Medicines Australia | Better health through research and innovation

Funding innovative medicines

October 2022

Medicines, vaccines and other health technologies are an investment in better health outcomes for Australians. The Australian Government's willingness to invest in medicines should be equal with comparable countries to ensure that Australians don't have to wait longer for affordable access to new health technologies, and that Australia's world class healthcare system remains internationally competitive for launching new technologies.

- To keep pace with the rapid emergence of new health technologies and determine how to invest to deliver the best health outcomes for Australians, decision makers require timely information on the value of new interventions and what constitutes a cost-effective health technology.

- Cost-effectiveness analyses compare the costs and effects of the new technology with currently available treatments, with the result expressed in terms of the incremental cost-effectiveness ratio (ICER). The ICER must then be compared to an explicit or implicit ICER threshold, which is defined as the maximum cost per health outcome that a health system is willing to pay, to decide what constitutes a cost-effective health technology.

- The Australian Government's willingness to invest in medicines is represented by the range of ICERs the PBAC accepts when recommending medicines for PBS listing, which are consistently lower than comparable thresholds used to make investment decisions in other sectors within Australia and below international recommendations.

- The PBAC should retain the flexibility to accept variable ICERs while acknowledging that a higher willingness to pay would allow patients faster access to innovative medicines.

Possible policy solutions

1. Agreement from the government to a principle that the PBAC should be willing to accept higher ICERs because the current implicit thresholds are resulting in significant

delays in affordable access to new health technologies for Australians which goes against the stated government goals of timely access and a world class system.

2. When considering revised ICER thresholds it is important to note that the current thresholds
    a. Have not kept pace with inflation.
    b. Are below international recommendations based on GDP/capita. [1]
    c. Place a lower value on a life and health outcomes than those used by other government departments. [2]
3. The PBAC should make its recommendation based on cost effectiveness without regard to budget impact. The expansion of the Committee's decision-making framework to include considerations related to budget impact has compromised the Committee's ability to focus on making recommendations which aim to optimise the health outcomes for Australians. Budgets and decisions on investment should sit with the Government.
4. The PBAC should collate and publish annually aggregated information about the ICER ranges accepted for listed medicines by broad therapeutic groups (for example, oncology, non-oncology, rare diseases) to allow tracking of the proportion of medications that have been accepted with ICERs in each ICER range.
5. To ensure transparency and consistency within PBAC decision making, the PBAC minutes should explain the Committee's rationale for each product's accepted ICER (for example, why $50K/QALY rather than $70K/QALY and why they thought the ICER was acceptable in each instance). This information should be redacted in PSDs.

What is 'willingness to pay'?

Essentially, willingness to pay (WTP) considers the question: 'How much is a year of life worth?' The Australian Government's willingness to invest in medicines is represented by the range of incremental cost-effectiveness ratios (ICERs) which the PBAC accepts when considering medicines for PBS listing. These implicit ICER thresholds determine the maximum cost per health outcome that a health system is willing to pay for a new healthcare intervention.

Under the National Health Act 1953, the PBAC can only recommend a medicine for funding if it is satisfied that it is sufficiently cost-effective. The ICERs commonly accepted by the PBAC in its decision-making are low compared to other sectors and international recommendations.[3,4] These low ICER thresholds mean that the Australian government's willingness to pay for new healthcare interventions is lower than other comparable countries and lower than the thresholds used to make investment decisions in other sectors within Australia, which means that Australians have to wait significantly longer for affordable access to new healthcare technologies.

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1 *Iino H et al. Estimating the range of incremental cost-effectiveness thresholds for healthcare based on willingness to pay and GDP per capita: A systematic review. PLOS ONE 2022. https://doi.org/10.1371/journal.pone.0266934*

2 *Cubi-Molla P et al. (2021) Resource Allocation in Public Sector Programmes: Does the Value of a Life Differ Between Governmental Departments? P30, OHE Research Paper. Available at https://www.ohe.org/publications/resource-allocation-public-sector-programmes-does-value-life-differ-between. Accessed 2 August 2022.*

3 *Iino H et al. Estimating the range of incremental cost-effectiveness thresholds for healthcare based on willingness to pay and GDP per capita: A systematic review. PLOS ONE 2022. https://doi.org/10.1371/journal.pone.0266934*

4 *Cubi-Molla P et al. (2021) Resource Allocation in Public Sector Programmes: Does the Value of a Life Differ Between Governmental Departments? P30, OHE Research Paper. Available at https://www.ohe.org/publications/resource-allocation-public-sector-programmes-does-value-life-differ-between. Accessed 2 August 2022.*

Why is willingness to pay important?

A key aspect which should be considered as part of the HTA review is Australian society's willingness to pay for medicines, as represented by the range of ICERs accepted by the PBAC (particularly the upper limit of these ICERs) when considering reimbursement for innovative medicines.

An ICER represents what society is willing to pay for health gains, hence its assumed value is important. The ICERs accepted for innovative medicines in Australia should reflect its standing as a highly developed country, which would enable more patients to access the medicines they need.

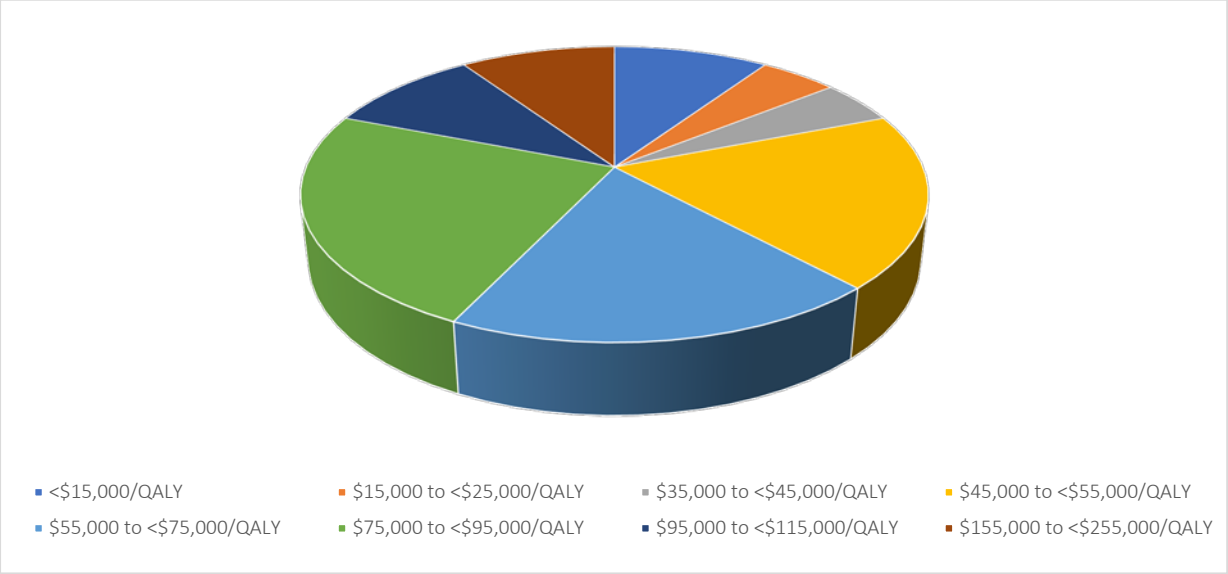
The World Health Organization (WHO) has recommended that accepted ICERs should be based on 1 to 3 times a country's Gross Domestic Product (GDP) per capita, with interventions that cost less than the national annual GDP per capita considered highly cost-effective; this is the most commonly referenced ICER threshold within the literature of global cost-effectiveness analysis. More conservative estimates have suggested that accepted ICERs should be based on 0.5 to 1.5 times a country's GDP/capita. [3]

Australia's 2020 GDP per capita was $85,915. This suggests that ICERs accepted for innovative medicines in Australia should fall between $85,000 and $220,000/QALY; even the more conservative estimates would value life at $42,500 to $127,500/QALY. While this represents a significant increase in the range of ICERs typically accepted in Australia (Error! Reference source not found.), it demonstrates that the range of ICERs accepted in Australia should be higher than they are currently.

Medicines Australia analysed the PSDs for medicines taking a cost-effectiveness approach that were recommended for listing by the PBAC in 2021. The analysis showed that lower ICERs were imposed for chronic conditions treated largely in the primary care setting, while higher ICERs were accepted for oncology, haematology and rare disease medicines with few alternatives and a higher clinical need.

Almost one in four (19%) medicines recommended for listing by the PBAC in 2021 were recommended with an ICER below $45,000/QALY. Around 40% were recommended with an ICER of $75,000/QALY or higher (Error! Reference source not found.). However, as the accepted ICERs increased, so too did the likelihood of risk-sharing arrangements that reduced the cost-effectiveness of the medication in real terms, for example through rebates if expenditure caps were exceeded or agreements to reduce the price of the medication over time.

Figure 1. Proportion of recommended PBAC submissions by accepted ICER range, 2021

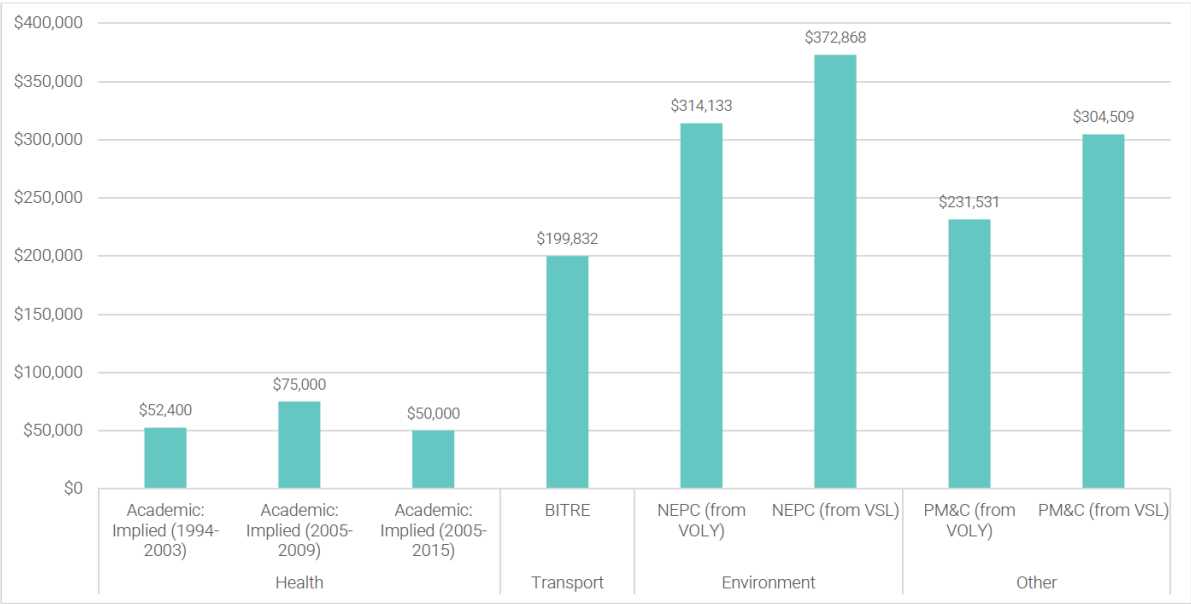


Source: Medicines Australia analysis of ICER ranges accepted by the PBAC in cost-effectiveness submissions recommended for listing in 2021

How do medicines compare to other areas of expenditure?

The value of a life used in Australian health assessments is significantly lower than other areas of government, such as transport (**Error! Reference source not found.**). For example, the PBAC's implicit range of accepted ICERs does not compare favourably with the value of a life of $199,832 for the cost per road fatality,[5] further demonstrating that the ICERs currently accepted by the PBAC should be higher.

Figure 2. Value of life in Australia across different sectors ($/QALY)



Source: Cubi-Molla et al, Figure 6

5 *Cubi-Molla P et al. (2021) Resource Allocation in Public Sector Programmes: Does the Value of a Life Differ Between Governmental Departments? P30, OHE Research Paper. Available at https://www.ohe.org/publications/resource-allocation-public-sector-programmes-does-value-life-differ-between. Accessed 2 August 2022.*

NOTE: This Discussion Paper is not a final position paper. It has been developed as a conversation starter and to support discussion and feedback

There is a clear need for more investment in health outcomes in Australia through increased willingness to pay for these outcomes, reflected in higher accepted ICERs. Not only would this help to ensure that Australia's world class healthcare system remains internationally competitive, but would benefit patients through faster access to innovative treatments and have broader beneficial impacts to Australian society as a whole.

Feedback

Do you have any thoughts on the policy ideas in these papers? We'd love to hear your feedback! Please let us know at this email address: HTA-Reform@medicinesaustralia.com.au.