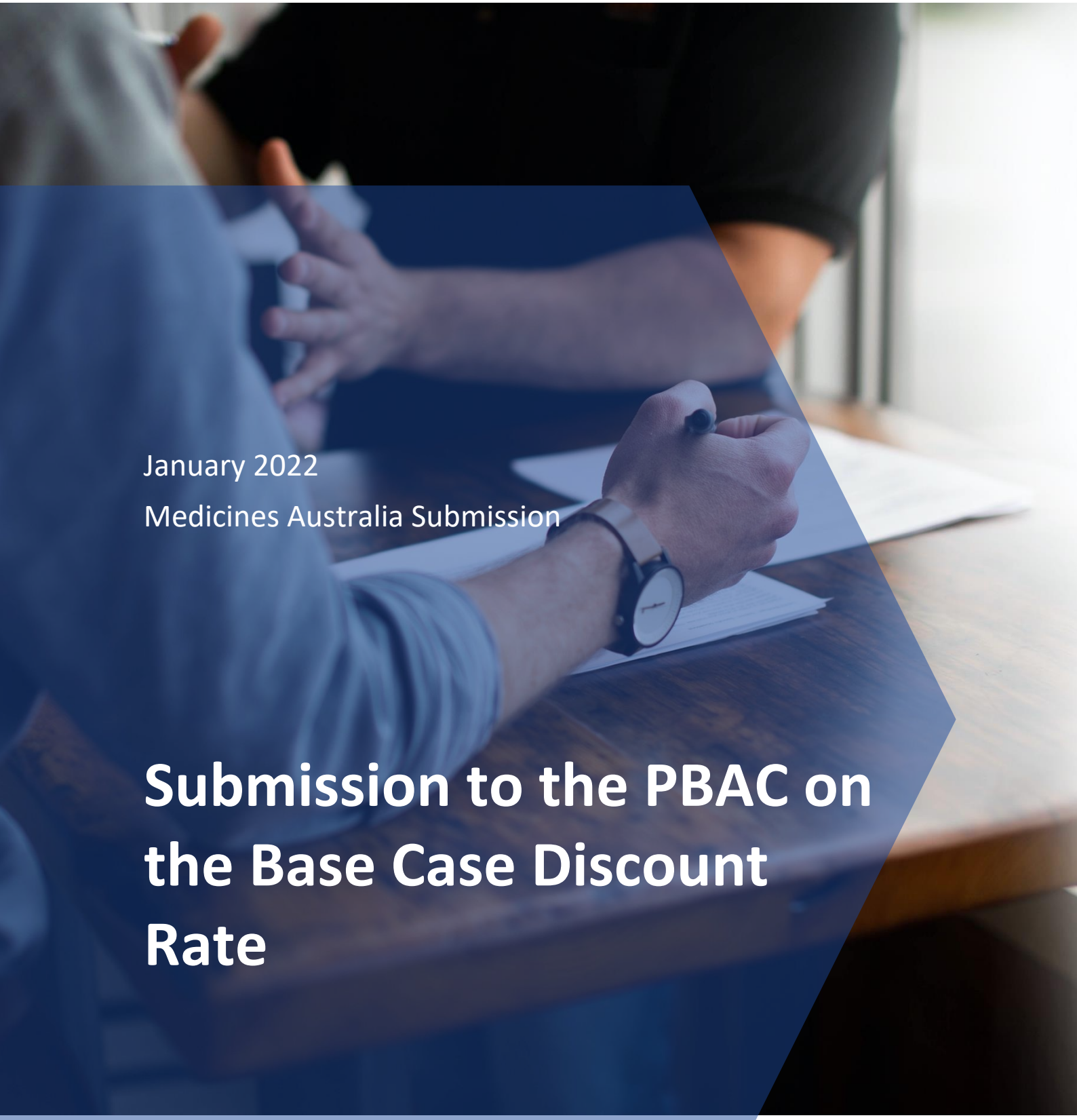


January 2022

Medicines Australia Submission

Submission to the PBAC on the Base Case Discount Rate

Medicines Australia

The report has been commissioned by Medicines Australia and prepared by Biointelect and Shawview Consulting.

Executive Summary

Discount rates reflect how society values future outcomes compared to present outcomes. When applied to medicines, inappropriately high discount rates disadvantage treatments which have longer-term health benefits, such as preventative or curative treatments, disproportionately discriminating against patients who could benefit from treatments where the benefits are realised over a longer period of time.

As an advanced economy which prides itself on its population's health, Australia must consider the value of the future long-term health of its citizens, especially its children. The COVID-19 pandemic has demonstrated the value of preventative therapies and the critical importance of thinking of the long-term. As advances in science and medical technology unlock new ways to correct or reverse diseases, potentially altering disease courses from certain death to a longer, healthy life, Australians risk missing out.

It is time to invest in health policies that match this need for longer-term health outcomes.

The *2022 to 2027 Strategic Agreement* between Medicines Australia and the Commonwealth Government commits to reviewing the Pharmaceutical Benefits Advisory Committee (PBAC) base case discount rate against international health technology assessment (HTA) best practice.

This paper recommends a reduction in the base case discount rate from 5% to 1.5%, based on a review of international HTA discount rate practice, the impact of high discount rates on access to medicines, and government policies which stress the importance of long-term health, such as *Australia's Long-Term National Health Plan*.

Recommendation: The PBAC base case discount rate should be reduced to 1.5%

The base case discount rate of 5% outlined in section 3A.1 of the PBAC Guidelines does not align with international HTA best practice.

It should be reduced to 1.5% to match that recommended in comparable 'best practice' HTA countries such as Canada and England. This would better recognise the value of long-term future health benefits and:

- Prove to the Australian people and the world that our population's future health is valued
- Contribute to improving the speed of patient access to new and innovative therapies
- Promote PBAC decision making equity
- Align with the Commonwealth Government's preventative health agenda.

The change could be affected by simple adjustment to the PBAC Guidelines and could be implemented by July 2022.

What is a discount rate?

A key part of HTA is economic evaluation, i.e., assessing the 'value for money' of medical interventions proposed for public funding. Medicines and vaccines often have costs and health benefits that are distributed differently over time. Further, society has a 'positive time preference', i.e., it values a given outcome occurring now more than if it occurred in the future.

Economic evaluation accounts for these issues through 'discounting'. This sees a discount rate (%), that reflects how much society values future outcomes relative to present outcomes, applied to all future costs and health benefits. In doing so, discounting provides 'like for like' assessment of the value for money of all medical interventions proposed for funding.

HTA discount rates are typically based on either the risk-free return on national government securities or social time preference, i.e., the 'pure' preference for outcomes now instead of the future.

Why does this matter?

While discounting is required in HTA, the higher the discount rate, the less cost-effective a treatment is considered. Inappropriately high discount rates unfairly disadvantage treatments which see upfront costs and longer-term health benefits. *It is therefore vital discount rates truly reflect how society values the present compared to the future*.

The impact of the discount rate used is stark: using the 1.5% rate recommended in Canada or England, the present value (PV) of a human life is 48.3 years; in Australia, *it is only 20.7 years*.

In Australia, the 5% discount rate has contributed to interventions not receiving positive PBAC recommendations or has considerably affected their estimated cost-effectiveness. This has delayed access to vital therapies, including vaccines for human papilloma virus (HPV) in adolescents, meningococcal disease in children and adolescents, zoster virus for 60 year-olds, and pneumococcal disease for adults, as well as medicines to treat hepatitis C, and treatments for spinal muscular atrophy in children.

Using an appropriately lower discount rate in HTA economic evaluation would have lasting, long-term benefits for Australians, including that of future generations. With the Australian therapeutic landscape expected to increasingly see innovative cell and gene therapies and personalised medicines offering new treatment possibilities, *the current 5% rate risks significantly reducing patient access to cutting edge therapies and affecting the long-term future health of generations of Australians.* In particular, the promise of cell and gene therapies and personalised medicines may potentially correct or reverse diseases, providing Australian citizens with life-long health benefits.

From a health policy perspective, the current rate is also inconsistent with the increasing investment of the Commonwealth Government in prevention, as reflected in the Commonwealth Government's *Long-Term National Health Plan*.

The result is that Australian patients – particularly children and future generations – are disadvantaged relative to those in comparable countries, inhibiting Australia's positioning as a 'first-launch' country providing patients timely access to affordable health care.

Put simply, Australia's high discount rate is discounting the future health of its citizens.

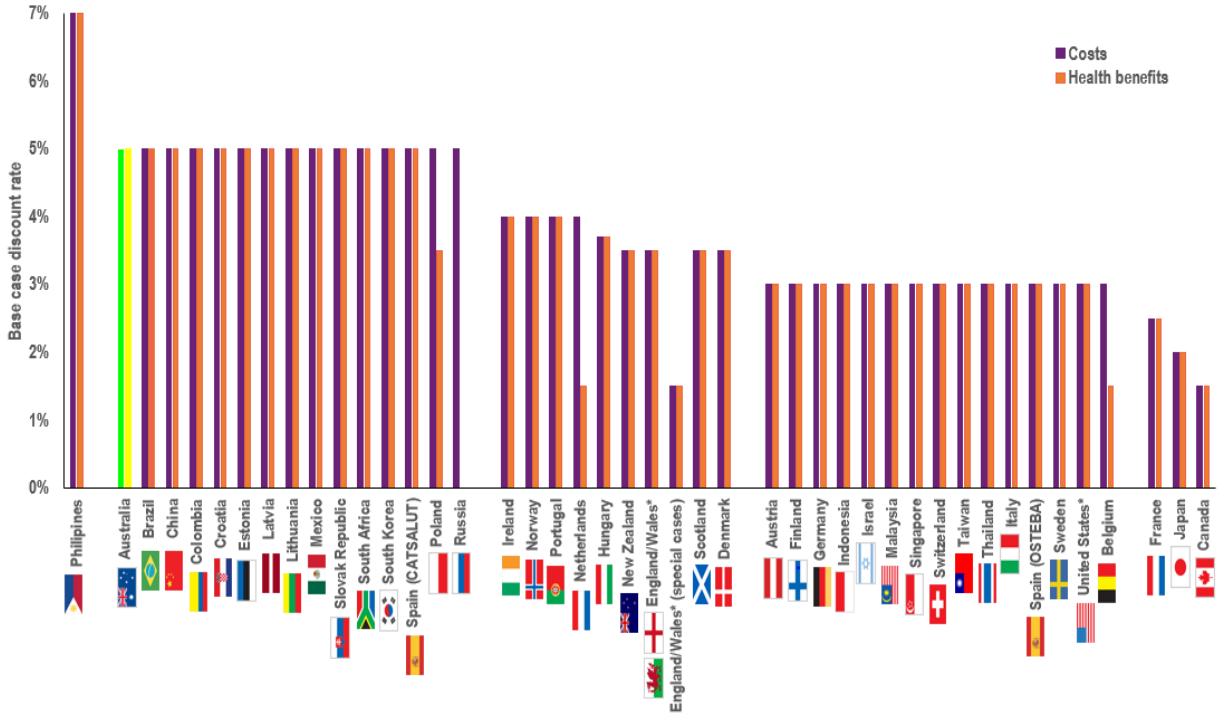
PBAC discounting practice: Australia's discount rate does not align with international best practice

Review of international HTA discounting practice compared with that of the PBAC finds that the PBAC's 5% base case discount rate is:

- **The highest of 40 countries** with established HTA practice
- **Equal highest out of 20** comparable OECD country HTA agencies
- **Greater than that of similarly economically developed countries with similarly-advanced HTA systems** including Canada, England, France, Germany, Ireland, the Netherlands, and New Zealand.

In particular, the rates used in the HTA systems of Canada, England, France, and New Zealand, should be considered. Over the last 20 years, Canada (1.5%), England (recommended 1.5% from 2022), France (2.5%), and New Zealand (3.5%) have made compelling case studies of HTA discounting 'best practice' that Australia should take notice of. Their HTA agencies have substantially reduced their discount rates, reflecting evolving HTA discounting practice and changing world circumstances. The PBAC's base case discount rate therefore does not align with international HTA best practice.

Figure 1 Comparison of Australian (PBAC) and international HTA base case discount rates



Sources: For full list, please consult 'References'.

Abbreviations: 'CATSALUT', Catalan Health Service; 'NICE', National Institute for Health and Care Excellence; 'OECD', Organisation for Economic Cooperation and Development: 'OSTEBA', Basque Office for Healt Technnology Assessment.

Notes:

1. For a full list of HTA agencies and bodies, please refer to Appendix.
2. All discount rates are expressed as half (i.e., .5%) or full (i.e., .0%) percentage points.
3. For Spain, two prominent regional based agencies, CATSALUT and OSTEBA, have been selected for comparison.
4. The United States does not have public financing and reimbursement decisions guided by HTA decision making processes. However, it has strongly influenced the international setting of discount rates, including through the work of the *US Panel on Cost-Effectiveness in Health and Medicine*, which convened in 1996 and 2016.
5. Countries, including England and France, provide for reduced yearly discount rates (i.e., hyperbolic discounting) after year 30 of analysis. For ease of comparison, these have not been included in the figure above. In England, a 1.5% discount rate for costs and health effects may be considered in cases in which treatment restores people who would otherwise die or have a very severely impaired life to full or near full health, and when this is sustained over at least 30 years (NICE, 2013).

Australia must catch up with the world and value its future health better

The PBAC published its first draft Guidelines in 1990 with a 5% discount rate, with reference to recommended Canadian rates.

A lot has changed since then: the theory and practice of HTA discount rates has become more sophisticated, with increasing recognition that as societies develop, they place more value on their health. In the last 30 years, world economies have developed significantly, with government security yields falling to historical lows.

Other countries with similarly-advanced HTA systems such as Canada, England, France, Germany, Ireland, the Netherlands, and New Zealand, have all reduced their discount rates over time in response. However, Australia has not changed its discount rate since 1990 and does not appear to have seriously reviewed it.

This sees comparable high-income countries increasingly valuing the health outcomes of their future generations more, while Australia values its future health more akin to that of a lower-income developing nation.

Currently, Australia values the lives of its citizens, less than comparable nations; morally and ethically, Australia has delayed for too long. Australia must value investing in the lives and health of successive generations of its population, including its future children. To catch up, the PBAC discount rate should be reduced to 1.5%.

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List of Abbreviations

Abbreviation	Description
ATMP	Advanced therapy medicinal products
CADTH	Canadian Agency for Drugs and Technologies in Health
CATSALUT	Catalan Health Service
CBA	Cost-benefit analysis
CEA	Cost-effectiveness analysis
COVID	Coronavirus
CPI	Consumer Price Index
CUA	Cost-utility analysis
CVZ	College voor Zorgverzekeringen
EU	European Union
EUnetHTA	European Network on Health Technology Assessment
GDP	Gross domestic product
GNI	Gross national income
HAS	Haute Autorité de santé
HRQoL	Health-related quality of life
HTA	Health technology assessment
HTAi	Health Technology Assessment International
ICER	Incremental cost-effectiveness ratio
INAHTA	International Network of Agencies for Health Technology Assessment
IQWiG	Institute for Quality and Efficiency in Health Care
ISPOR	International Society for Pharmacoeconomic and Outcomes Research
JCVI	Joint Committee on Vaccination and Immunisation
LMIC	Low and middle income countries
LY	Life years
MA	Medicines Australia
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIP	National Immunisation Program
OECD	Organisation for Economic Cooperation and Development
OSTEBA	Basque Office for Health Technology Assessment
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PFPA	Prescription for Pharmacoeconomic Analysis
PHARMAC	Pharmaceutical Management Agency
PV	Present value
QALY	Quality-adjusted life year(s)
QoL	Quality of life
RBA	Reserve Bank of Australia
SDR	Social discount rate
STPR	Social time preference rate
ZIN	Zorginstituut Nederland

1. Introduction

On 7 September 2021, the Commonwealth Government announced the 2022 to 2027 Strategic Agreement with Medicines Australia ('MA'). The Agreement is based on principles of:

- Stewardship of the health system
- Stability and certainty in investment in innovative medicines
- Partnership in delivery of the National Medicines Policy
- Transparency, predictability, and efficiency of PBS listing processes
- Integrity of the Australia's health system; and
- Acknowledgement of the value of the innovator pharmaceutical industry and medicines sector to ensure a healthy Australia for a vibrant economic recovery.

The new Agreement provides for review of HTA policy and methods ('Review'). This aligns with the Commonwealth's goals for:

- Reducing time to access for Australian patients to new health technologies; and
- Maintaining Australian attractiveness as a 'first launch' country to build on Australia's status as a world leader in providing patients access to affordable health care.

The Review includes a commitment by the Minister to seek advice from the PBAC as to whether Australia's base case discount rate outlined in Section 3A.1 of the Guidelines aligns with international best practice. Any recommended changes are to be incorporated into the Guidelines by July 2022.

This submission outlines:

- The role and importance of discounting in HTA;
- The rationale for discounting practice in Australia that has developed;
- How discount rates used by the PBAC compare to international HTA practice, including recent developments;
- The case for change in order to bring the Australian rate into alignment with international HTA best practice;
- The implications of changes to PBAC discounting; and
- Recommendations for PBAC discount rates.

Once the evidence has been reviewed, it will be impossible to argue for Australia to maintain a discount rate of 5%. The community's need for rapid access to new and emerging treatments is clear. Investing in, and better valuing, the long-term benefits for Australia's future health is essential.

2. Importance of Discounting in Health Technology Assessment

Summary

The central role of governments in financing and reimbursement of healthcare systems requires them to address the 'economic problem', i.e., the allocation of scarce societal resources to infinite health care needs and wants.

Economic evaluation is a key part of HTA. It assesses the cost-effectiveness (i.e., 'value for money') of new interventions by calculating incremental cost effectiveness ratios (ICERs).

Because society prefers present outcomes to future ones, economic evaluation must determine the present value (PV) of future costs and benefits. This allows economic evaluation to make consistent, 'like-for-like' comparison of interventions.

Discounting applies an annual discount rate to all future costs and health outcomes. Discounting is not related to inflation and does not attempt to account for any uncertainty regarding outcomes.

As outcomes occur further into the future and higher discount rates are applied, the 'value' attributed to them in cost-effectiveness assessment becomes smaller.

Preventative interventions and innovative medicines, including cell and gene therapies and other personalised medicines, typically have upfront costs and longer-term health benefit profiles.

Discounting sees these medicines experience a '*double whammy*' effect, with their costs considered at their full value, but their health benefits at a reduced value. Discount rates used therefore can reduce the likelihood these treatments are considered cost-effective.

Importantly, this can create a generational effect where particular medicines are perpetually disadvantaged, locking in decision making 'short-sightedness', where the long-term benefit of avoiding, arresting, or reversing an illness is valued less.

This has implications for ongoing patient access, particularly as Australia seeks to position itself as a 'first-launch' country for innovative medicines, and for the population's long-term health.

Section 2 considers the role of discounting in HTA, including the implications for economic evaluation outcomes and HTA decisions. Section 2.1 considers the government's central role in the healthcare system and resulting importance of the HTA function. Section 2.2 describes the role of economic evaluation in HTA. Section 2.3 explains the critical function of discounting in economic evaluation and Section 2.4 broadly considers its impact on economic evaluation outcomes.

2.1 Government's central role in the healthcare system: the importance of HTA

Governments have a central role in setting policy for, and the implementation of, the financing and reimbursement of health care. While there will always be a need for health care, resources are finite and so governments must address the 'economic problem', i.e., the allocation of scarce societal resources to infinite needs and wants (Samuelson et al., 1980).

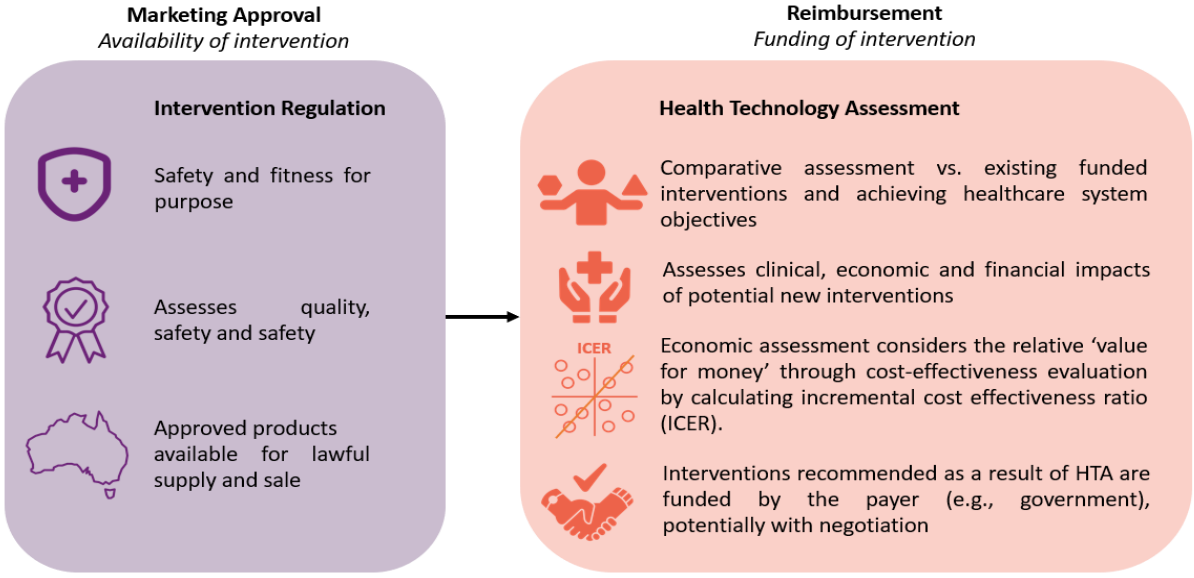
This occurs in a broader environment of government accountability for the healthcare system and health outcomes; existing and proposed health policies and priorities; and the need to keep pace with medical innovation.

This has necessitated an objective mechanism for making funding and reimbursement decisions amongst competing alternatives which may address different health care needs or meet them in different ways.

HTA provides this objective decision making function. It assesses the quality, safety, efficacy, effectiveness, and cost effectiveness (i.e., 'value for money') of medical interventions (Department of Health, 2019). It generally consists of two phases (Figure 2):

1. **Marketing approval**. This assesses the safety, clinical efficacy, and quality of medical interventions.
2. **Reimbursement assessment**. This typically occurs after marketing approval and involves appraisal of the comparative clinical, economic, and financial impacts of proposed interventions to make decisions regarding funding.

Figure 2 The HTA Process: Marketing approval and reimbursement



The two steps are generally conducted by different bodies.
Parallel marketing and reimbursement assessment occurs in some jurisdictions.

Abbreviations: 'HTA', health technology assessment; 'ICER', incremental cost-effectiveness ratio.

HTA is largely associated with reimbursement. Over the last 40 years, as government decision makers have increasingly required a comprehensive approach to set priorities and obtain maximum benefit

from resources (Sorenson et al., 2008), this function has grown rapidly internationally, providing the opportunity for impartial, rigorous value for money assessment, and efficient resource allocation (Kim et. al., 2021).

HTA for pharmaceuticals is almost universal across Europe, is well established in Australia, New Zealand, and Canada, and is increasingly used in Asia and South America. The function is variously undertaken by government departments (e.g., a ministry of health), independent agencies or other organisations. The role of the PBAC as Australia's medicines and vaccines HTA reimbursement advisory body, is described in Section 3.1.

2.2 Role of economic evaluation in HTA

Economic evaluation is a key part of HTA, assessing whether allocating societal resources to a new intervention would be 'value for money'. It compares the costs and consequences (i.e., health benefits) of new treatments to currently funded treatment(s) (Drummond et al., 2005) to determine their cost-effectiveness (i.e., 'How much extra will the health benefits of the treatment cost?).

Most interventions assessed for reimbursement will claim a superior health benefit compared to funded treatments. As such, cost-utility analysis (CUA) is the most commonly used form of economic evaluation in HTA. It compares the costs, including treatment and disease management costs, and health outcomes, commonly measured in quality-adjusted life years (QALY). The QALY measures the years of life (LY) lived with a condition and the associated health-related quality of life (HRQoL). HRQoL is measured on a scale of 0 (death) to 1 (perfect health).

CUA estimates cost effectiveness by calculating an incremental cost-effectiveness ratio (ICER) (Figure 2). This measures the additional cost of an extra year of life lived in full health (i.e., one QALY) due to the new treatment. The result is known as a 'incremental cost per QALY'. The lower the cost per QALY, the more cost-effective a proposed medicine, and all other things being equal, the more likely it will be funded.

Figure 3 Calculating cost effectiveness: the ICER Formula

$$ICER = \frac{\left(Total\ cost\ proposed\ (\$) - Total\ cost\ comparator\ (\$)\right)}{\left(Total\ effects\ proposed (QALY) - Total\ effects\ comparator\ (QALY)\right)}$$

Abbreviations: 'ICER', incremental cost effectiveness ratio; 'QALY', quality-adjusted life years

2.3 Role of discounting in economic evaluation

2.3.1 Rationale for discounting

Society generally values a given outcome occurring in the future *less* than that same outcome occurring now. This is known as 'positive time preference' (Frederick et al., 2002).

This means given costs and benefits occurring in the future are valued less than if they occurred in 'the present' (i.e., the current year). For every year further into the future they occur, their value becomes less and less. Economic evaluation must therefore account for this societal preference so it can make objective, consistent, 'like-for-like' estimations of cost-effectiveness. This means adjusting

costs and benefits for their timing across future years to their 'present value' (PV). This is known as 'discounting' and results in the final ICER formula as described in Figure 4.

Figure 4 Discounting in the ICER formula

$$Incremental\ cost\ per\ QALY\ (PV) = \frac{\sum(Discounted\ (PV)\ total\ incremental\ costs)}{\sum(Discounted\ (PV)\ total\ incremental\ QALYs)}$$

$$= \frac{(\sum(Total\ cost\ proposed\ (\$)) - \sum(Total\ cost\ comparator\ (\$))), discounted\ by\ year}{(\sum(Total\ effects\ proposed\ (QALY)) - \sum(Total\ effects\ comparator\ (QALY))), discounted\ by\ year}$$

Abbreviations: '∑ ', sum of; ICER', incremental cost-effectiveness ratio; 'PV', present value; 'QALY', quality-adjusted life years

Importantly, discounting is solely concerned with time preference (UK Treasury, 2020). Discounting does not account for inflation, i.e., the increase in prices or cost levels over time. Generally, inflation is accounted for by ensuring all cost items are measured at current price levels.

Also, discounting does not account for 'uncertainty' in future costs or health outcomes (Pharmaceutical Management Agency (PHARMAC), 2015; Haute Autorité de santé (HAS), 2020). Any uncertainty is generally tested in sensitivity analysis by varying the magnitude or settings of assumptions or inputs.

2.3.2 Estimating the discount rate

Approaches to estimating the discount rate for HTA generally reflect either *social opportunity cost* or *social time preference* (Attema et al., 2018).

The **social opportunity cost** reflects the real interest rate on low-risk or riskless long-term investments such as government bonds (Attema et al., 2018).

The **social time preference rate (STPR)** approach reflects that society prefers to receive goods and services sooner rather than later and is the sum of:

- 'Pure time preference' – the rate at which consumption and public spending are discounted over time, assuming no change in per capita consumption. This captures the preference for outcomes now rather than later; and
- The 'wealth effect' – as per capita consumption grows over time as societies become wealthier, each unit of future consumption will be valued less due to 'diminishing marginal utility' (i.e., less satisfaction with each additional amount of consumption).

  (UK Treasury, 2020).

2.3.3 Discounting in economic evaluation

Discount factor

Discounting applies an annual percentage rate (%), i.e., a discount rate, to future cost and health outcomes to convert them to their PV. To do so, the discount rate (%) is applied as a 'discount factor'. The discount factor is the percentage of the original value of a cost or health outcome retained in the PV calculation (Figure 5). Costs and benefits are then multiplied by the discount factor specific to the year in which they occur to determine their PV.

Figure 5 The discount factor formula

$$Discount\ factor^{n} = \frac{1}{(1+r)^{n-1}}$$

Where:

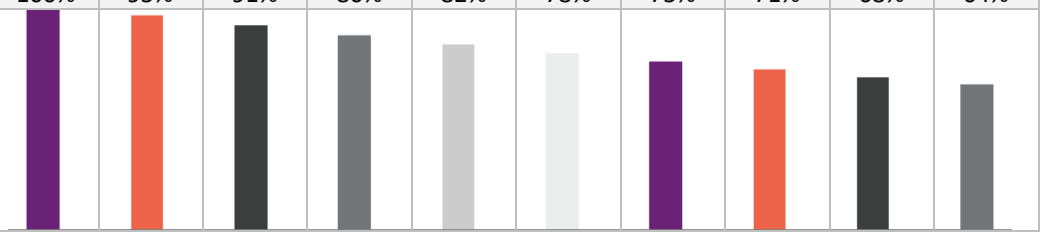
n= Year of cost or health outcome

r= Annual discount rate

Assuming a 5% annual discount rate, the PV of a given outcome continually declines with each year into the future it is assumed to occur: should it occur 10 years into the future, it retains only 64% of its original value in PV calculations for CUA (Table 1).

Table 1 Example: Yearly discount factor assuming a 5% annual discount rate, present to 10 years

Year	1	2	3	4	5	6	7	8	9	10
Discount Factor	100%	95%	91%	86%	82%	78%	75%	71%	68%	64%



Note: Discount factor is the proportion (%) of a given cost or health outcome value maintained in PV calculations. 'Year 1' refers to the time period between the present day (t=0) and one year from then. Outcomes within this time period are considered to occur in the present and as such are not discounted.

By applying the relevant discount factors to costs and health outcomes as they occur across the analysis time period, the total PV of costs and health outcomes for respective treatments can be summed and compared to calculate an ICER for the proposed treatment (Figure 6).

Figure 6 ICER Formula reflecting discount factor

$$ICER=\frac{\sum Treatment(\frac{Costs_{yr\ 1}}{(1+r)^{1-1}}+\frac{Costs_{yr\ 2}}{(1+r)^{2-1}}+\cdots\frac{Costs_{yr\ N}}{(1+r)^{N-1}})-\sum Comparator(\frac{Costs_{yr\ 1}}{(1+r)^{1-1}}+\frac{Costs_{yr\ 2}}{(1+r)^{2-1}}+\cdots\frac{Costs_{yr\ N}}{(1+r)^{N-1}})}{\sum Treatment(\frac{QALYs_{yr\ 1}}{(1+r)^{1-1}}+\frac{QALYs_{yr\ 2}}{(1+r)^{2-1}}+\cdots\frac{QALYs_{yr\ N}}{(1+r)^{N-1}})-\sum Comparator(\frac{QALYs_{yr\ 1}}{(1+r)^{1-1}}+\frac{QALYs_{yr\ 2}}{(1+r)^{2-1}}+\cdots\frac{QALYs_{yr\ N}}{(1+r)^{N-1}})}$$

-Where:

∑= sum of

r=discount rate

N=analysis period (years)

ICER=incremental cost-effectiveness ratio

QALY=quality-adjusted life years

2.3.4 Discounting example

Figure 7 considers two hypothetical economic evaluation scenarios with three treatments (Treatment A, Treatment B and Treatment C). Treatment A and B are proposed for funding, with Treatment C already funded.

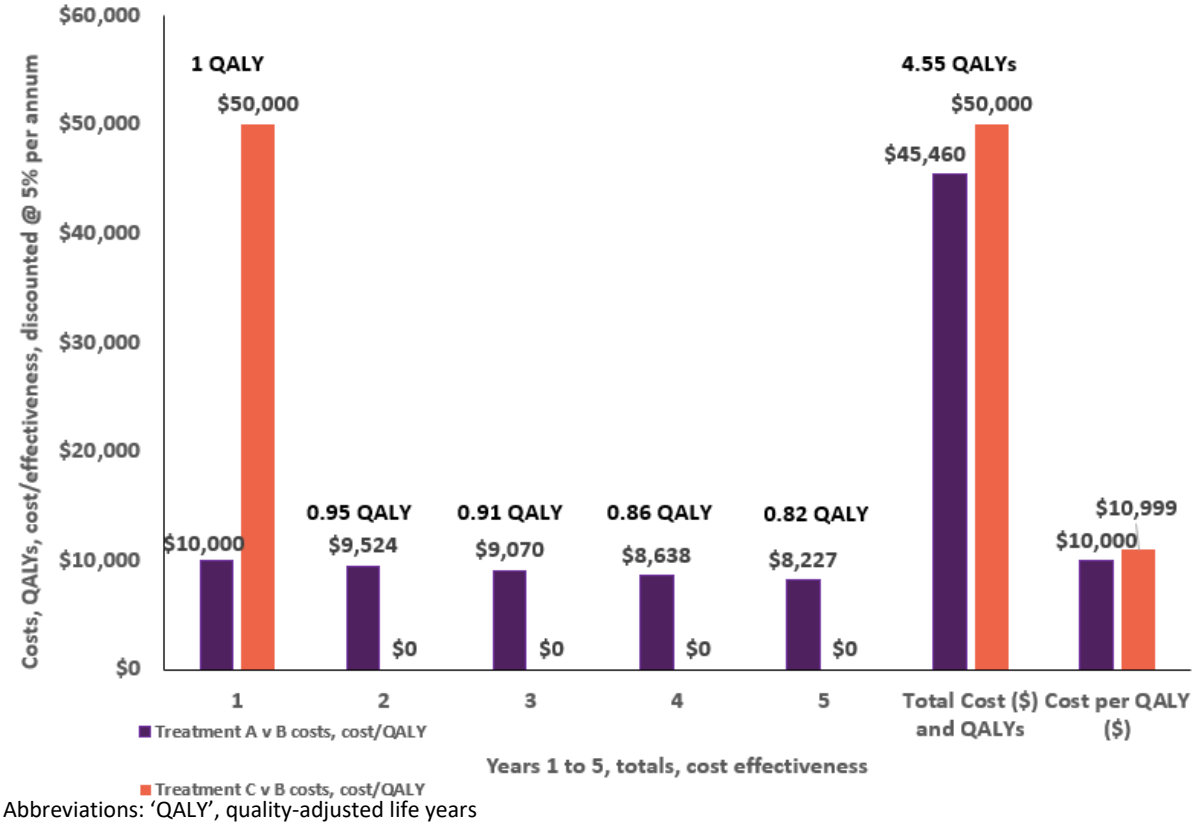
The total analysis period is 5 years. Treatment A and B are assumed to have the same total incremental health benefits (i.e., 5 QALYs) compared to Treatment C, with the incremental health benefits distributed in the same way, evenly over time (i.e., 1 QALY per year).

Treatment A and B have the same incremental costs (i.e., $50,000) compared to Treatment C. However, the timing of the incremental costs associated with A and B differs: A has costs equally

distributed over the analysis period ($10,000 per year for 5 years), while Treatment B costs are in the first year ($50,000 in year one only).

The ICERs for Treatments A and B demonstrate discounting's impact: Treatment A is more cost-effective ($10,000 per QALY) than Treatment B ($10,999 per QALY). This is because while they have the same incremental costs, *the PV* of Treatment A incremental costs is $45,460, while the PV of Treatment B incremental costs is the full $50,000.

Figure 7 Illustrative example of discounting impact assuming a 5% annual discount rate, present to 10 years



Abbreviations: 'QALY', quality-adjusted life years

Notes:

1. 'Year 1' refers to the time period between the present day (t=0) and one year from then. Outcomes within this time period are considered to occur in the present and as such are not discounted.
2. A 5% rate is applied to both costs and health benefits.
3. Estimates subject to rounding.

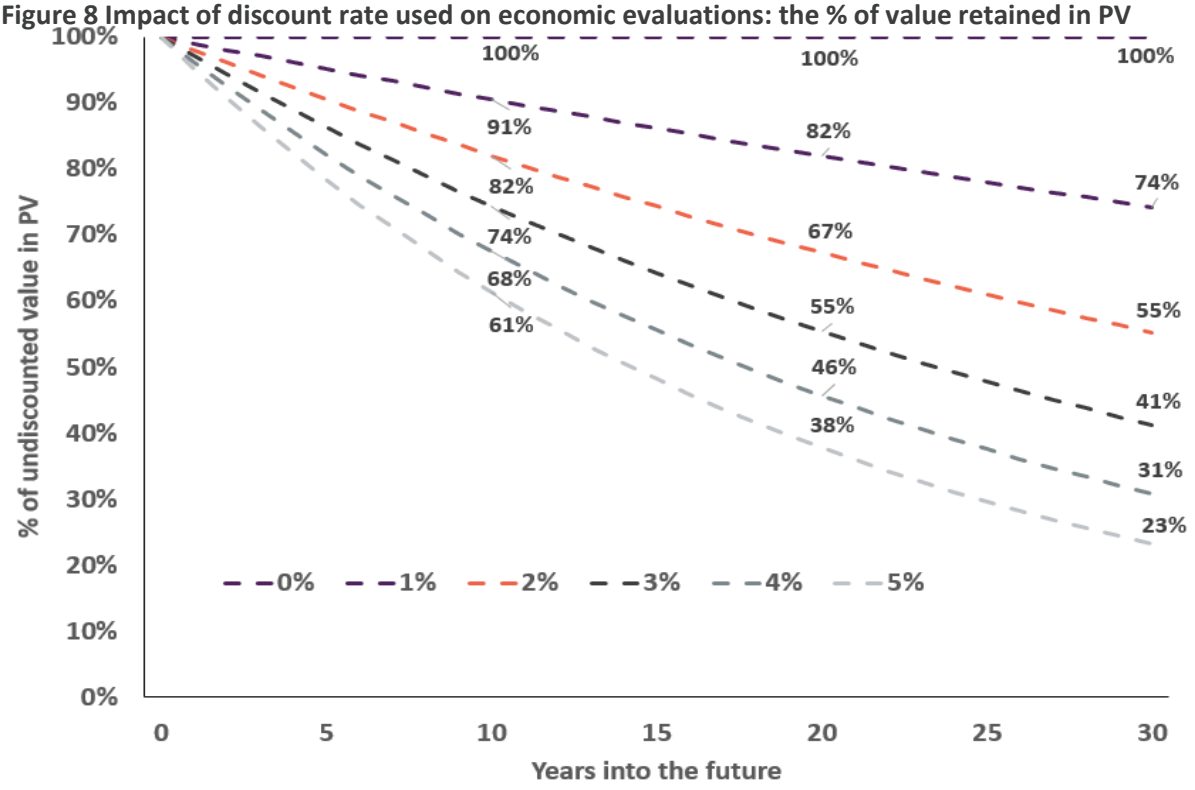
2.4 Impact of discounting on economic evaluation outcomes

Discount rates can significantly impact economic evaluation outcomes, particularly *when the distribution of costs and health benefits of a therapy differ over time*. Figure 8 demonstrates this effect. As outcomes occur further into the future and at greater discount rates, the 'weight' attributed to them in cost-effectiveness assessment becomes smaller.

Discounting's compounding nature means its proportionate impact on PV increases with the time horizon of CUA analysis. With a 5% discount rate, the PV of a given outcome in 10 years is 61% of its

original, compared to 91% with a 1% discount rate. However, at 20 years, the PV of that same outcome at a 5% rate is 38%, compared to 82% with a 1% rate.

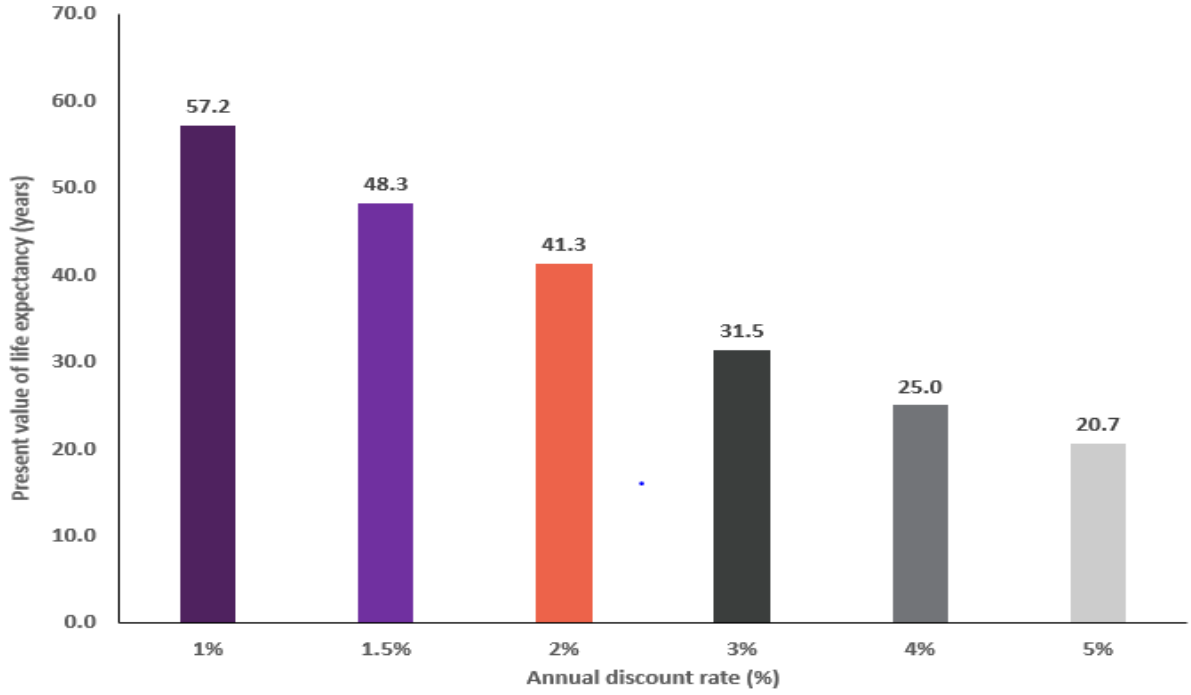
Figure 8 Impact of discount rate used on economic evaluations: the % of value retained in PV



Abbreviation: 'PV', present value.

The impact of discounting on the value of a human life is stark **(**Figure 9). Assuming the current Australian life expectancy of approximately 84 years (United Nations, 2019) the health benefit of an intervention which prevents loss of a life is captured in economic evaluation as 20.7 years of life saved; in contrast a 1% rate means a human life saved is worth 57.2 years.

Figure 9 Impact of discount rates 1% to 5% on the present value (in years) of a human life



Practical reimbursement and patient access implications

Preventative interventions and innovative medicines, including cell and gene therapies and other personalised medicines, typically have upfront costs and longer-term health benefit profiles. Relative to other medicines, they experience a '*double whammy'* effect:

- Their health benefits are valued less than those for treatments with shorter-term health effect profiles.
- Their treatment costs are not discounted, while those of other treatments are.

Referencing the PBAC decision-making process, this can therefore reduce the likelihood of, or delay, PBS listing, creating an inequitable patient access environment (See Section 5.3 for a number of case studies illustrating this point).

Discounting practice can therefore have material impacts, with the potential for systematic undervaluation of longer-term health benefits (Devlin, 2020). This can see medicines for particular therapeutic areas perpetually disadvantaged, locking in decision making 'short-sightedness', and creating funding decision inequity, counter to broader healthcare system objectives and priorities, including prevention (Devlin & Scuffham, 2020)[1].

With Australia aiming to position itself as a 'first-launch' country for innovative medicines, this has implications for Australian patients' ongoing access to new, innovative therapies including vaccines, cell and gene therapies and precision medicines. As advances in science and medical technology unlock new ways to correct or reverse diseases, potentially altering disease courses from certain death to a longer, healthy life, Australians risk missing out.

Discount rates must therefore accurately reflect how society values the future, including the life of our children. Specific implications of discounting policy for PBAC decision making, including the impacts of any changes, are considered in Section 5.

[1] *It is noted that while overall a reduced discount rate is expected to have a beneficial impact on economic evaluation assessments, there may however be cases where a reduced discount rate may unfavourably impact the assessed cost-effectiveness of a treatment (e.g., where the cost of a treatment increases every year, for example chronic treatments). Cases such as these would benefit from consideration when considering any changes to PBAC Guidelines.*

3. Australian discounting practice: the PBAC

Summary

Discount rate: base case

The PBAC Guidelines require base case economic evaluation to discount costs and benefits at 5% per annum.

The base rate has remained unchanged since PBAC Guidelines were first developed in 1990.

When first selected, the discount rate reflected 1970s and 1980s international health economic discounting practice, including that recommended by the Canadian Government.

International HTA studies in the 1990s most commonly used 5%. Further, Australian macroeconomic conditions suggested the PBAC rate was relatively appropriate during that time.

However, since then Australia does not appear to have seriously reviewed its base discount rate.

Discount rate: sensitivity analysis

Sensitivity analysis rate guidance has evolved from generally providing for it, to providing vaccine specific guidance in 2015 and then replacing it with generally applicable rates of 0% and 3.5% for the 2016 Guidelines.

Section 3 examines PBAC discount rate history, describing rationales for PBAC discount rates and subsequent consideration in Guideline revisions. Section 3.1 briefly outlines the PBAC role in medicines reimbursement. Section 3.2 describes current Guideline requirements. Section 3.3 examines the history of PBAC discounting guidance from 1990. Section 3.4 examines the PBAC discount rate relative to the history of the Australian macroeconomic environment both before and after the original setting of the PBAC base case discount rate.

3.1 The PBAC role in medicines reimbursement

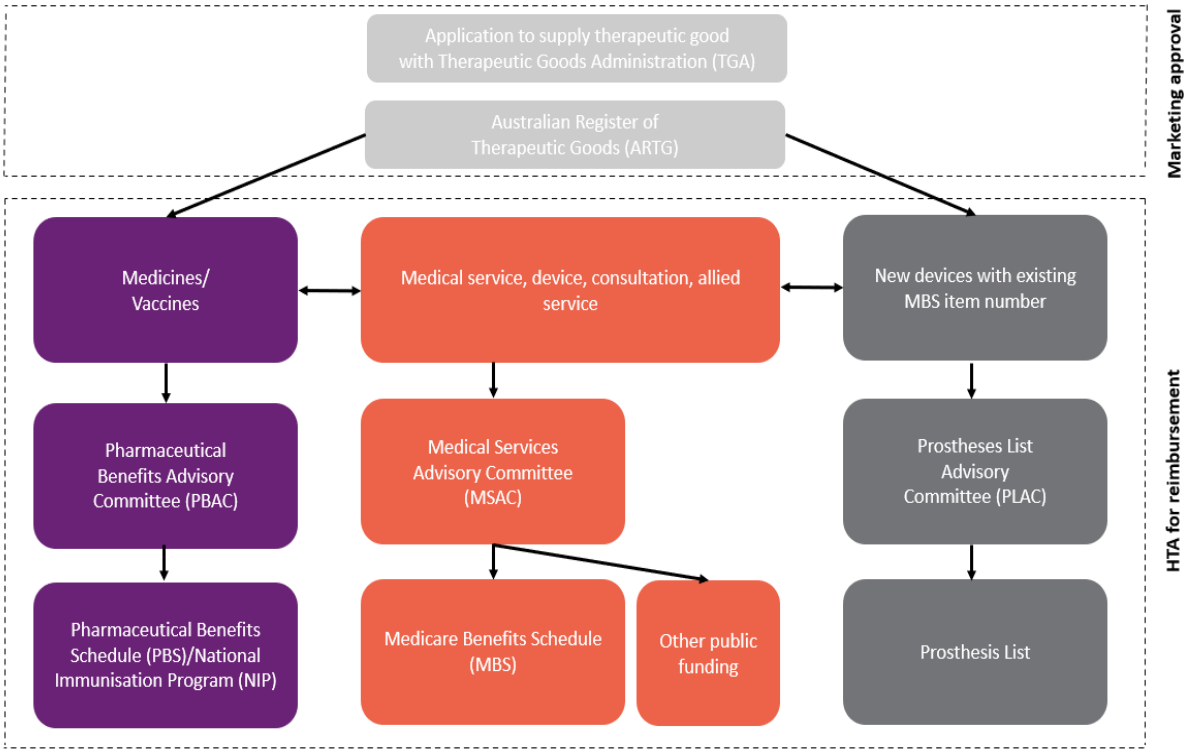
Because Australia's Government cannot financially support every new health technology that comes onto the market, it aims to subsidise those that are safe, clinically relevant, and cost-effective (Department of Health, 2019). Australia's HTA system is therefore vital to ensuring patients get timely access to affordable, new, innovative health technologies that sustainably maximise Australian health outcomes into the future.

Australia's HTA system provides policy-makers, funders, and health professionals with the information on the benefits and comparative value of health technologies to inform funding decisions. It informs decision making for pharmaceuticals (including vaccines), diagnostic tests, medical devices, surgically implanted prostheses, medical procedures, and public health interventions.

The PBAC was established in 1953 (Australian Parliament House, 2002) and is a central part of Australia's HTA system, undertaking medicines and vaccines HTA for reimbursement. It is an

independent expert advisory body appointed by the Commonwealth Government. No new medicine can be listed on the PBS Schedule unless the PBAC makes a positive recommendation to the Minister (PBAC, 2016). The PBAC typically considers submissions for PBS listing from industry sponsors of medicines and medicinal products. Vaccines proposed by sponsor companies for funding under the National Immunisation Program (NIP) must also go through the PBAC evaluation process. Figure 10 summarises the key elements of the national Australian HTA system for reimbursement, including the PBAC. In addition to these key national HTA agencies, HTA assessments in Australia are undertaken by a variety of agencies and committees at the state, and hospital level, and in the private sector.

Figure 10 The national level Australian HTA system for reimbursement including the PBAC



Source: Adapted from Commonwealth Department of Health, 2019.

Crucially, the PBAC is required to consider the cost-effectiveness (i.e., 'value for money') of the proposed medicine compared to existing funded options through economic evaluation (PBAC, 2016). The PBAC Guidelines detail the requirements for submissions. Australia was the first country to develop and implement guidelines for the economic evaluation of pharmaceuticals (Canadian Agency for Drugs and Technologies in Health (CADTH), 1997). In 1992, Australia became one of the first countries to require HTA evidence be submitted for pharmaceutical reimbursement (Kim et al., 2021).

3.2 Current PBAC Guidelines

Section 3A.1.5 of the Guidelines (v5.0; 2016) states:

- Base case economic evaluation to discount costs and benefits at 5% per annum for all costs and health outcomes that occur or extend beyond one year.
- Sponsors can submit sensitivity analyses using 3.5% and 0% discount rates, applied to both costs and health benefits.

- Submissions can, "*If relevant, present supplementary analyses using other discounting methodologies (e.g., a different uniform rate, differential rates, time-varying rates) and justify the alternative approach*."

  (PBAC, 2016)

Both sensitivity analysis rates are below the base rate; usual economic evaluation practice sees them above and below. A 0% sensitivity analysis is recommended practice (Severens & Milne, 2004), while 3.5% reflects base case rates of the National Institute for Health and Care Excellence (NICE) (NICE, 2021) and the UK Joint Committee of Vaccination and Immunisation (JCVI) guidelines (UK DHS, 2019).

3.3 History of PBAC guidance development

Since 1990, there have been five primary Guideline versions (1990, 1992, 1995, 2006 and 2016) (PBAC, 2016). The base case rate has remained unchanged, but sensitivity analysis guidance has evolved.

3.3.1 Base case rates

The first version of the Guidelines draft in 1990 is not publicly available. The published 1995 version required 5% for costs and benefits, with it implied this rate was originally set in 1990. In advising on discount rates, it refers to Chapter 6 of a 'Background Document':

> *"Discounting of future costs and benefits is a standard feature of economic evaluation. Costs or benefits are discounted at an annual rate of 5%. For discussion of the rationale, see Chapter 6 of the* Background Document*."*
>
> (PBAC, 1995)

The 1993 Commonwealth Department of Health, Housing, Local Government and Community Services publication "BACKGROUND DOCUMENT on the use of economic analysis as a basis for inclusion of pharmaceutical products on the Pharmaceutical Benefits Scheme" was based on contracted work completed in 1989. The document aimed to provide a rationale for, and to suggest a general approach to, the preparation and evaluation of economic analysis. It advised a base case discount rate of 5%:

> *"…. the recommendation of the New England Journal of Medicine that 5% be used seems reasonable. This is also the rate suggested by the Canadian Government for studies in that country."*
>
> (Commonwealth Department of Health, Housing, Local Government and Community Services, 1993)

This article from the New England Journal of Medicine was not identified and has been unable to be found. Ultimately, the 5% rate appears to reflect international literature recommendations and its common use in the 1970s and 1980s in international health economic evaluations (Devlin & Scuffham, 2020). A systematic review of international practice between 1992 and 1998 notes this was the most common rate used (Gravelle & Smith, 2001). In the 1990s, the PBAC rate was arguably aligned with common international practice. However, since then, it does not appear to have been formally reviewed. It is worth noting here that Canada has since reduced its discount rate to 1.5% (see Section 4).

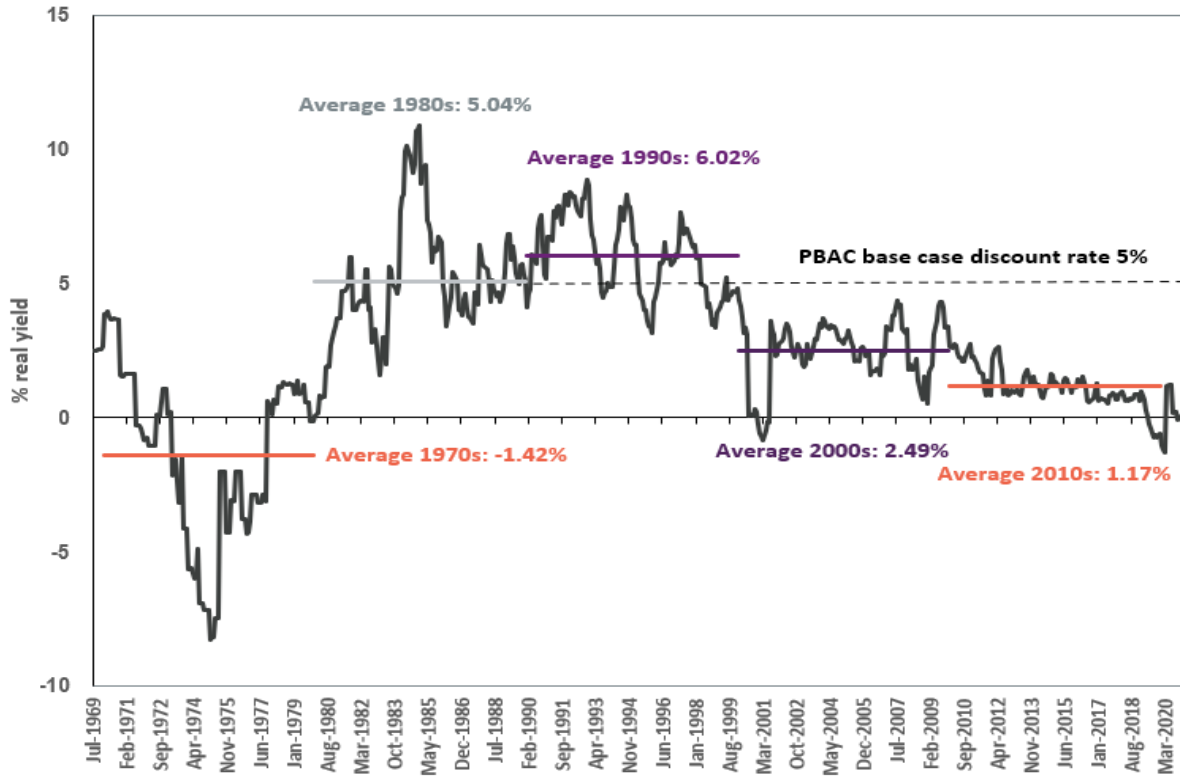
3.3.2 Sensitivity analysis rates

PBAC guidance has evolved from suggesting sensitivity analyses (1995), to advising it (2002), to providing for vaccine submission-specific sensitivity analysis (2015, v4.5), and then specified rates (0% and 3.5% for costs and health outcomes) and allowing alternative discounting constructions for all submissions (2016). The PBAC rationale for sensitivity analysis guidance is unclear. Comparison and benchmarking analyses internationally has long been important (Weinstein et al., 1996). It is noted both NICE (NICE, 2013) and the JCVI in England currently use 3.5% as their base rates (UK, Department of Health and Social Care, 2019) (although NICE recommends further reduction to 1.5% (NICE, 2021).

3.4 Comparison of PBAC discount rate with Australian economic conditions

As stated in Section 2.3.2, the return on risk-free, long-term investments such as government bonds is often considered as the basis for HTA discount rates (Attema et al., 2018). Given the PBAC rate has not changed since 1990, it is worth noting the trend in the real (i.e., after accounting for inflation) 10-year average yield (i.e., return) on Commonwealth 10-year bonds has steadily declined from 5.04% in the 1980s to an average of 1.17% in the 2010s. The PBAC 5% base case rate was arguably reflective of opportunity cost in the 1980s and marginally less than that implied by average yields in the 1990s (6.02%). However, Australian societal time preference implied by these rates and the PBAC discount rate have increasingly diverged since.

Figure 11 Comparison of PBAC discount rate and historical and 10-year average of real Commonwealth 10-year bond yields, 1969 to 2020



Source: Reserve Bank of Australia data. Available at: www.rba.gov.au/statistics/historical-data.html.
Abbreviation: 'PBAC', Pharmaceutical Benefits Advisory Committee.
Note: Calculations based on 10-year Commonwealth Government bond yield minus quarterly CPI

4. Comparing PBAC and international discount practice

Summary

Comparison of Australian and international HTA base case discount practice shows:

- Of countries with established HTA practice, Australia uses the highest rate (5%), which is the same rate as less economically developed, lower-income South American, European, and Asian countries.
- Countries with arguably similar economic development and advanced HTA systems, including New Zealand, England, Scotland, Germany, and Canada use significantly lower rates than Australia, ranging from 3.5% to 1.5%.
- These 'advanced' HTA countries actively define and review their discount rates to keep pace with HTA methodological practices and macroeconomic conditions.
- Some countries like the Netherlands have been increasingly valuing the future health of their citizens at a greater value than the associated costs.

England, Canada, New Zealand and France are considered examples of international HTA best practice.

Australia's HTA discount rate is therefore not valuing the long-term future health of its population in the way it should be.

At present, Australia's base case discount rate does not align with international HTA best practice.

Section 4 compares Australian and international HTA discounting practice. Section 4.1 describes the methodology used to compare Australia with international HTA agencies. Section 4.2 summarises how Australia compares internationally. Section 4.3 examines why world HTA discounting practice has changed over the last 30 years. Section 4.4 summarises how these factors have subsequently decreased HTA discount rates used. Section 4.5 considers the evolution of Australian discount rates compared to identified international 'best practice' countries over the last 30 years. Section 4.6 considers international case studies which represent international 'best practice'. Section 4.7 highlights the growing value placed on health through differential discounting. Section 0 considers how Australia ultimately compares to international best practice.

4.1 Methodology

Reflecting the scope of the Strategic Agreement and the identified bases of HTA discount rate setting, consideration of international HTA discount rate best practice involved a comprehensive review of HTA practice worldwide, including review of HTA agency (and that of other bodies) guidelines, HTA discount rate methodological developments and world economic conditions.

HTA Guidelines Review

Pragmatic literature and desktop searches were conducted. The search aimed to identify relevant government agencies, independent HTA organisations and other relevant bodies, and published guidelines. The desktop search included consideration of international HTA organisations and associations such as Health Technology Assessment

International (HTAi), the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), the International Network of Agencies for Health Technology Assessment (INAHTA) and the European Network on Health Technology Assessment (EUnetHTA).

HTA guidelines of identified agencies, bodies or groups were subsequently sourced, both current and historical (back to 1990 reflecting when the PBAC first developed HTA submission guidelines). These included from governments, national HTA agencies or other relevant bodies undertaking, recommending, or providing for economic evaluation and/or reimbursement decision making, or providing HTA practice guidance (in the case of historical guidelines, including those of now defunct organisations or bodies).

Specific consideration was given to the United States. While HTA does not guide public reimbursement and pricing decisions like in other countries, HTA experts, in particular the *US Panel on Cost-Effectiveness in Health and Medicine,* have long been influential in advising on international HTA practice.

Analysis subsequently assessed both current and historical discount rates. Identification of 'best practice' approaches to discount practice was also considered through assessment of approaches and methodologies used to set and review rates.

Ultimately, this provided for a diverse range of countries, with varying economic development; HTA functionalities and objectives; history of use and guideline operability (i.e., compulsory, recommended or advisory).

It was acknowledged there may be some limitations in sourcing historical HTA guidelines, potentially reflecting the still developing nature of HTA prior to mainstream web-based publication, however this is not considered to materially impact the conclusions drawn.

HTA Literature Search: Economic evaluation methodological developments

To understand the underlying bases for HTA discount rates set, literature search considering the evolution of HTA discounting practice over the past 30 years was undertaken. This considered the methodology and rationale of discounting, the level of discounting, practice for costs and health effects and discounting functional form (e.g., constant, differential, hyperbolic, etc.).

World economic conditions

A review of international macroeconomic conditions since 1990 was conducted to explore trends in how societies are valuing the future. This analysis focused on those countries of similar economic development to Australia, sourcing data from the OECDs online database.

4.2 Results

4.2.1 Australia compared to current international HTA discount rate practice – the highest of established HTA countries

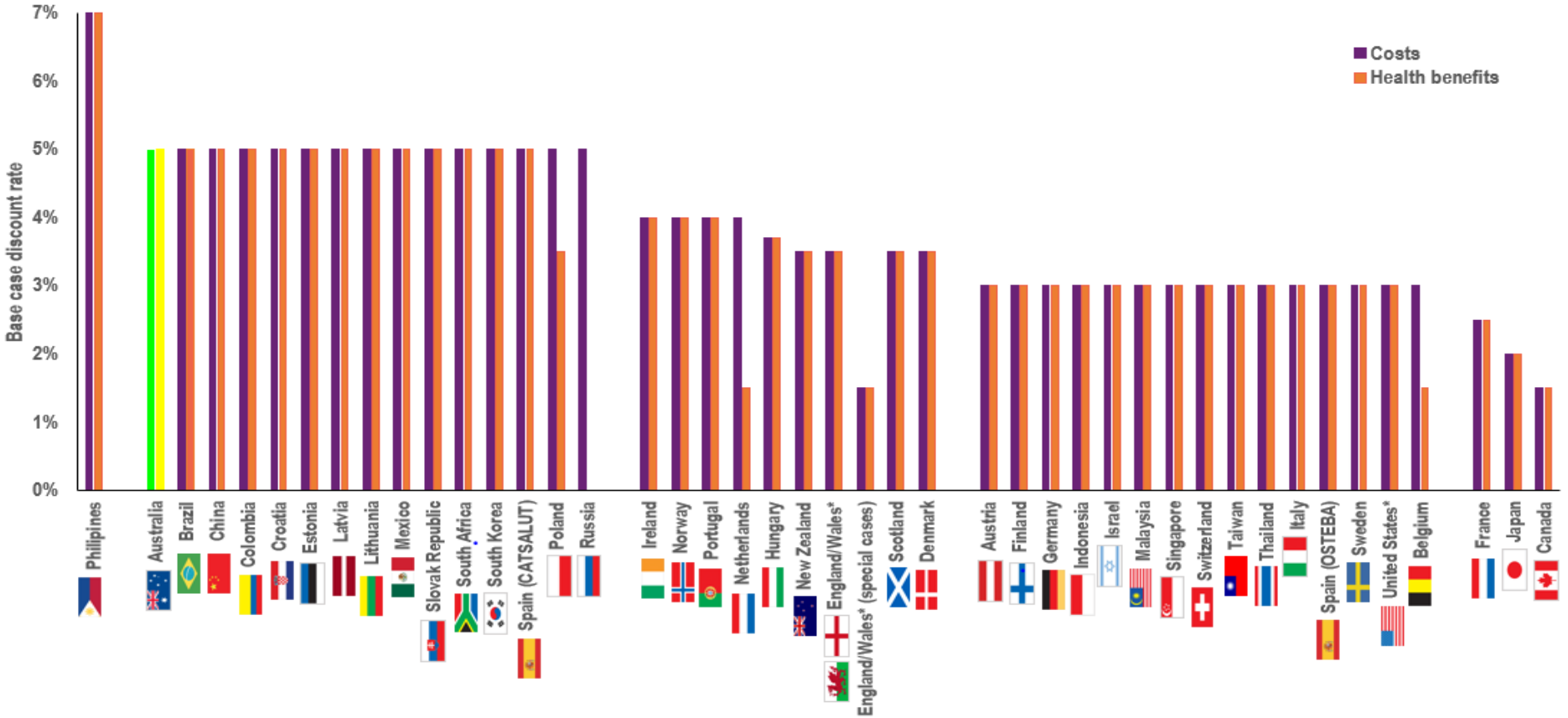
Figure 12 summarises current HTA discount rate practices and recommendations of HTA agencies and other bodies in 41 countries across North America, South America, Europe, the Middle East, and the Asian-Pacific region. A list of the associated HTA organisations and bodies is provided in the Appendix. Key findings include:

- Countries use between 1.5% and 7%.
- **Of 40 countries with established HTA histories, Australia uses the highest discount rate (5%)** along with Brazil, China, Colombia, Croatia, Estonia, Latvia, Lithuania, Mexico, Poland, Russia, Slovak Republic, South Africa, and Spain (CATSALUT - Catalonia). These countries are mostly less economically developed (i.e., lower gross domestic product (GDP) per capita) and with less advanced or prominent HTA systems. In the

European Union (EU), these include 'Cohesion Member States', who have materially lower Gross National Income (GNI) than the EU average.

- **Countries with similar economic development and similarly-advanced HTA systems, including New Zealand, England, Scotland, Germany, Spain (OSTEBA – Basque Country) and Canada use significantly lower rates than Australia,** ranging from 1.5% to 3.5%. **Australia is at the opposite end of the discount rate spectrum** as its original reference country, Canada.
- **Four countries – the Netherlands, Belgium, Poland, and Russia - value the future health benefits from medicines at a rate more than their costs**. They do this by using *differential discounting*, i.e., they discount health benefits at a rate *less than* costs.
- **At least 15 countries** – Austria (3.0%), Belgium (3.0% costs/1.5% benefits), Canada (1.5%), Denmark (3.5%), England/Wales (3.5%, proposed to reduce to 1.5% from 2022), France (2.5%), Germany (3.0%), Hungary (3.7%), Ireland (4.0%), the Netherlands (4.0% costs/1.5% benefits), New Zealand (3.5%), Poland (3.5% benefits), Portugal (4.0%), Taiwan (3.0%) – have reduced their discount rates over the last 30 years. Most of these countries, including Austria, Canada, England/Wales, Hungary, Ireland, New Zealand, Poland, Portugal, and Taiwan had previously had at least a 5.0% discount rate like Australia at some point in time, with Germany's initial draft HTA guidelines also proposing 5.0% (IQWIG, 2008).

Figure 12 Comparison of PBAC and international HTA base case discount rates



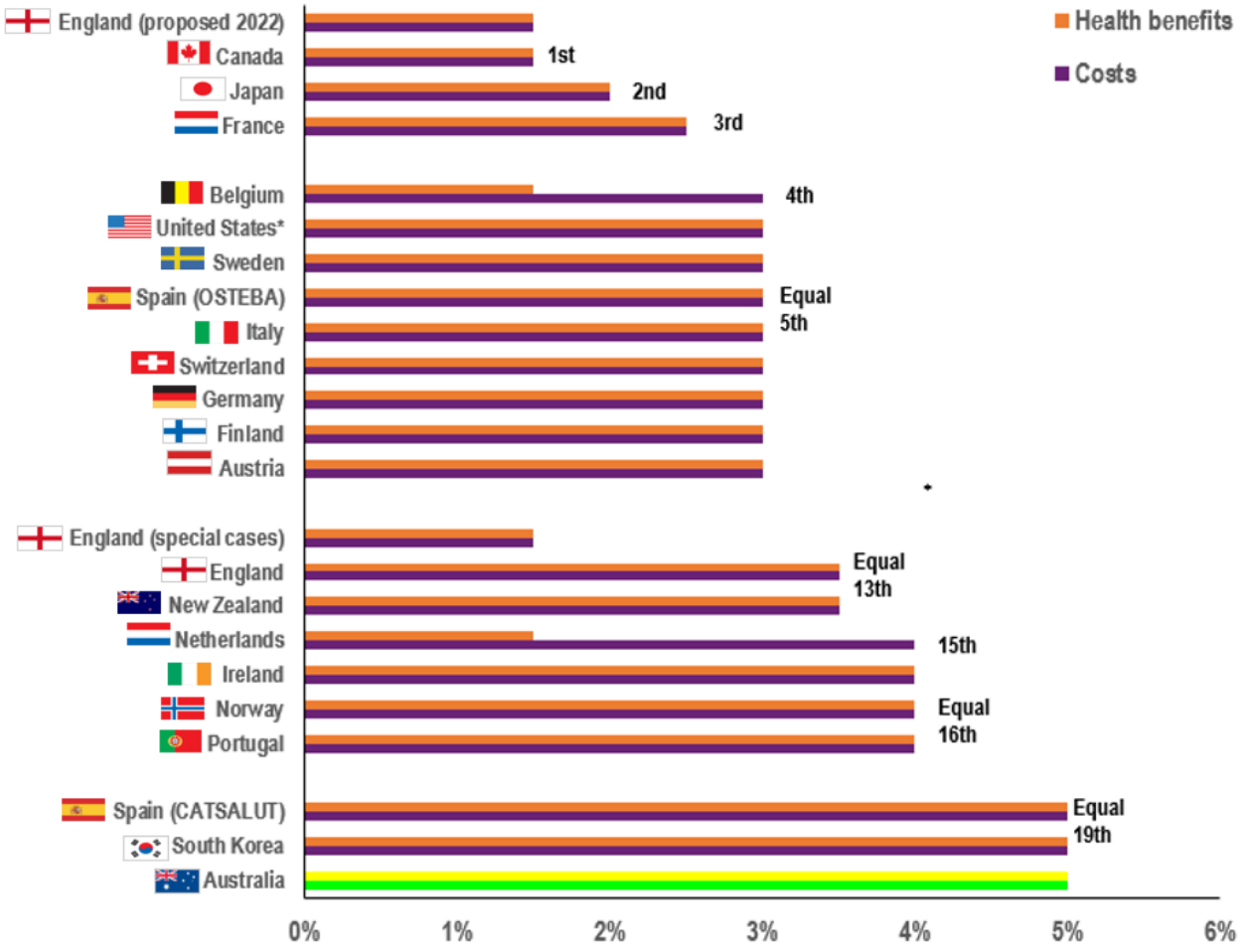
Sources: For full list, please consult 'References'.
Abbreviations: 'CATSALUT', Catalan Health Service; 'HTA', health technology assessment; 'NICE', National Institute for Health and Care Excellence; 'OSTEBA', Basque Office for Health Technnology Assessment, 'PBAC', Pharmaceutical Benefits Advisory Committee.
Notes:

1. For a full list of HTA agencies and bodies, please refer to Appendix.
2. All discount rates are expressed as half (i.e., .5%) or full (i.e., .0%) percentage points, with the exception of Hungary (3.7% for costs and health benefits).
3. Russia has a 0% rate for benefits.
4. For Spain, two prominent regional based agencies, CATSALUT and OSTEBA, have been selected for comparison.
5. The U.S. does not have a specific agency for public reimbursement; however, the *US Panel on Cost-Effectiveness in Health and Medicine,* which convened in 1996 and 2016, has been influential in international HTA practice.
6. Several countries, including England/Wales, France, and Thailand, provide for reduced yearly discount rates (i.e., hyperbolic discounting) after year 30 of analysis. For ease of comparison, these have not been included in the figure above. Nonetheless, they reflect an increasing value placed on longer-term outcomes. In England/Wales, a 1.5% discount rate for costs and health effects may be considered in cases in which treatment restores people who would otherwise die or have a very severely impaired life to full or near full health, and when this is sustained over at least 30 years (NICE, 2013).

4.2.2 Australia in the OECD: equal 19th out of 20 comparable countries

Australia relative to comparable OECD countries should also be noted. The top 20 OECD countries by GDP per capita and/or total GDP ('OECD20') are most similar to Australia in terms of social and economic factors. **Australia's discount rate ranks equal 19th with Spain's Catalonia and South Korea.** This means Australia is effectively valuing its citizens' future health less than almost all similarly high-income countries.

Figure 13 Comparison of Australia and 19 comparable OECD nations base case discount rates



Sources: For full list, please consult 'References'.

Abbreviations: 'CATSALUT', Catalan Health Service; 'NICE', National Institute for Health and Care Excellence; 'OECD', Organisation for Economic Cooperation and Development: 'OSTEBA', Basque Office for Healt Technnology Assessment.

Notes:

6. For a full list of HTA agencies and bodies, please refer to Appendix.
7. All discount rates are expressed as half (i.e., .5%) or full (i.e., .0%) percentage points.
8. For Spain, two prominent regional based agencies, CATSALUT and OSTEBA, have been selected for comparison.
9. The United States does not have public financing and reimbursement decisions guided by HTA decision making processes. However, it has strongly influenced the international setting of discount rates, including through the work of the *US Panel on Cost-Effectiveness in Health and Medicine*, which convened in 1996 and 2016.
10. Countries, including England and France, provide for reduced yearly discount rates (i.e., hyperbolic discounting) after year 30 of analysis. For ease of comparison, these have not been included in the figure above. In England, a 1.5% discount rate for costs and health effects may be considered in cases in which treatment restores people who would otherwise die or have a very severely impaired life to full or near full health, and when this is sustained over at least 30 years (NICE, 2013).

4.3 What has happened in the last 30 years?

Since the PBAC first set its base case discount rate at 5% in 1990 with reference to Canada and existing practice at the time, much has changed:

1. International HTA discounting theory and knowledge have evolved.
2. World economic conditions have changed.
3. International HTA discount rates have changed.

4.3.1 International HTA discounting theory and knowledge have evolved

As noted by Devlin & Scuffham (2020), a 5% discount rate was commonly used internationally in the 1970s and 1980s and was recommended by the Canadian Government (Commonwealth Government, 1993). Since 1990 the theoretical basis and body of knowledge on HTA discounting has developed considerably seeing:

1. Clear articulation of the basis for discount rates used.
2. Greater recognition of the increasing value of health as societies economically develop.

Clear articulation of the basis for setting HTA discount rates

As per Section 2.3.2, the theoretical basis for discount rates has become more clearly articulated[2], referencing:

1. The **social opportunity cost**, reflecting the real interest rate on low-risk or riskless long-term investments such as government bonds) (Attema, 2018); or
2. The **social time preference** approach reflecting 'pure time preference' and the 'wealth effect' (UK Treasury, 2020).

Increasingly, HTA agencies and bodies have clearly defined their discount rate practice with reference to these two approaches. The use of the first approach has in particular been influenced by the work of the *US Panel on Cost-Effectiveness in Health and Medicine* ('US Panel').

[2] *In determining how the PBAC base case discount rate compares to international best practice as part of the HTA Policy and Methods Review, this is an important point. HTA discounting practice is distinct from discounting for other types of appraisals. It is noted, for example, the Australian Department of Prime Minister and Cabinet's Office of Best Practice Regulation (OBPR) requires use of an annual real 7% discount rate to compare the cost and benefits of a policy proposal (https://obpr.pmc.gov.au/sites/default/files/2021-09/cost-benefit-analysis.pdf). This rate intends to reflect return on investment of alternative projects and capture 'project risk'. However, such an approach is not applicable to the considerations of this submission due to: 1. As per the requirements of the HTA Policy and Methods Review, assessment of international HTA best practice overwhelmingly sees discount rates based on either the riskless, return on long-term government securities, or the STPR. 2. At its core, discounting attempts to account for the different timing of costs and benefits by adjusting for preferences for present outcomes relative to future ones. As outlined in section 2.3.1, discount rates do not attempt to account for uncertainty of resulting outcomes, rather they are used to express a preference for present outcomes from a societal perspective. 3. Cost-benefit analysis (CBA) involves assessment of monetary costs and benefits. Such discount rates as recommended by the OBPR are usually applied to capital investment projects, whereas discount rates used for HTA typically are involved with valuing human health, something widely accepted as being different to typical consumption and investment of goods and capital equipment (UK, Treasury, 2020).HTA most commonly uses CUA, which measures health benefits non-monetarily (i.e., uses QALYs). As noted by the UK Treasury, health is unique in that it is not subject to diminishing marginal returns as incomes increase, meaning discount rates based on pure social time preference are appropriate (see Section 4.3.1).*

US Panel on Cost-effectiveness in Health and Medicines

The US Panel is a United States-based academic HTA expert panel that has influenced HTA practice of the last 30 years, including international discounting practice (see box below). It first convened in 1996 to review the theoretical foundations of cost-effectiveness analysis (CEA), consider current practices, and explore alternative methods. It subsequently developed a comprehensive set of recommendations on the basis of theory, balanced against pragmatic and end user considerations such as the need for consistency and comparability of economic evaluations. The US Panel recommended a 3% discount rate for costs and health benefits based on the return on riskless, long-term government securities. It reconvened in 2016 and re-affirmed its original recommendation.

US Panel on Cost-effectiveness in Health and Medicines (US Panel)

The *US Panel on Cost Effectiveness in Health and Medicines* ('US Panel') was established by the US Public Health Service in the early 1990s to review existing cost effectiveness practice. In 1996 it released its recommendations on various methodological components including time preference and discounting (Weinstein et al., 1996).

It believed that a convention was needed to achieve consistency [i.e., comparability] across analyses. It proposed time preference be reflected in the rate on riskless, long-term securities. Empirical evidence at the time put this at a 3% *nominal annual rate*.

At the time many analyses used 5%, so it recommended 5% *sensitivity analyses*. To ensure initial comparability, it recommended 3% and 5% continue to be used for at least the following decade. It also recommended rates be **reviewed and possibly revised on a regular basis, reflecting the fact that macroeconomic conditions change over time**. The US Panel reconvened in 2016 (Sanders et al., 2016) and re-affirmed its recommendation.

Social time preference rate (STPR) development

There has been increasing development of the STPR approach, with the UK Treasury particularly active in the development and re-assessment of this approach for application in UK Government decision making. The UK Treasury *Green Book* issues guidance to UK public agencies, including NICE, on economic appraisal of public policies, programmes, and projects. It regularly assesses the appropriacy of the discount rate in terms of the methodological applicability to specific categories of appraisals (e.g., health) and the rate (currently 3.5%), with reference to its components, 'pure time preference' (1.5%) and the 'wealth effect' (2.0%).

Greater recognition of the increasing value of health as societies economically develop

There has been growing recognition that the value of health (i.e., the rate at which consumption is exchanged for health), is expected to grow with increases in income and life expectancy over time (Hout BA van (1998); Brouwer WBF et al. (2000); Gravelle H et al. (2001)). Accordingly, this must be accounted for in economic evaluations (Attema et al., 2018). This has seen increasing recognition of differential discounting, where the health discount rate is lower than the cost rate.

Where HTA discount rates are explicitly defined based on STPR, this has been expressed as a reduced discount rate for both costs and health benefits because the 'wealth effect' component does not apply to health. This reflects that the diminishing marginal utility of consumption associated with higher incomes does not apply to health

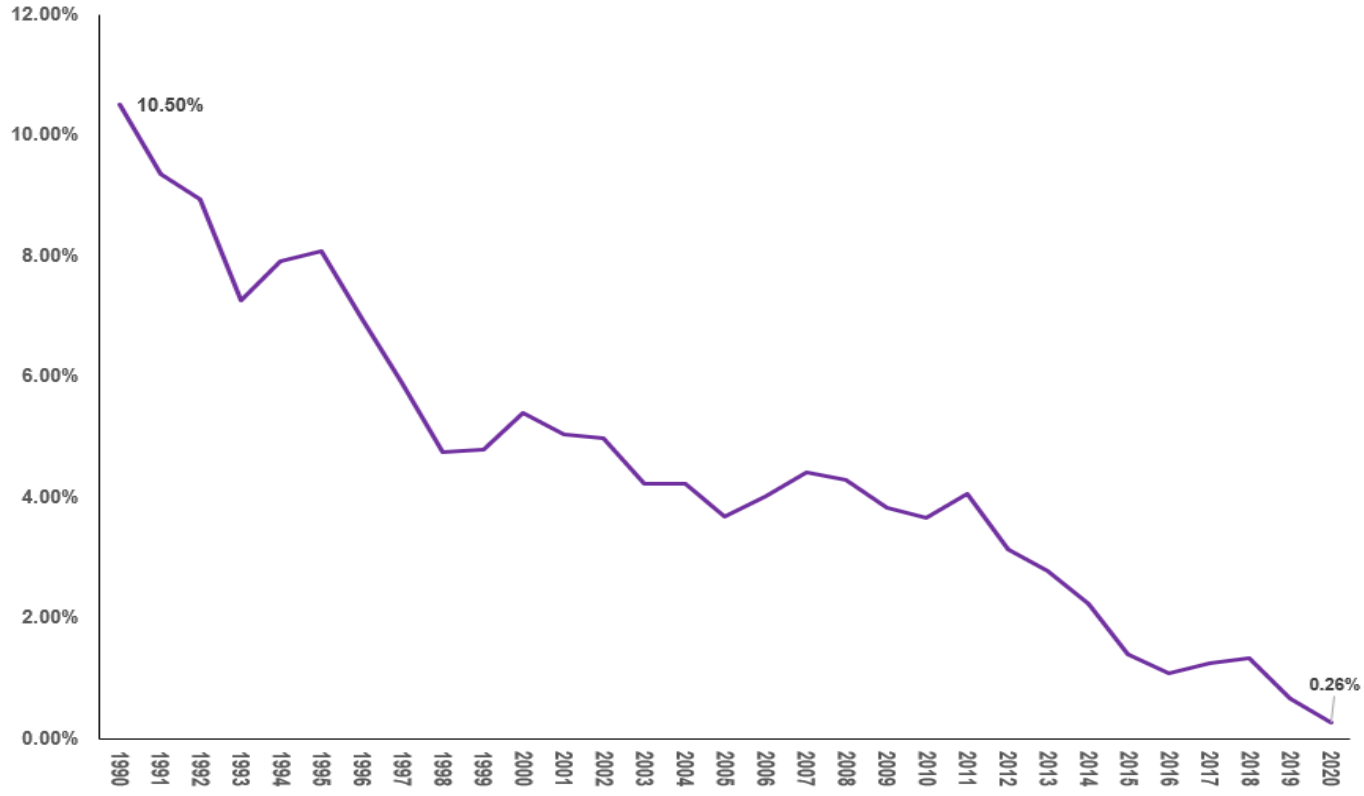
economic evaluations where health outcomes are expressed non-monetarily (Attema et al., 2018; UK Treasury, 2020), as is predominantly the case for HTA economic evaluation (EUnetHTA, 2015). In 2020, the UK Treasury published revised guidance on the applicability of the 3.5% Green Book discount rate to health appraisals. In 'Exceptions to the standard STPR' it noted:

> *"The recommended discount rate for risk to health and life values is 1.5%. This is because the 'wealth effect', or real per capita consumption growth element of the discount rate, is excluded. As set out in Annex 2, health and life effects are expressed using welfare or utility values, such as Quality Adjusted Life Years (QALYs), as opposed to monetary values. The diminishing marginal utility associated with higher incomes does not apply as the welfare or utility associated with additional years of life will not decline as real incomes rise."*
>
> (UK Treasury, 2020)

4.3.2 World economic conditions have changed

Considering long-term government security returns of the OECD20 since 1990 clearly demonstrates changing world macroeconomic conditions. Since the 5% discount rate was predominant in HTA practice 30 years ago, all OECD20 countries have seen their nominal (i.e., unadjusted for inflation) yield (i.e., return) on 10-year government bonds decline, with the OECD20 average decreasing from 10.50% to 0.26% (Figure 14). The effect would be starker when considering real yields.

Figure 14 OECD20 countries average nominal long-term government bond yield (%) 1990 to 2020



Source: OECD, 2021.
Abbreviation: 'OECD', Organisation for Economic Cooperation and Development.
Note: Defined OECD20 countries are: Australia, Austria, Belgium, Canada, Finland, France, Germany, Ireland, Italy, Japan, the Netherlands, New Zealand, Norway, Portugal, South Korea, Spain, Sweden, Switzerland, United Kingdom (England, Scotland, Wales, and Northern Ireland), and the United States.

4.4 International HTA practice has consequentially changed

Evolving international HTA discounting theory and knowledge and world economic conditions have subsequently impacted HTA discount rate practice. Analysis identified 20 countries where HTA agencies and bodies have either explicitly set their discount rate referencing the work of the US Panel, used a 3% rate, or prescribe the discount rate to be set with reference to prevailing long-term government bond rates (Table 2). *In all cases, the rate used is less than that of the PBAC.*

Table 2 Countries setting HTA discount rates reflecting US Panel findings

Rationale	Country
Guidelines referencing 3% discount rate/long-term government securities	Austria, Belgium, Canada, Colombia, Croatia, Finland, Germany, Japan, Indonesia, Israel, Italy, Malaysia, the Netherlands, New Zealand, Portugal, Taiwan, Thailand, Singapore, Spain (OSTEBA), Sweden

Sources: For all sources, please refer to References.

It is worth noting in this context that the *NICE Methods Review* (see Section 4.6) believes that discount rates used in many countries may be too high given that the interest rate that governments are able to borrow at has continued to decline (NICE, 2021).

Analysis identified at least 7 countries (England/Wales, France, Hungary, Ireland, the Philippines, and Scotland) where HTA agencies set their rates based on a STPR approach. *Again, with the exception of the Philippines, all resulting rates are less than that of the PBAC.*

Further, at least 15 countries – Austria (3.0%), Belgium (3.0% costs/1.5% benefits), Canada (1.5%), Denmark (3.5%), England/Wales (3.5%), France (2.5%), Germany (3.0%), Hungary (3.7%), Ireland (4.0%), the Netherlands (4.0% costs/1.5% benefits), New Zealand (3.5%), Poland (3.5% benefits), Portugal (4.0%), Taiwan (3.0%) – have been identified as reducing their discount rates (at least from the time of the first US Panel).

The countries where HTA agencies use a 5% rate (Brazil, Estonia, Latvia, Lithuania, Mexico, Poland, Russia, Slovak Republic, South Africa, South Korea, Spain (CATSALUT)) are mostly less economically-developed countries with less-advanced HTA systems. In the case of those that are European Union (EU) countries, these include 'Cohesion Member States', who have materially lower GNI than the EU average. European Commission economic evaluation guidance broadly recommends these countries use 5% discount rates for economic evaluation (European Commission, 2014); these countries cannot afford to consider long-term benefits the way a wealthier economy should and therefore should be using a higher discount rate.

4.5 Considering international HTA 'best practice' countries

In considering international best practice, no specific documents defining discounting 'best practice' were found. However, the extent to which the following factors were identified was considered indicative of the degree of methodological and process robustness:

1. Methodology and/or rationale for discount rate were specified.
2. Process for setting and review.
3. Frequency of setting or reviewing.
4. Rates reflecting state of:
    a. Underlying drivers, i.e., country-specific opportunity cost or time preference; and
    b. HTA discount rate methodological developments (as reflected in health economic literature).

On these criteria, several countries were considered to have particularly high quality discounting practice, including England, Scotland, Ireland, Canada, New Zealand, Germany, the Netherlands and Hungary.

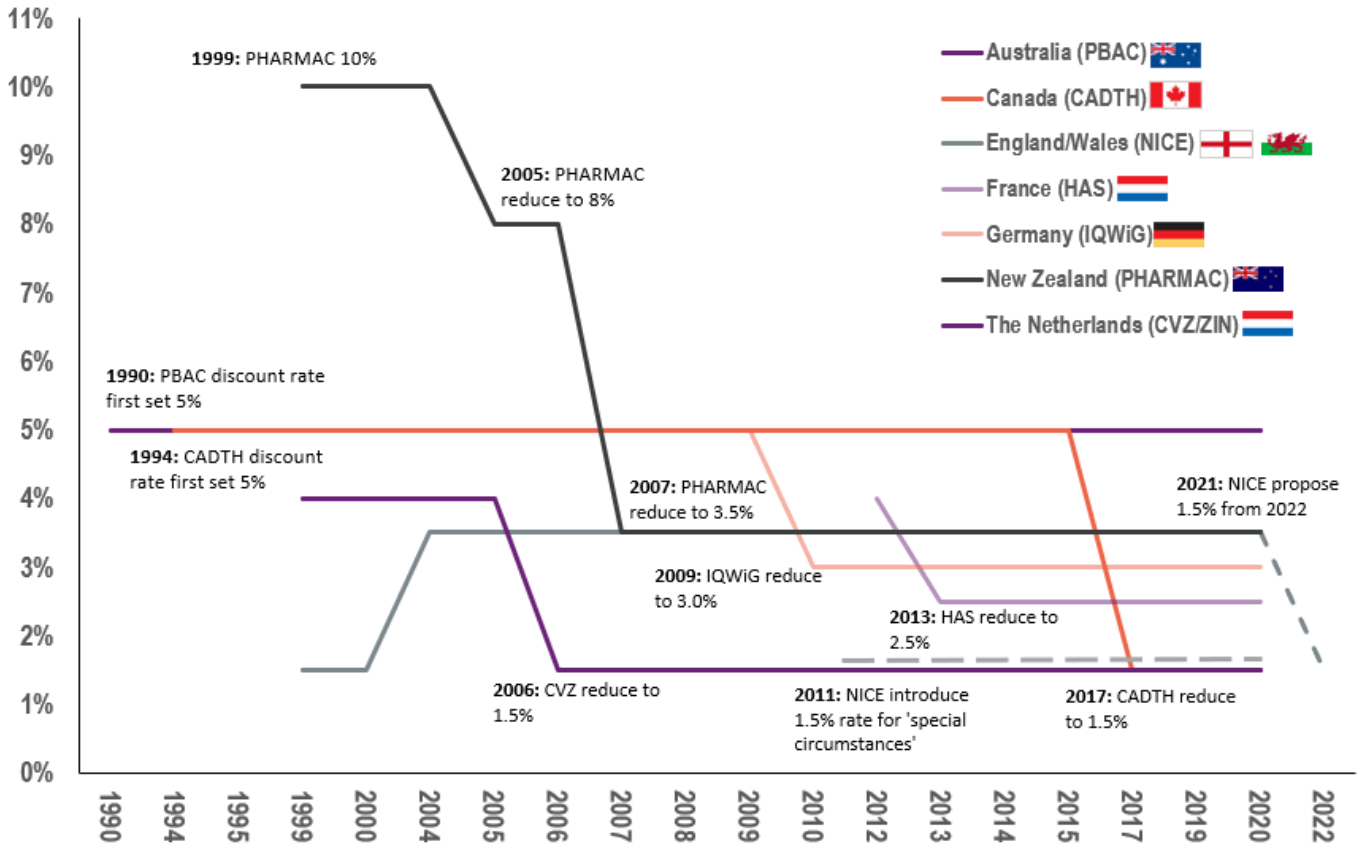
Of these, England, Canada, New Zealand, France, Germany and the Netherlands are of particular note. These countries have HTA agencies with, like Australia's PBAC, long-established histories of reimbursement decision making or guidance provision.

Figure 15 compares the historical evolution of discount rates used by these international HTA agencies and Australia's PBAC since 1990. Key points include:

- **There is a clear downwards trend in discount rates for these HTA agencies**.
- Rates are between 1.5% and 3.5%, meaning that Australia's rate is at minimum 1.5% higher than comparable HTA countries. Canada, Australia's original reference country, reduced their rate to 1.5% in 2017 (CADTH, 2017).
- The HAS (France) discount rate is based on the French Government's centrally-calculated social discount rate (SDR). The HAS commenced responsibility for economic evaluation in 2012. The French SDR has steadily declined, from 8% between 1985 and 2004, to 4% between 2004 and 2012, before reducing to 2.5% in 2013 (HAS, 2020).
- NICEs discount rate is proposed to reduce to 1.5% from 2022 onwards (NICE, 2021) and the HAS discount rate is currently recommended as appropriate till 2070 (Ni, 2017).
- For the last 15 years, the Netherlands has used a lower rate for health benefits (1.5%) than costs (4%) to reflect increased value placed on the future long term health of its citizens as it economically develops.
- As a result of changing economic conditions and revision of its methodology, between 1999 and 2007, New Zealand's (PHARMAC) discount rate significantly dropped from 10% to 3.5%, with its rate remaining there ever since.

Appropriately, these countries have progressively chosen to value the long-term health of their citizens and future generations more as they have become wealthier, and their societies' preferences have changed. Australia has not.

Figure 15 Comparison of historical evolution of discount rates of prominent international HTA agencies: 1990 to 2020 (HTA agency in brackets)



Sources: For all sources, please refer to References.

Abbreviations: 'CADTH', Canadian Agency for Drugs and Technologies in Health; 'CVZ', College voor Zorgverzekeringen; 'HAS', Haute Autorité de santé; 'IQWiG', Institute for Quality and Efficiency in Health Care; 'NICE', National Institute for Health and Care Excellence; 'PBAC', Pharmaceutical Benefits Advisory Committee; 'PHARMAC', Pharmaceutical Management Agency; 'ZIN', Zorginstituut Nederland.

Notes:

1. Beginning of individual series reflect commencement of available HTA agency guidance on discount rates.
2. Between 1999 and 2014, the CVZ (or Healthcare Insurance Board) published '*Dutch guidelines for pharmacoeconomic research*' as part of its role advising on inclusion of health care in the basic health insurance package. In 2014, it became ZIN (also known as the National Health Care Institute).
3. With the exception of CVZ/ZIN (the Netherlands) who discount costs at 4.0%, all agencies discount costs and health benefits at the same rate.
4. IQWiGs first draft version of 'Methods for Assessment of the Relation of Benefits to Costs in the German Statutory Health Care System' proposed 5.0% as the discount rate, before the second version subsquently revised this down to 3.0% reflecting government security returns (IQWiG, 2008)

4.6 International 'best practice' case studies

The following selected case study vignettes of comparable HTA agencies of Canada, England, New Zealand and France are used to consider how Australia compares internationally to 'best practice'. These agencies represent leading examples with respect to the level, and practice of setting, appropriate HTA discount rates.

4.6.1 Canada

Canadian Agency for Drugs and Technologies in Health (CADTH): reduction of base case discount rate to 1.5%

The Canadian Agency for Drugs and Technologies in Health (CADTH) was originally created in 1989 as the Canadian Coordinating Office for Health Technology Assessment, before subsequently evolving into CADTH by 2006 (Hailey 2007).

The first economic evaluation guidelines were developed in 1994 (CADTH, 2006) with a 5% discount rate, reflecting Canadian HTA economic evaluation practice in the 1980s and 1990s and international health economics literature.

As discussed in Section 3.3.1, Canada was referenced by the Commonwealth Government's 'Background Document' used to establish the PBACs 5% discount rate in 1990. CADTH has since regularly reviewed its HTA economic evaluation guidelines. CADTH's 2006 guidelines (version 3) recommended:

> "*The standard rate for the Reference Case is set at 5% per year. A rate of 0% should be analysed to show the impact of discounting. In addition, a 3% discount rate must be used in a sensitivity analysis for a comparison with published evaluations in other jurisdictions using 3% as the standard discount rate.*"

CADTH's 2016 Report, "Discounting and the Evaluation of Health Care Programs" (CADTH, 2016) acknowledged that Canada's prevailing discount rate was:

> "*Substantially higher than the discount rate used by equivalent organizations in other economically developed countries*."

The 4th version of its economic evaluation guidelines, *Guidelines for the Economic Evaluation of Health Technologies: Canada*, was released in 2017 (CADTH, 2017). CADTH revised its base case discount rate to 1.5% for costs and health benefits, a significant reduction. It noted:

> "*The discount rate is expressed in real (i.e., constant, inflation-adjusted) terms, which is consistent with valuing resources in real dollars. Nominal provincial bond rates were adjusted for inflation using the Bank of Canada's target inflation rate.*"

4.6.2 England

National Institute for Health and Care Excellence (NICE): A case for change for a 1.5% base case rate

In England, NICE undertakes economic evaluation of pharmaceuticals financed for use in the National Health Service (NHS).

Generally, NICE discounting practice has been informed by the UK Treasury's *Green Book*. The Green Book issues guidance to UK public agencies on economic appraisal of public policies, programmes, and projects. In turn, the JCVI has followed NICE guidance.

Since 2004, NICE has specified preferred discount rates for costs and health effects of 3.5% per year. In 2011, NICE introduced a 1.5% discount rate for health benefits potentially applicable for cases in which treatment 'restores' people who would otherwise die or have a very severely impaired life to full or near full health, and when this life would be sustained over at least 30 years (O'Mahony, 2014). The 2013 guidelines revision subsequently amended this to allow 1.5% for both costs and health benefits (NICE, 2013).

UK Government Green Book (2020)

The Green Book Social Time Preference Rate (STPR) rate of 3.5% consists of 1.5% pure time preference and a 2.0% 'wealth effect' component. The wealth effect component reflects the decreasing value of consumption as income increases (i.e., diminishing marginal utility').

In 2020, the UK Government reviewed the Green Book. In undertaking the review, it noted:

> *"The Government is committed to ensuring the UK's methodology for appraising environmental impacts remains at the forefront of international best practice. This means consistently ensuring that both the framework and methodology are underpinned by the latest empirical and academic evidence and can be practically applied to real-world policies."*

The UK Government's 2020 Green Book notes a 1.5% discount rate as appropriate for health stating:

> *"The recommended discount rate for risk to health and life values is 1.5%. This is because the 'wealth effect', or real per capita consumption growth element of the discount rate, is excluded. As set out in Annex 2, health and life effects are expressed using welfare or utility values, such as Quality Adjusted Life Years (QALYs), as opposed to monetary values. The diminishing marginal utility associated with higher incomes does not apply as the welfare or utility associated with additional years of life will not decline as real incomes rise."*

NICE Methods Review (2020-2021)

The purpose of the *NICE Methods Review* has been to optimise its evaluation methods to support the ambition the ambition of the NHS to provide high quality care that offers good value to patients and to the NHS. In particular, **NICE has ambitions for early access to valuable innovative treatments and more equitable access to treatments for severe diseases** (NICE, 2020).

> **"***Ensuring rapid access to clinically and cost-effective health technologies is critically important to patients and their families, the NHS and the life sciences industry…. As health technologies rapidly advance, so too do methods of evaluation. To continue to support the needs and objectives of all parts of the healthcare and life sciences ecosystem, NICE must ensure that its methods remain cutting edge."*

Referencing current academic thinking, **NICE stated that discount rates currently used by HTA bodies in many countries may have been too high, including the 3.5% discount rate for health effects (and costs) used by NICE**.

This reflects both the low long-term government bond rate and that the 2% 'wealth effect' component of the UK Green Book STPR may have set England's discount rates too high.

In November 2020, NICE released its 'case for change' noting:

> *"Ensuring that our methods are clear, transparent and predictable should allow us to speed up evaluation processes for new and emerging technologies. This is particularly important in our response to COVID-19, but also allows us to further consider how to best evaluate the value of specific new technologies such as cell and gene therapies."*

NICE proposed to change the base case discount rate from 3.5% to 1.5% for costs and health effects:

> "*We took into account all of this evidence and the perspectives of working group members and concluded that the best available evidence suggests there is a case for changing the reference-case discount rate from 3.5% to 1.5%, for both costs and health effects. We consider that the argument that the 2% 'wealth effect' does not apply to health (as described in the Green Book) is important."*

NICE noted the important impact on advanced therapy medicinal products (ATMPs), including cell and gene therapies:

> "*The finding that the discount rate can significantly affect how we value costs and health benefits that occur in the future, particularly for technologies such as ATMPs and other potential cures, is important. It emphasises that a discount rate of 3.5% decreases the value placed on longer-term benefits, compared with 1.5%, and so affects the apparent cost-effectiveness of such technologies*."

In making the recommendation, NICE noted:

> *"The potential change to the discount rate, if implemented, would seek to reflect as accurately as possible the value of costs and health effects in the future."*

The discount rates applied to NICE evaluations from 2022 onwards are currently being considered as part of the broader overall NICE Methods Review.

4.6.3 New Zealand

Pharmaceutical Management Agency (PHARMAC): From the world's highest discount rate to one of the lowest

PHARMAC was established in 1993. An independent New Zealand Government Crown Agency, it is responsible for decisions on the funding of pharmaceuticals and vaccines to be listed on New Zealand's Pharmaceutical Schedule.

In 1996, PHARMAC commenced using CUA to assess treatment cost-effectiveness (Grocott et al., 2006). PHARMAC's Prescription for Pharmacoeconomic Analysis (PFPA), first published in 1999, outline- required methodology.

Originally, PHARMAC used a discount rate loosely tied to that used by the New Zealand health sector for evaluating capital investments. This was known as a 'capital charge'. This rate was based on the risk-inclusive long term cost of capital to the Health Funding Authority.

At one point it was using a rate of 11.3%, however because the capital charge fluctuated generally around 10%, it used a rate of 10.0% from 1999 to 2005. In July 2005, PHARMAC reduced the discount rate to 8% following a reduction in the capital charge (Metcalfe, et al., 2005).

The discount rate was subject to much debate, with Milne (2005) noting that inappropriately high rates can:

> *"…profoundly increase cost-effectiveness ratios of preventive healthcare programmes, particularly those targeted to children. This will drastically reduce the apparent value of such programmes… High discount rates are particularly debilitating for preventive healthcare and public health programmes that target fatal illnesses in young people."*

In 2007, PHARMAC released version 2 of the PFPA with a revised discount rate of 3.5% discount rate based on the 5-year average real risk-free long-term government bond rate. It noted:

> "*Using a lower discount rate is likely to …. impose less of a disadvantage on treatments that confer long-term benefits (i.e., pharmaceuticals that have high up-front costs and long-term benefits are likely to appear more cost-effective)."*

The current PFPA (2015) notes:

> *"PHARMAC considers that the social rate of time preference is the most relevant approach for PHARMAC to use when determining the discount rate, as it reflects society preferences. This requires the use of the long-term government bond rate."*

From having the highest HTA discount rate in the world, PHARMAC ultimately came to have one of the lowest and has maintained this discount rate for the last 14 years.

4.6.4 France

Haute Autorité de santé (HAS): the continued decline in the French social discount rate

The Haute Autorité de santé (HAS) - or French National Authority for Health - was set up by the French Government in August 2004 as an independent government body to streamline activities for assessing drugs, devices and procedures.

In 2012, the Economic Evaluation and Public Health Commission (Commission d'Evaluation Economique et Santé Publique) was created within the HAS to conduct and review economic evaluations of health technologies and to inform decision makers on the economic value and efficiency of the interventions assessed (Massetti et al., 2015).

In France, the applicable discount rate is defined by E. Quinet (Commissariat général à la stratégie et à la prospective 2013). It sets the social discount rate (SDR), which reflects pure preference for the present and the elasticity of the marginal utility of consumption applied against the consumption growth rate (i.e., the extent additional future consumption is subject to diminishing marginal utility and is thus discounted).

Historically the French SDR was 8% between 1985 and 2004 (Zhuang et al., 2007), declining to 4% in 2005. As such, original HAS economic evaluation guidelines set a 4% discount rate (HAS, 2012). In 2013, the SDR reduced to 2.5% (HAS, 2020).

The 2020 edition of "*Choices in methods for economic evaluation – HAS"* requires a discount rate of 2.5%, noting:

> *""It reflects the relative price in present terms and sets the limit we are willing to accept for the future… The discount rate does not take account of the uncertainty associated with the interventions, which is dealt with separately…To appraise the robustness of the conclusions of the evaluation, sensitivity to the discount rate is tested using, as a minimum, an increased rate (4.5%) and a zero rate."*

In setting the rate at 2.5% in 2013, E. Quinet recommend it apply until 2070 (Ni, 2017). As such, this is indicative of a continued long-term trend in advanced economies of a decline in discount rates reflecting greater societal preference for the future.

4.7 Differential discounting

It is also worthwhile noting the increasing trend of differential discounting, i.e., placing greater value on future health benefits than the costs of achieving them.

Of the four countries using differential discounting (the Netherlands, Belgium, Russia, and Poland), the Netherlands has been at the forefront of considerable academic work on the increasing value society places on health in CUA. Since 2006, the Netherlands has used 4% discounting for costs and 1.5% for benefits (see box below).

As the NICE Methods Review demonstrates (Section 4.6), there is increasing recognition of the merits of placing increasing value on long-term future health. Differential discounting is a further option that could be considered for Australia by the PBAC in the future, with lower discount rates applied to health benefits and higher rates applied to costs.

The College voor Zorgverzekeringen (CVZ)/ Zorginstituut Nederland (ZIN): Differential discounting – valuing longer-term future health

Also known as the Healthcare Institute Netherlands, the ZIN (formerly the CVZ) advises on the standard package of mandatory insured healthcare, including medicinal products. The original CVZ's *Guidelines for Pharmacoeconomic Evaluation* (2006) first acknowledged changing perceptions about constant discounting:

> *"The choice of discount rates for effects and costs should be based on changing assessment of effects and costs over time. The choice of a discount rate of 4% for costs was based partly on current returns on obligations and the literature. The choice for a discount rate of 1.5% for the effects is also based on the literature, and on the fact that the (healthy) life expectation of the population is still increasing."*
>
> (CVZ, 2006)

The Guidelines specifically refer to the works of van Hout (1998) and Gravelle H et al. (2001) which cite the growing trend for placing greater value on future health effects. The ZINs most recent HTA Guidelines (2016) maintain this approach.

The approach also influenced Belgium's Healthcare Knowledge Centre (KCE), who used a 1.5% rate for health effects:

> "*The choice of the discount rate for costs is based on the return on risk-free government bonds, currently about 3% in Belgium. The choice of the discount rate for outcomes is based on the expected change in the value of health over time and the expected relative changes in budgets and productivity over time."*
>
> (KCE, 2008)

4.8 Conclusion: Australia's discount rate does not align with international HTA best practice

Australia's base case discount rate does not align with international HTA best practice:

- The PBAC base case discount rate of 5% was set in 1990.
- While comparable to international HTA practice and Australian economic conditions in the 1990s, HTA theory, international practice and economic conditions have since evolved.

- Countries with similarly advanced economies and comparable HTA systems include England, Canada, France, and New Zealand. Over time, they have continued to revise their rates downwards, reflecting evolving HTA academic best practice developments, economic conditions and the increasing societal value being placed on investing in long-term health benefits as they economically develop.
- These countries are therefore considered to be relevant examples of international HTA best practice to compare Australia against. Ultimately, they all have lower base case rates than Australia, regardless of their underlying approach to setting them.
- Australia's initial 1990 reference country, Canada, revised their rate down to 1.5% in 2017, reflecting macroeconomic conditions.
- In some cases, HTA systems (e.g., the Netherlands), in recognition of the increasing value being placed by society on long-term health, are discounting health benefits at a lower rate than costs.
- Other countries currently using 5% are lesser-developed economies with less advanced HTA systems, and for which such a rate is more appropriate (these countries typically cannot afford to invest in long-term health outcomes the way wealthier economies can).
- Australia's discount rate is reflective of a low-to-middle-income country (LMIC) (i.e., a developing country) rather than a mature, high-income developed economy with a higher standard of living, societal values, and future expectations.
- Australia's PBAC discount rate is therefore not valuing the long-term future health of Australia's population in the way comparable countries are and is in fact discriminating against those with most to benefit from preventative or long-term health benefits, such as our children.

5. Recommendations: The Case for Change

Summary

The PBAC base case discount rate should be revised down to 1.5% for costs and health effects.

The case for change is simple and compelling: the world has changed since 1990 and Australia should change with it. Economic theory, economic conditions and international HTA best practice have all changed. Australian HTA practice should also change.

Revising the base case rate to 1.5% would:

- Prove to the Australian people and the world that our population's future health is valued
- Contribute to improving the speed of patient access to new and innovative therapies
- Promote PBAC decision making equity
- Align with the Commonwealth Government's preventative health agenda

There have been instances of PBAC submissions where discount rates were influential in their rejection, assessed cost-effectiveness and/or the delay in achieving a positive recommendation.

It should be noted that there are many reasons for PBAC submission outcomes. A reduction in the discount rate may not immediately lead to substantially more positive PBAC recommendations. Instead, it will ensure economic evaluations appropriately capture the value of medicines in a way that reflects the societal value placed on future health outcomes.

Section 5 recommends a revised PBAC base case discount rate, the case for change and positive implications of a reduction. Section 5.1 summarises recommended changes to discount rates. Section 5.2 describes the case for change. Section 5.3 considers potential implications of the proposed revision, including illustrative examples where it will likely have a positive effect on patient access outcomes.

5.1 Recommendation: reduce the PBAC base case discount rate to 1.5%

The PBAC base case discount rate in the Guidelines should be revised to 1.5% for costs and health effects from 1 July 2022.

Revising the base case discount rate to 1.5% would be a straightforward adjustment that will align Australia with international HTA best practice.

It would require a simple administrative amendment to the Guidelines, without any regulatory or legislative changes.

5.2 The Case for change

The case is simple and compelling: the world has changed

The world has changed since 1990 and Australia should change with it.

While a 5% base case rate may have been appropriate 30 years ago, economic conditions, economic theory and international HTA best practice have all changed.

International HTA agencies with which Australia is often categorised, set, and review their discount rate to keep pace with best practice and world economic conditions. This has seen their discount rates drop to between 1.5 and 3.5 percentage points *below* the PBAC rate.

Australia should reduce its discount rate to align with international HTA best practice.

Prove to the Australian people and the world that our population's future health is valued as much as other high-income countries

Other countries with similarly developed and regarded HTA systems have reduced and maintained their discount rates at levels that reflect the increasing value placed on their population's longer-term future health.

As an advanced economy which prides itself on its population's health, Australia must value the future long-term health of its citizens, especially its children, equally to those of Canada, England, Belgium, Japan, the Netherlands, and many other OECD countries.

Australia should follow suit.

Contribute to improving the speed of patient access to new and innovative therapies: Australia as a 'first launch' country

The COVID-19 pandemic has highlighted the value of preventative therapies and the critical importance of thinking of the long term. Further, Australia's emerging therapeutic landscape will see new and innovative therapeutic categories including cell and gene therapies and personalised medicines (i.e., ATMPs).

As noted in the fifth edition of MA's *COMPARE: Comparison of Market Access and Reimbursement Environments* report (Medicines Australia, 2019), Australia ranks 16th out of a group of 20 comparable OECD countries in terms of patient access to new medicines.

Bringing the PBAC discount rate into alignment with international HTA best practice would be a relatively small, but important step in ensuring the Australian HTA environment does not unnecessarily impede new medicine and vaccine access because of outdated HTA methodology settings.

A discount rate that values future health outcomes in the same way as society will underpin HTA assessments that appropriately assess their value.

Reducing the discount rate would help develop Australia's international status as a 'first-launch' country that provides early access to therapies that will sustain the long-term health of its people.

Promote PBAC decision making equity

One of the PBAC's key decision making criteria is equity. While discounting is considered a necessary component in economic evaluation and sees present outcomes having more value than future ones, a discount rate that truly

reflects Australian societal preferences for the future would implicitly provide for a more equitable approach to PBAC decision making across different patient groups (age, socioeconomic and geographical), therapy profiles (preventative, curative, long-term health benefit profiles) and generations (present and the future).

This is particularly important as Australia's medicine profile evolves to include more innovative therapies. In the context of the PBAC decision-making process, this may delay or reduce the likelihood of PBS listing for specific therapeutic product types and disease areas, contributing to an unnecessarily inequitable patient access environment.

The current 5% rate disproportionately discriminates against patients who could benefit from treatments where the benefits are realised over a longer period of time.

The reduction of the base case discount rate to 1.5% would help to address the inequitable imbalance in cost-effectiveness assessment of many therapy areas inherent with the current rate. Otherwise, as advances in science and medical technology unlock new ways to correct or reverse diseases, potentially altering disease courses from certain death to a longer, healthy life, Australians risk missing out.

Simply put, it would provide all patients, including children and future generations of Australians, with a more 'level footing'.

Align with the Commonwealth Government's preventative health agenda

A reduced discount rate would align with the increasing recognition of the value of prevention in Commonwealth Government health policy, as reflected in the Commonwealth Government's *Long-Term National Health Plan*, including component parts the *National Preventative Health Strategy*, and the *Primary Care Health 10 Year Plan*.

Australia's Long Term National Health Plan charts the way forward over the next 10 years in the key areas of mental health, primary care, hospitals, preventive health, and medical research.

As part of this, the Department of Health is currently developing the 10-year National Preventative Health Strategy, which aims to help Australians improve their health and wellbeing at all stages of life and will be a key pillar of Australia's Long Term National Health Plan (Commonwealth Department of Health, 2019).

The Australian Government has also clearly recognised the importance of primary health care in providing high quality outcomes and experiences for all Australians with the development of a Primary Health Care 10 Year Plan.

The Commonwealth Government health policy settings must be appropriately consistent in supporting such objectives. It is noted that even in New Zealand, the decision in 2007 to reduce high discount rates to more appropriate levels occurred in an environment of concerns regarding the inconsistency of high rates with the array of government policy strategies and initiatives (including those with preventative focus) directed towards improving population health (Milne, 2005).

High discount rates are particularly discriminatory for preventive healthcare evaluations. With COVID-19 highlighting the vital nature of preventative medicines and vaccines to not only the population's health, but a fully functional society, a reduced discount rate would assist in ensuring the full value of preventative therapies are recognised.

5.3 Positive impacts: PBAC case studies

As described in Section 2.5, preventative interventions, and innovative medicines, including cell and gene therapies and other personalised medicines, typically have upfront costs and their greater health benefit payoffs spread out over the longer-term. The higher the discount rate, the less cost effective these therapies are deemed.

The following case studies demonstrate where the discount rate has, or may have had, a material impact on PBAC outcomes, including economic evaluation results, recommendations, and timing until funding.

As Australia's therapeutic profile changes to provide for more innovative medicines with different cost and benefit profiles, the choice of discount rate will have an increasing impact on recommendation decisions and their timeliness and thus Australians' access to them.

5.3.1 Bexsero: Meningococcal B – 2013 to 2019

Bexsero®, a meningococcal group B vaccine (4CMenB) proposed for the NIP Schedule for prevention of meningococcal B disease in infants and adolescents, was considered by the PBAC in November 2013, July 2014, July 2015, and November 2019.

It was rejected three times before receiving a positive recommendation in November 2019, but only for a high-risk population of Aboriginal and Torres Strait Islander children, rather than the proposed general Australian population.

The time period between initial PBAC consideration in November 2013 and ultimate recommendation was more than six years. The Sponsor company's economic evaluation modelling used alternative discounting approaches differing from Guideline base case guidance in three of the four submissions.

At the time, NICE (England)[3] and PHARMAC (New Zealand) were using a 3.5% rate, HAS (France) a 4% rate, while ZIN (the Netherlands) used 4% for costs and 1.5% for health benefits.

While it is noted that discount rates employed are not the only factor driving CUA outcomes analyses and PBAC recommendations, these decisions nonetheless demonstrated the significant impact that discount rates can have on preventative therapies.

In this situation, PBAC discount rates were a key driver of ICER outcomes, with the PBAC noting, "*the ICER remains highly sensitive to the discount rates applied*" (PBAC, 2019).

Table 3 summarises the different discount rate approaches used for each submission and the impact this had on cost per QALY outcomes. As can be seen, discount rates had a significant impact on cost-effectiveness outcomes.

Table 3 Summary of Bexsero submission outcomes with different discount rate approaches

	November 2013	July 2014	July 2015	November 2019
Discounting approach submission	Differential discounting: 5% for costs, 1.5% for health outcomes	5.0% for costs and health outcomes	5% for costs and health outcomes in years 1 to 30, stepped to 1.5% p.a. for costs and health	3.5% for costs and health benefits.

[3] *The effect of discount rate on the valuation of HPV vaccination program health benefits has also been noted in the UK (Westra, et al. (2012). On Discounting of Health Gains from Human Papillomavirus Vaccination: Effects of Different Approaches. Value in Health 15 (2012) 562–567. Available at: www.valueinhealthjournal.com/article/S1098-3015(12)00018-6/pdf*

	November 2013	July 2014	July 2015	November 2019
			outcomes in years 31-100	
Cost per QALY: Sponsor submission	$45,000 to $75,000 per QALY	>$200,000 per QALY	The preferred vaccination program, 'Program #5', $105,000/QALY - $200,000/QALY gained	$15,000 to $45,000 per QALY (general population); <$15,000 per QALY (Aboriginal and Torres Strait Islander population)
Cost per QALY using Guidelines discount rate	> $200,000/QALYG	Estimated close to $309,344 per QALY as per PBAC preferred approach	ICER of preferred 'Program #5' increased to more than $200,000 per QALY	>$200,000 per QALY (general population); $105,000 to $200,000 per QALY (Aboriginal and Torres Strait Islander population)
PBAC outcome	Rejected	Rejected	Rejected	Recommended for Aboriginal and Torres Strait Islander children only
Time between first submission and recommendation	>6 years			

Source: PBS (www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd)
Abbreviations: 'ICER', incremental cost effectiveness ratio; 'PBAC', Pharmaceutical Benefits Advisory Committee; 'QALY', quality-adjusted life years; 'QALYG', quality-adjusted life years gained.

5.3.2 Other PBAC submissions

Other submissions for infectious disease vaccines which raised the impact of discounting on economic evaluation results included those for HPV, herpes zoster, meningococcal serogroups A, C, W and Y, pneumococcal, and hepatitis C.

In addition, the emergence of new drugs for rare diseases, including for SMA, has seen discounting emerge as an issue. With new and innovative treatments expected to increasingly arrive in the Australian market, discounting is expected to continue to be an issue.

Table 4 Other PBAC submissions where discounting has been raised as an issue

PBAC Submission	Issue Description	PBAC Outcome
Infectious Diseases		
HPV: Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) recombinant vaccine, injection, 0.5 mL, Gardasil for 12 year old girls and for a catch-up program for all girls and women 13-26 years (November 2006)	Sponsor expressed concern regarding PBAC discount rate practice	Rejected
Zoster virus vaccine (Oka/Merk), injection, 0.65 mL, Zostavax for the vaccination of an ongoing cohort of 60 year-old individuals and for a catch-up cohort of all individuals 61 years and older (November 2007)	Sponsor expressed concern about the application of a 5% discount rate disadvantaging vaccines relative to other pharmaceuticals	Rejected
Meningococcal ACWY: meningococcal polysaccharide conjugate vaccine serogroups A, C, W-135 and Y Pre-	CUA results sensitive to the discount rate	Recommended

PBAC Submission	Issue Description	PBAC Outcome
filled syringe, 0.5mL, Nimenrix ® in adolescents (March/August 2018)		
Pneumococcal: Pneumococcal conjugate vaccine (13-valent); 0.5 mL injection; Prevenar 13® for adults (March/July 2015)	CUA results sensitive to the discount rate	Recommended on a cost-minimisation basis (July 2015)
Hepatitis C: Sofosbuvir, 400mg tablet, Sovaldi®, for chronic hepatitis C (July 2014)	CUA results sensitive to the discount rate	Rejected. Subsequently recommended following March 2015 for a smaller patient population than originally requested.
Rare diseases		
Solution for injection 12 mg in 5 mL, Spinraza®, for the pre-symptomatic initiation of treatment of patients with SMA (July 2019/November 2019)	CUA results sensitive to the discount rate	Rejected
Onasemnogene abeparvovec: Solution for injection, customised based on patient weight; Zolgensma® for treatment of SMA Type I in patients under 2 years of age (November 2020/May 2021)	The PBAC considered a cost-minimisation analysis included in any revised proposal should discount costs as per the PBAC guidelines	Deferred

Source: PBS (www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd)

Abbreviations: 'CUA', cost utility analysis; 'HPV', human papillomavirus; 'PBAC', Pharmaceutical Benefits Advisory Committee; 'QALY', quality-adjusted life years; 'SMA', spinal muscular atrophy.

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Appendix

Summary: HTA agencies and other bodies identified

Country	Agency
Australia	Pharmaceutical Benefits Advisory Committee (PBAC)
Austria	Austrian Institute for Health Technology Assessment AIHTA)
Belgium	Health Care Knowledge Centre (KCE)
Brazil	Ministerio da Saude (Ministry of Health)
Canada	Canadian Agency for Drugs and Technologies in Health (CADTH)
China	China Society for Pharmacoeconomics and Outcomes Research ISPOR Beijing Chapter
Colombia	Instituto de Evaluación Tecnológica en Salud (IETS) (Institute of Health Technology Assessment)
Croatia	Agency for Quality and Accreditation in Health Care (AAZ)
Denmark	Medicinrådet (Danish Medicines Agency)
England/Wales	National Institute for Health and Clinical Excellence (NICE)
Estonia	The Centre for Health Technology Assessment, University of Tartu
Finland	Pharmaceuticals Pricing Board, Ministry of Social Affairs and Health
France	Haute Autorité de santé (HAS)
Germany	Institute for Quality and Efficiency in Health Care (IQWiG)
Hungary	Division for Health Technology Assessment at the National Institute of Pharmacy and Nutrition of Hungary (OGYÉI)
Indonesia	Indonesian Health Technology Assessment Committee (InaHTAC), Ministry of Health
Ireland	Health Information and Quality Authority (HIQA)
Israel	Ministry of Health
Italy	Agenza Italiana del Farmaco (AIFA) (Italian Drug Agency)
Japan	Central Social Insurance Medical Council ('Chuikyo')
Latvia	State Agency of Medicines
Lithuania	State Health Care Accreditation Agency (Ministry of Health)
Malaysia	Ministry of Health
Mexico	Centro Nacional de Excelencia Tecnologica en Salud (National Center for Health Technology Excellence (CENETEC))
Netherlands	Zorginstituut Nederland (ZIN) (National Health Care Institute)
New Zealand	Pharmaceutical Management Agency (PHARMAC)
Norway	Statens legemiddelverk (Norweigan Medicines Agency (NOMA))
Philippines	Health Technology Assessment Unit Department of Health - Philippines
Poland	Agencja Oceny Technologii Medycznych i Taryfikacji, (AOTMiT) (Agency for Health Technology Assessment
Portugal	INFARMED
Russia	Center for Healthcare Quality Assessment and Control, Ministry of Health
Scotland	Scottish Medicines Consortium (SMC)
Singapore	Agency for Care Effectiveness (ACE)
Slovak Republic	Ministry of Health
South Africa	Department of Health
South Korea	Health Insurance Review and Assessment Service (HIRA)
Spain (CATSALUT)	Catalan Health Service
Spain (OSTEBA)	Basque Office for Health Technology Assessment
Sweden	Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU)
Switzerland	Federal Office of Public Health (FOPH)
Taiwan	Centre for Drug Evaluation Taiwan
Thailand	Health Intervention and Technology Assessment Program (HITAP): Ministry of Public Health