threatening, patients need all stakeholders to collaborate urgently to find solutions.

Background

Cancer is a complex disease, requiring intensive scientific exploration and investment in order to discover, develop and bring much needed treatments to patients. Cancer is not one disease, but many, and over 200 types of cancer have been identified so far¹. It accounts for more than a third of the burden of premature death², yet only receives 7% of Australian health expenditure on chronic disease³. Roche is the leading supplier of cancer medicines in Australia⁴, with thirteen registered cancer medicines⁵ and over 40 new cancer molecules in development⁶.

Roche position

Challenges in the assessment and reimbursement of innovative cancer medicines are delaying access to advances in treatment and creating inequalities between patients. This applies to all innovative medicines to some extent, yet cancer faces particular challenges related to the pace of innovation, the complexities of clinical evidence and limited patient survival times. While Roche does not advocate that cancer treatments should be held to different standards than other specialty medicines, cancer medicines highlight the need for urgent policy reform.

Australia lags behind international peers in terms of access to cancer medicines, consistently falling at the bottom of rankings for highly-developed countries^{7,8,9}. A review of Pharmaceutical Benefits Advisory Committee (PBAC) decisions from 2010-2016 found that the annual recommendation rate for cancer medicines “was never greater than 50%” and on average new medicines took two years to be PBS-listed after the initial PBAC submission¹⁰. Eight PBAC rejections during that time were for medicines that had generally positive health technology assessment (HTA) outcomes globally, suggesting that “the PBAC may be applying a more stringent standard than several of its

peer agencies”¹¹.

These challenges are primarily due to the “one-size-fits-all” approach to HTA performed by the PBAC, with a narrow focus on cost effectiveness and budget impact, and very low tolerance for uncertainty. All HTA must grapple with uncertainty around value, yet the PBAC’s approach usually results in a rejection, potentially multiple re-submissions and access delays for patients, particularly in less common cancers. This creates serious inequalities: patients who need innovative therapies now are disadvantaged compared to those who will be diagnosed in the future if these medicines are eventually listed; and patients requiring the same targeted cancer medicine may have different levels of access because of the organ where their cancer first occurred.

One particular challenge is the PBAC’s preference for the use of overall survival (OS) data in cancer trials. Demonstrating OS is complex and may not always be feasible, as survival of patients beyond progression of their cancer is influenced by subsequent treatments. A significant impact comes from the ethical imperative to give access to the new medicine or regimen to patients enrolled in a clinical trial whose disease progressed while on the comparator treatment arm. This approach, known as “cross-over”, masks the ability to measure the OS benefit in the trial. As patients in both treatment arms receive the experimental treatment at some time, this creates uncertainty as to the extent of therapeutic benefit and subsequently reduces the likelihood of reimbursement in Australia.

The Australian HTA system must become increasingly flexible, taking account of the value of medicines to patients, carers, clinicians and society and adopting a willingness-to-pay in line with other developed countries. While no country’s HTA system is “perfect”, there are important lessons from other countries that routinely consider indirect costs and benefits (such as patient and carer work productivity), involve citizens in decision-making and adopt a fit-for-purpose process for medicines for the treatment of rare diseases or with low budget impact¹².

In order to improve timely access, Roche supports a more dynamic approach to HTA for innovative medicines, through different evaluation pathways based on complexity and unmet need, and the appropriate use of managed entry schemes. Earlier and increased engagement between expert clinicians, academics, the PBAC, patient organisations and companies could also help address technical and methodological issues in advance of a first PBAC submission and allow for consistency and agreement on treatment algorithm, comparators, evidentiary requirements, as well as economic model inputs and structure. Roche also endorses rapid resolution of outstanding issues following a PBAC rejection. The responsibility rests with both the sponsors of new medicines and the PBAC to develop and implement constructive solutions together in order to address uncertainty.

This position paper was adopted by the Roche Australia (Pharmaceuticals) Leadership Team on 15 September 2017 and entered into force the same day

¹ Cancer Research UK. Accessed from <http://www.cancerresearchuk.org/about-cancer/what-is-cancer>, 6/06/17

² AIHW 2015. "Australian Burden of Disease Study: Fatal burden of disease 2010". Australian Burden of Disease Study Series no. 1. Cat. no. BOD 1. Canberra

³ AIHW. 2013. "Health system expenditure on cancer and other neoplasms in Australia: 2008–09". Cancer Series no. 81. Cat. no. 78. Canberra

⁴ IMS data. October 2016

⁵ Roche Australia. "Products List". Accessed from <http://www.roche-australia.com/home/products/pharmaceuticals.html?showProductsList=true>, 6/07/17

⁶ Roche. 2017. "Annual Report 2016". p48

⁷ Office of Health Economics. 2014. "International Comparison of Medicines Usage: Quantitative Analysis". Report for Association of the British Pharmaceutical Industry. London

⁸ Cheema PK, Gavura S, Migus M, Godman B, Yeung L and Trudeau ME. 2012. "International variability in the reimbursement of cancer drugs by publically funded drug programs", *Curr Oncol*. Jun 2012; 19(3): e165–e176.

⁹ Medicines Australia. 2015. "Comparison of Access and Reimbursement Environments", Edition 1, March 2015. Canberra

¹⁰ Wonder M. 2016. "Analysis of PBAC submissions and outcomes for medicines for patients with cancer (2010-2016)". Report prepared for Medicines Australia Oncology Industry Taskforce. Sydney

¹¹ Wonder M. 2016. "Analysis of submissions and outcomes for medicines for patients with cancer; an international comparison (2010- 2016)". Report prepared for Medicines Australia Oncology Industry Taskforce. Sydney

¹² Kerr A, Todd C, Ulyate K, Hebborn A. 2014. "A Comparison of International Health Technology Assessment Systems – Does the Perfect System Exist?" Presentation to the ISPOR 17th Annual European Congress, Amsterdam