

## 11.03 Review of base-case discount rate in the PBAC Guidelines

### 1. Purpose of item

- 1.1 To seek the PBAC’s advice on whether the discount rate at 3A.1 of the PBAC Guidelines (Version 5.0, 2016) aligns with international best practice.
- 1.2 To ask the PBAC to incorporate any recommended change to the base-case discount rate into its Guidelines by July 2022.

### 2. Background

#### *Discounting*

- 2.1 Discounting in economic evaluations is undertaken to reflect social time preferences for costs and benefits now relative to the future. The theoretical basis for discounting is understood to be either:
  - social opportunity cost, which is the rate of return foregone when public expenditure diverts resources from the private capital market, or
  - social time preference, on the concept of “positive time preference,” meaning that society prefers to benefit sooner rather than later.
- 2.2 The resulting ‘social time preference rate’ (STPR),  $r$ , may be expressed as  $r = \rho + \mu g$ , where
  - $r$  is the social time preference rate
  - $\rho = (\delta + L)$  is the so-called ‘pure’ time preference rate ( $\delta$ ), plus the likelihood that expected benefits will not accrue due to catastrophe (e.g., natural disaster, war), changing preference, technological obsolescence, or systemic factors linking the real value of costs and benefits to income ( $L$ )
  - $\mu$  is a factor representing the decreasing marginal utility of health consumption relative to per-capita income
  - $g$  is the expected annualised growth rate in per-capita income (i.e., GDP per capita).

2.3 The PBAC noted that the discounting requirements for submissions to the PBAC and the Medical Services Advisory Committee (MSAC) set out in section 3A.1.5 of the current PBAC Guidelines (Version 5.0, 2016) and section TG17.4 of the current MSAC Guidelines (Version 1.0, 2021) state:

The values of costs and benefits incurred or received in the future are generally discounted to reflect the present value. Discount both costs and outcomes at a uniform, annual (compounding) rate of 5% per year for all costs and health outcomes that occur or extend beyond one year in the base-case. Present sensitivity analyses using fixed discount rates of 3.5%, and 0% per year (applied to both costs and outcomes). 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 advice on discount rate**

2.4 Clause 5.2 of the Strategic Agreement between Medicines Australia and the Commonwealth from 1 July 2022 to 30 June 2027 (Strategic Agreement) states:

- Upon entry into this Agreement, the Minister will seek early advice from the PBAC as to whether the base-case discount rate outlined in section 3A.1 of the PBAC Guidelines aligns with international best practice; and
- when seeking such advice, ask the PBAC to incorporate any recommended change to the base-case discount rate into its Guidelines by July 2022; and
- Medicines Australia will make a submission to the PBAC in this regard.

2.5 Medicines Australia lodged a submission on 17 January 2022 to the PBAC, arguing that the discount rate used in the current PBAC Guidelines should be reduced from the current 5% to 1.5%, to match what it considered was ‘best practice’ in HTA countries such as Canada and England.

2.6 In April 2022, an independent evaluator, the Centre for Health Economics Research and Evaluation (CHERE), was commissioned to prepare a report on discounting in economic evaluations (the Report). The Report reviewed literature on the theoretical rationale for discounting, international discounting practice, different methods of determining discount rates, current and historical practices of discounting in Australia and other countries, and discussion of the submission from Medicines Australia.

**Committee-In-Confidence information**

2.7



**End Committee-In-Confidence information**

*For more detail on PBAC’s view, see section 6 PBAC outcome.*

### 3. Stakeholder consultation

3.1 A two-phased consultation approach was used to inform the PBAC consideration.

#### ***Phase 1 stakeholder feedback***

3.2 Phase 1 consultation was open from 5 April 2022 to 29 April 2022, and stakeholders were invited to answer the following questions:

- How does the discounting method in section 3A.1 of the PBAC Guidelines compare with discounting methods used in economic evaluations that support other public funding decisions in Australia and in comparable overseas jurisdictions?
- Does the base-case discount rate outlined in section 3A.1 of the PBAC Guidelines need to be changed? If so, what should it be and why?

3.3 Twenty-one stakeholder submissions to the Phase 1 consultation were received, including 17 respondents from pharmaceutical companies, one from a consulting company, one from a university, one from a clinical group and one from Medicines Australia. Specifically, the following stakeholders have provided feedback in the Phase 1 consultation:

- AbbVie Pty Ltd
- Amgen Australia Pty Limited
- Biogen Australia Pty Ltd
- BioMarin Pharmaceutical Australia Pty Ltd
- Bristol Myers Squibb Australia Pty Ltd
- CSL Behring
- GlaxoSmithKline Australia Pty Ltd
- Janssen-Cilag Pty Ltd
- Macquarie University
- Medicines Australia
- Novo Nordisk Pharmaceuticals Pty Ltd
- Pfizer Australia Pty Ltd
- Private
- Private
- Private
- Private
- Rare Voices Australia
- Sanofi-aventis Australia Pty Ltd

- Shawview Consulting
- Vertex Pharmaceuticals (Australia) Pty Ltd
- Vifor Pharma Pty Ltd

3.4 A summary of thematic issues raised in stakeholder submissions in the Phase 1 consultation was provided in the Report and is reproduced below.

**Table 1: Summary of thematic issues raised in stakeholder submissions in the Phase 1 Consultation**

Issue raised by stakeholder	Report comments
The PBAC's base-case discount rate should be reduced to 1.5% for costs and benefits.	This position, put forward by Medicines Australia on behalf of the innovator medicines industry, was explicitly supported by 20 of 21 respondents from whom submissions were received. All respondents supported a reduction in the discount rate.
Discounting disadvantages therapies with relatively high up-front costs and long-term benefits, including emerging biological therapies, vaccines and preventive therapies, life-saving therapies, and therapies for childhood diseases.	The choice of discount rate may have a substantial impact on the estimated cost-effectiveness of a health intervention, especially when the benefits of an intervention accrue over a long period of time.
The PBAC's base-case discount rate of 5% is higher than the rates used in most similarly economically developed countries with established HTA practice. Over the past three decades, international HTA discount rates have trended downward.	This observation is supported by the available data. The PBAC's base-case discount rate is, however, lower than the discount rate of 7% commonly used in the evaluation of public investment in non-HTA settings in Australia.
Discounting at the PBAC's base-case rate of 5% may have contributed to delays in access to therapies in Australia.	See the Report for elaboration.
Discounting at the PBAC's base-case rate of 5% may disincentivise development of emerging biological therapies and medicines for rare-diseases.	See the Report for elaboration.
The PBAC should consider the use of differential discounting.	There is theoretical support for differential discounting in the literature, though it is rarely used in practice internationally.
The PBAC should consider the use of time-variable discounting.	There is evidence of hyperbolic (i.e., time-variable) discounting in the literature, though it is rarely used in practice internationally.
The PBAC should consider the use of a non-base-case rate of 1.5% for curative therapies.	NICE (UK) recommends use of a non-reference case discount rate of 1.5% for curative therapies.
The PBAC's base-case rate should be benchmarked against rates used in health economic analysis in similarly economically developed countries with established HTA practices	International comparison may provide an appropriate basis for understanding social time preference and the choice of discount rate level in comparable contexts.
There is support in the research literature and policy sphere for reducing the discount rate in use by most Australian government agencies since the 1980s from 7% to 3.5%-4%. Cited examples note that the risk-free rate has fallen considerably since the 7% rate was established.	Reference to the 'risk-free' interest rate implies that the PBAC discount rate is (or should be) linked to Government's cost of borrowing, i.e., a social opportunity cost model.
The discount rate used in health economic evaluation should not be benchmarked against discount rates used by other Government agencies to assess public infrastructure expenditure; Discounting in HTA should not be used to account for 'project-risk.'	There is evidence in the research literature that individuals' time preference for health consumption may not be reflected in governments' cost of borrowing. The literature suggests that the discount rate is generally not an appropriate mechanism to account for project-specific risk.

Issue raised by stakeholder	Report comments
The utility associated with additional years of life does not decline as real incomes rise.	The literature suggests that the marginal utility of health consumption decreases with income due to individuals' time preference but may also increase as social expectations of health change. The net effect of these counterinfluences is not clear.
The PBAC's base-rate discount rate of 5% is at odds with Government health policy commitments to invest in preventive therapies.	The literature suggests that adjusting the discount rate may not be an economically efficient means to impact equity and other health policy objectives, and that Government's use of the tax and transfer systems may be more suited to these ends.
Changing the PBAC's base-case discount rate is likely to have significant knock-on policy and distributional impacts, including in decision-making by the Medical Services Advisory Committee (MSAC).	See the Report for elaboration.
A reduction in the discount rate implies a lower opportunity cost of displaced healthcare interventions and should entail a corresponding reduction in the PBAC's implicit cost-effectiveness threshold.	If the discount rate and effective willingness-to-pay threshold are reduced, then the proportion of treatments yielding benefits further into the future is likely to increase, displacing healthcare interventions whose benefits accrue over shorter time horizons.
The PBAC and MSAC are interdependent and their respective discount rates should be aligned.	Respondent noted that in some cases, nomination of the assessment body (PBAC vs MSAC) is solely a function of the funding regime through which a therapy is proposed to be made available.
Whilst alternative discount rates may be presented in sensitivity analyses, the PBAC does not apparently or sufficiently take alternative rates into account in cost-effectiveness determinations.	Uncertainty of future cost and health outcome values should be addressed through direct appraisal of these flows and via sensitivity analysis.
The PBAC's base-case discount rate of 5% has contributed to an impression among international pharmaceutical industry stakeholders that Australia is "a challenging market with uncertain approval processes," and may lead to feelings of despair among patients for whom relevant medicines are only available abroad.	The literature suggests that adjusting the discount rate may not be an economically efficient means to impact equity and other health policy objectives, and that Government's use of the tax and transfer systems may be more suited to these ends
There may be a misalignment of the PBAC's risk preferences with respect to societal risk preferences, reflected in the PBAC's base-case discount rate and 'conservative' ICER threshold.	Respondent bases this on the following: the Department of the Prime Minister and Cabinet's estimated value of a statistical life year is AU \$217k; assuming a utility of 0.75 would imply a willingness-to-pay of approximately AU \$160k per QALY, relative to the respondent's assumed PBAC threshold of approximately AU \$80k per QALY. It should be noted that the PBAC does not have an explicit willingness-to-pay threshold.

### **Phase 2 stakeholder feedback**

- 3.5 Phase 2 consultation was open from 25 May 2022 to 1 June 2022, and stakeholders were invited to comment on the Report.
- 3.6 The Department received 24 stakeholder submissions to the Phase 2 consultation, including 16 respondents from pharmaceutical companies, 4 from universities, 2 from clinical groups, one from an individual respondent, and one from Medicines Australia. Specifically, the following stakeholders have provided feedback in the Phase 2 consultation:
- A.Menarini Australia Pty Ltd
  - AbbVie Pty Ltd
  - Alexion Pharmaceuticals Australasia Pty Ltd
  - Amgen Australia Pty Ltd
  - Bristol Myers Squibb Australia Pty Ltd
  - GlaxoSmithKline Australia Pty Ltd
  - Griffith University
  - Leukaemia Foundation
  - Lucid Health Consulting
  - Macquarie University
  - Medicines Australia
  - Melbourne University
  - Merck Sharp & Dohme (Australia) Pty Ltd
  - Novo Nordisk Pharmaceuticals Pty Ltd
  - Pfizer Australia Pty Ltd
  - Private
  - Private
  - Private
  - Private
  - Private
  - Rare Voices Australia
  - Roche Products Pty Ltd
  - Sanofi-aventis Australia Pty Ltd
  - Vifor Pharma Pty Ltd.
- 3.7 A summary of thematic issues raised in stakeholder submissions in the Phase 2 consultation is summarised below.

**Table 2: Summary of thematic issues raised in stakeholder submissions in the Phase 2 Consultation**

Issue raised by Respondent	Detail
The PBAC's base-case discount rate should be reduced to 1.5% for costs and benefits.	This position, put forward by Medicines Australia on behalf of the innovator medicines industry, was explicitly supported by a majority of respondents from whom submissions were received in the Phase 2 consultation.
The PBAC's base-case discount rate should be calculated by using the 30-year Government bond rate minus the most recent estimate of health inflation (currently 1.325%).	Respondent concludes that the PBAC takes a 'social decision making' perspective and that, in practice, the PBS budget is constrained. Respondent suggests that the appropriate discount rate is the STPR for health costs (assumed to be equal to the real rate of interest on Government debt minus real growth in the total health price index), plus the rate of growth in the cost-effectiveness threshold (assumed to be nil).
The PBAC's base-case discount rate should be zero for health outcomes.	Respondent maintains that discounting should only apply to non-variable costs and that health outcomes should not be discounted.
The PBAC's base-case discount rate should be increased to 7% for costs and health outcomes.	Respondent maintains that the discount rate is a critical factor constraining rising healthcare costs, which should not be placed on the community.
PBAC Guidelines should be amended to allow for the use of differential and time-variable rates.	Respondent advocates use of differential and time-variable discounting for interventions with very high upfront costs and long-term realisation of health benefits.
It is not problematic for the base-case discount rate to vary over time.	Respondent points out that a wide variety of inputs in economic evaluations vary over time and maintains that there is no reason for the PBAC to compare the cost-effectiveness of different treatments over time.
The PBAC should allow for greater flexibility in HTA to allow for more competitive valuation of certain treatment classes.	Respondent advocates a less rigid application of a single rate in order not to disadvantage vaccines and preventive/curative therapies, as the discount rate cannot capture myriad therapies' unique uncertainty profiles.
Discounting guidelines may be made more robust.	Respondent concurs with findings of the report that discounting in health economic evaluation may be made more robust by specifying a theoretical rationale for discounting costs and health benefits; a methodology for estimating the discount rate based on underlying parameters; and the process and timing of periodic reviews.
Any potential increase in health investment required as a result of reducing the base-case discount rate should be considered in the context of an uncapped PBS.	Respondent maintains that the PBS has actualised significant savings across multiple agreements and reform processes across the last decade, and that these savings warrant greater spending for new treatments.
The relative value of medicines cannot be appropriately determined if the inputs and methods used to determine that value, such as discount rates, are inappropriately constrained based on a fixed budget, zero-sum perspective.	Respondent considers concerns about potential cost increases and displacement effects to be subordinate to productivity and efficiency improvements purported to result from a lower discount rate (i.e., ostensibly leading to greater availability and use of preventive and curative therapies). Respondent maintains that non-health investment (e.g., infrastructure) is an inappropriate comparator for the evaluation of the social opportunity cost of public investment.
Opportunities to reform to HTA methods, such as the lowering of discount rates, must not be counter-balanced	A downward adjustment to discount rates may need to be accompanied by a commensurate adjustment to implied

Issue raised by Respondent	Detail
by the adoption of more conservative methods in other areas of HTA.	ICER thresholds. A lower discount rate implies lower perceived opportunity cost of public investment. In this context, a higher dollar cost per QALY may be considered more acceptable (i.e., increasing the numerator of the ICER signifies a lowering of the implicit threshold). Implicit ICER thresholds may be appropriately addressed in the forthcoming HTA process review.
The discount rate should not be used as a mechanism to re-prioritise investments in healthcare.	Respondent concurs with the findings of the Review that adjusting the discount rate to address equity would be inconsistent and is not feasible.
Whilst other mechanisms exist to allow public subsidy of medicines deemed desirable but rejected by the PBAC on the basis of cost-effectiveness, the use of such mechanisms is rare and only applied in very specific circumstances.	Respondent maintains that the appropriate (and effectively only) pathway to ensure patients equitable access to medicines and vaccines is via a positive recommendation by the PBAC.
The relative cost-effectiveness of new health technologies may be more appropriately assessed by restricting comparison to a subset of similar comparators.	Respondent maintains that a single discount rate that facilitates evidence-based decision-making and enables comparisons to other healthcare interventions with different cost and benefit horizons is unlikely to be achieved. Respondent advocates an explicit and transparent approach with respect to the like-for-like assessment of value, whereby 'envelopes' of ICER acceptability are established in accordance with broadly defined intervention categories based on initial cost, ongoing cost, benefit horizon and benefit magnitude.
While the PBAC does not have an explicit ICER threshold, it is common understanding within the industry and among experts that informal ICER thresholds exist and have remained relatively stable over time and across various changes within the PBAC.	Respondent maintains that all assumptions and parameters of the economic analysis, including the discount rate and resultant ICER, influence PBAC determinations.
Conclusions should not be based solely upon the financial implications to the health system.	Respondent considers that insufficient attention has been paid in the Report to patient access and health outcomes.
Changing the discount rate would need to be accompanied by a broader consideration of the potential economic impacts, including displacement effects on the health budget. It is unclear how broader economic and societal values are considered alongside technical/medical ones, and whether or not those values impact purchasing decisions.	Respondent maintains that HTA in Australia, including the negotiation process between sponsor and Government following a positive recommendation, should be more transparent and include more substantive consideration of patient perspectives.
Generics should be exempt from discounting.	Respondent maintains that generics are available in a highly competitive market that ensures low prices.
Current discounting practices discourage PBAC submissions for generic products and reduce competition in Australia.	Respondent maintains that the 5% discount rate contributes to an impression that Australia is a challenging market with uncertain approval processes and may discourage innovation of generic dosage forms and lead to higher prices for generics.
Current discounting practices discourage new drug innovation.	Respondent claims that lowering the discount rate will signal Australia's attractiveness as a 'first-launch' market for innovative therapies and encourage local participation in clinical trials.
Current discounting practices also have knock-on policy impacts.	Whilst changing the discount rate is likely to have knock-on policy impacts, so do current practices. A full consideration

Issue raised by Respondent	Detail
	of these impacts may be appropriately addressed in the forthcoming HTA review.
Case-study	Respondent provided details of a submission that was considered at the July 2022 meeting. Submission demonstrated benefits over a longer time horizon and was demonstrably sensitive to the discount rate.
The document fails to address real vs nominal rates within the STPR approach	Authors of the Review may clarify that in accordance with international convention and economic theory, discount rates as described in the report pertain to real rates, that is, they do not account for inflation of cost and benefit values over time, which are reported in constant dollars.
The report cites an inappropriate proxy for the risk-free market interest rate.	Respondent maintains that the 30-year Government bond is the appropriate proxy for the risk-free rate of interest.
PBAC should investigate role of discounting as it relates to project uncertainty.	Respondent advocates exploration of the extent to which discount rates reflect not only time-preference, but also risk-preference with respect to future predicted outcomes, including potentially more appropriate methods for explicitly dealing with uncertainty of future events.
The Review has apparently not consulted with international experts.	Respondent recommends soliciting the input of Prof Mark Sculpher, Prof Karl Claxton and Prof Mike Drummond (University of York), Prof Milton C. Weinstein (Harvard University) and Prof Paul Hansen (University of Otago).
It is important to ensure impartiality in reports prepared for the Government on matters of the appropriateness of HTA methodologies and processes used by PBAC.	While recognising that CHERE is one of Australia’s leading expert HTA evaluation groups, the Respondent notes that there may be a real or perceived conflict of interest in the work of the report by virtue of it being prepared by PBAC evaluators contracted by the Department of Health.
The conclusions drawn from the Report are misaligned with the key findings of the report body.	Based on the evidence presented in the report, respondent deems it appropriate to explicitly recommend lowering the discount rate.

For more detail on PBAC’s view, see section 6 PBAC outcome.

## 4. Key findings

### ***Australian discount rate for HTA compared to other similar countries***

- 4.1 The Report presented historical data on discount rates used for HTA in 19 economically similar countries with established HTA practices, including Australia. The majority of countries applied the same discount rate for costs and benefits. Among the 19 countries included in the Report, current discount rates for costs and benefits ranged from 1.5% to 5%, with 3% and 5% being the most common (5 of 19 and 5 of 19 (26%), respectively).
- 4.2 The PBAC’s base-case discount rate of 5% for health benefits and costs is higher than many other countries with comparable levels of economic development and similarly advanced HTA systems, including: France (4%), Ireland (4%), New Zealand (3.5%), Scotland (3.5%), UK (3.5%), Germany (3%), Singapore (3%), Sweden (3%), US (3%), Japan (2%), Belgium (1.5% benefits, 3% costs), Canada (1.5%), and The Netherlands (1.5% benefits, 4% costs). Among economically developed countries with established

HTA practices, only South Korea and Australia currently use a discount rate of 5% for costs and health outcomes.

### ***Discounting in non-HTA settings in Australia***

- 4.3 Since 1980, a standard discount rate of 7% had been used in most Australian governmental guidelines for cost-benefit analyses and other economic appraisals.
- 4.4 In 2018, Applied Economics, the Grattan Institute and the House of Representatives Standing Committee on Infrastructure variously recommended discount rates ranging from 3.5% to 6.5% in the context of built infrastructure, primarily on the basis that discounting reflected the social opportunity cost of investment and that real borrowing rates are a key component of the discount rate.

### ***Review of literature, rationales for discounting and arguments for change***

- 4.5 The Report noted that discounting is a tool to improve economic efficiency in decision-making. The Report reasoned that no matter how the discount rate is derived, it cannot say what a society's preferred outcomes and investment priorities should be from an ethical perspective. The Report found that, as an approach to evaluating the differential timing of resource use and outcomes, discounting is well-established in the academic literature and is a common practice internationally.
- 4.6 The Report found that the PBAC's base-case discount rate of 5% was lower than the discount rate used in the appraisal of infrastructure and other forms of public investment in Australia. The Report noted that lowering the HTA discount rate without a commensurate decrease in the rate used elsewhere would exacerbate this difference.
- 4.7 The Report found no academic, professional, or international consensus concerning the theoretically or practically preferred choice of the discount rate in health economic evaluation, nor whether differential or time-variable rates should be applied.
- 4.8 The Report noted that all else being equal, discounting future costs and health benefits has a higher impact on the estimated cost-effectiveness of therapies with high up-front costs and long-term realisation of health benefits (such as preventative interventions and interventions for children). The Report noted statements from stakeholders that this is a disadvantage to these therapies and may result in inequities. However, the Report found that adjusting the discount rate is not generally considered an appropriate mechanism to promote distributional equity or particular health policy priorities. Further, the Report found that explicit use of the discount rate to address health policy priorities was not common international practice.
- 4.9 The Report also noted that since Australia does not have a fixed incremental cost-effectiveness (ICER) threshold, it was not possible to determine the extent to which use of the 5% discount rate impacted previous PBAC's decisions. The Report found that while the discount rate did impact the estimated ICER in those submissions, other contributing factors, including the strength of evidence presented, clinical effectiveness for the requested indication and price, among others, were taken into consideration by the PBAC in its recommendations.

- 4.10 The Report noted that without adjustment to other parameters in an economic evaluation, changing the PBAC’s base-case discount rate would likely have significant financial implications and associated knock-on effects throughout the health system.
- 4.11 The Report concluded that while adjusting the discount rate may not be an economically efficient method to support particular health policy preferences or priorities, there may be a case to support a reduction, in line with economic theory and international practice.
- 4.12 The Report considered that any change to the PBAC’s base-case discount rate, including the application of differential or time-variable rates, should be informed by an empirical analysis of the estimated cost to Government, price impacts, cost-effectiveness thresholds, likely approval and displacement of therapies. The Report also noted that a range of knock-on policy impacts are likely to result across the health sector, including MSAC decision-making, and other areas of public investment.
- 4.13 The Report reasoned that within the health care portfolio, a change in discount rate should also be weighed against the purpose of discounting, which is to enable the comparison of the costs and outcomes of health interventions over time. Moreover, since a lower discount rate may increase the chance an intervention will be deemed cost-effective at a given requested price, and hence more amenable to public subsidy, the case for change must also consider the implications for total investment in healthcare via the PBS relative to other sectors of public investment.

**Committee-In-Confidence information**

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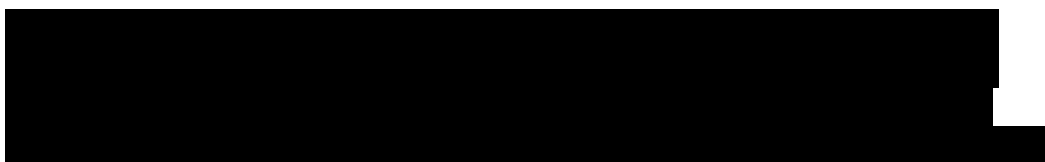
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**End Committee-In-Confidence information**

4.34 Reducing the discount rate will reduce ICERs in most, if not all, submissions.

*For more detail on PBAC’s view, see section 6 PBAC outcome.*

**5. PBAC consideration of the request**

5.1 The PBAC acknowledged and thanked stakeholders who provided input and made submissions regarding the base-case discount rate specified in the PBAC Guidelines.

5.2 The PBAC provided its advice after considering the following:

- Medicines Australia’s submission on the discount rate used by the PBAC
- the Report prepared by CHERE
- stakeholder comments received via the two consultation phases
- advice from the PBAC Economic Sub-Committee (ESC)
- advice from the MSAC and its Evaluation sub-committee
- advice from the Australian Technical Advisory Group on Immunisation (ATAGI)
- Pre-PBAC Response from Medicines Australia.

***Consistency with International HTA and Australian non-HTA settings***

**International HTA settings**

5.3 The PBAC noted that the ESC agreed with the Report that there is no academic, professional, or international consensus on what is a ‘best practice’ discount rate for the purposes of an economic evaluation in the HTA setting.

5.4 In its pre-PBAC response, Medicines Australia disagreed with this conclusion and claimed that the PBAC’s base-case discount rate is not aligned with international best practice because it is higher than discount rates used for HTA in several countries with similarly advanced economies, and that several countries have reduced their discount rates for HTA over the past 30 years.

- 5.5 The PBAC noted that other countries with comparable levels of economic development used discount rates ranging from 1.5% to 5% in the HTA setting, and that among the 19 countries included in the Report, current discount rates for costs and benefits of 3% and 5% were the most common (5 of 19 and 5 of 19 (26%), respectively). While at the upper end of discount rates used in comparable HTA settings, the PBAC did not consider that use of 5% for HTA made Australia an outlier compared to other countries. The PBAC also noted that, in contrast, only Canada had adopted a standard 1.5% discount rate for HTA (the rate proposed by Medicines Australia) and that this was the lowest rate used among countries surveyed in both the Report and in Medicines Australia's submission.
- 5.6 The PBAC acknowledged that most countries surveyed in the Report had reduced their discount rates in the HTA setting over the past 30 years and that this trend has been attributed to the progressive reduction in the cost of borrowing. The PBAC acknowledged that over the same period its discount rate had not changed. The PBAC accepted that there was some support in the research and policy sphere for reducing the discount rates used across government agencies. The PBAC noted that the proxy for the risk-free rate is generally understood to be the long-term bond rate, and that the current yield for Australian 10-year Government bonds is 3.8% (as of June 2022) and climbing (low point 0.8% at October 2020, RBA Statistical Tables F2.1). The PBAC agreed with the ESC that if the cost of borrowing were the sole justification for reducing the discount rate, it could be argued that it should move in tandem with the risk-free rate. The PBAC also agreed with the ESC that this would be impractical and risk inconsistency across decision making. Further, the PBAC agreed with the ESC that the risk-free rate may not always be the sole justification for discounting, for example, if there are additional risks of further costs, or benefits that will not eventuate, not otherwise accounted for in the economic model. Accordingly, the PBAC did not consider that discount rate should move in tandem with the bond rate.
- 5.7 The PBAC agreed with the ESC that variation between countries in other economic evaluation methods used in the HTA setting limited the relevance of international comparison of discount rates alone. The PBAC noted that other methods used in international HTA settings significantly impact the influence discounting has on decision making. The PBAC noted, for example, that discount rates have a much greater influence in HTA settings that use fixed ICER thresholds. The PBAC agreed with the ESC that it was not reasonable to directly compare the discount rate used by the PBAC with that used, for example, by the National Institute for Health and Care Excellence (NICE) in the United Kingdom (which uses a fixed ICER threshold of £20,000 per QALY gained, or £100,000 per QALY gained for highly specialised technologies). The PBAC noted that, unlike NICE, it has more flexibility in how it interprets ICERs for each application and that it is therefore possible to make recommendations based on a range of factors including the impact discounting has on ICERs.
- 5.8 The PBAC therefore agreed with the ESC that differences between the PBAC's base-case discount rate and those used by some HTA bodies in other countries alone did not create a strong rationale for change.

### Australian non-HTA settings

- 5.9 The PBAC noted the ESC's observation that the PBAC's base-case discount rate (5%) is already lower than the discount rate of 7% commonly used in the economic evaluation of public investments in Australian non-HTA settings at the state and federal government levels. However, it did note a recent example, the Treasury's Fiscal Impact of New Australians model, which applied a 5% nominal discount rate. The ESC noted that health interventions with high upfront costs and long-term benefits that would be most impacted by a reduction in the discount rate, such as cell and gene therapies are often jointly funded by Commonwealth and State and Territory Governments under the National Health Reform Agreement. The ESC noted that if the PBAC/MSAC discount rate were reduced further, it would exacerbate the difference with discount rates used by states and territories, making the PBAC/MSAC derived ICERs less relevant to decision-making at the state and territory level. The ESC therefore considered that reduction of the discount rate is unlikely to be considered reasonable if it is necessary to align with rates used by Governments for public investments across Australia.
- 5.10 In its pre-PBAC response, Medicines Australia suggested that the PBAC could decide to reduce the discount rate for evaluations of medicines for the PBS without having to align with rates used by different areas of government across Australia noting that there are differences in how economic evaluations are conducted between different government jurisdictions in Australia.
- 5.11 The PBAC considered that this argument was consistent with its view that variation in other economic evaluation methods across HTA bodies in other countries limited the relevance of international comparison of discount rates. The PBAC nevertheless considered that change to its discount rate would impact opportunity costs of displaced interventions that would otherwise be funded by governments in Australia and that the Government would need to consider the implications of moving away from discount rates used for other (non-health) interventions.

### ***Impacts of varying the base-case discount rate***

- 5.12 The PBAC noted the ESC's advice that, all else held constant, lowering the discount rate would reduce ICERs for most, if not all, new interventions, with the largest impact seen for interventions that have the largest differences in front-ended costs and ongoing long-term benefits (such as preventative interventions or some interventions for children). The ESC advised that models with a shorter time horizon, or no time difference between accumulation of costs and benefits, are less sensitive to discounting.
- 5.13 In its pre-PBAC response, Medicines Australia stated that this implied that the ICERs for a range of medicines, vaccines and other medical therapies have been higher than they should be.
- 5.14 The PBAC did not accept this inference. The PBAC considered that the varying sensitivity of ICERs between different health interventions is consistent with the overall purpose of discounting in economic evaluations – to reflect social time preferences for costs and benefits now, relative to the future. The PBAC considered

that a consequence of discounting is that current costs and benefits are valued more highly than future costs and benefits.

- 5.15 The PBAC noted that reducing the discount rate would increase the proportionate value of long-term benefits compared to short-term benefits. The PBAC noted that longer term benefits are inherently more uncertain than short term benefits. The PBAC agreed with the ESC that a reduced discount rate would result in ICERs that would be more sensitive to assumptions about long term benefits, and reduced confidence in benefits extrapolated beyond observed data. The PBAC accepted advice from the ESC that a reduction to the discount rate would result in the PBAC inherently accepting greater economic uncertainty if it did not also change how it considered uncertainty and interpreted ICERs.
- 5.16 The PBAC noted the ESC's view that a reduction to the discount rate may be interpreted as an indication that willingness-to-pay has increased, with flow on effects to the prices requested by sponsors. The PBAC agreed that adjusting a single component of HTA without considering unintended consequences, or how participants in the HTA process might respond to that change, is problematic. The PBAC also agreed with the ESC that if higher prices were requested, this would reduce overall cost-effectiveness of new interventions submitted to the PBAC.
- 5.17 The PBAC noted that reducing the discount rate, and assuming the ICER calculated using the 5% discount remained acceptable to the PBAC under a lower discount rate, could have potentially very large impacts on prices and costs of new interventions with front ended costs and ongoing long-term benefits recommended by the PBAC.
- 5.18 The PBAC noted that while changing the discount rate in an economic model may make certain interventions appear more cost-effective, it would not change the actual costs or effectiveness of new interventions. The PBAC noted advice from the ESC that a lower ICER resulting only from application of a lower discount rate should not be taken to mean an intervention is more cost-effective. The PBAC noted the ESC did not accept claims that reducing the discount rate would automatically increase the likelihood that an intervention would be considered cost-effective by the PBAC, or that certain interventions (such as preventative therapies) would be more likely to be accepted as cost-effective.
- 5.19 In its pre-PBAC response, Medicines Australia did not accept this advice and claimed that the discount rate can have a large impact on what the resulting ICER is, and what is deemed cost-effective.
- 5.20 The PBAC accepted that the ICERs for some interventions are more sensitive to the impact of the discount rate on longer term costs and benefits. The extent of impact is related to the pattern of differential timing of the accrual of costs and health outcomes, where costs occur early, and health outcomes accrue over a longer time horizon. The PBAC noted that therefore there may be a greater impact of discount rate changes on the ICERs of certain types of interventions, including some vaccines, other preventive treatments, or gene therapies. However, the PBAC also noted that it considers several model outputs (including ICERs calculated using different discount rates) when assessing cost-effectiveness and has accepted a wide range of ICERs in its recommendations for new PBS listings.

- 5.21 The PBAC noted the ESC’s advice that if the PBAC did not change its interpretation of ICERs in the context of a lower discount rate, this may result in acceptance of higher, less cost-effective prices for some proposed listings. The PBAC agreed with the ESC’s view that reducing the discount rate without changing ICER interpretation could result in additional expenditure that could displace care and services from other areas funded by Governments (opportunity cost). The PBAC therefore considered that a reduction to the discount rate would necessitate change to the interpretation of ICERs for interventions sensitive to a change to the discount rate.
- 5.22 In its pre-PBAC response, Medicines Australia disagreed with this advice claiming that, because the PBS and the National Immunisation Program (NIP) are not capped schemes, adjustment of the discount rate would not disadvantage new health interventions.
- 5.23 The PBAC noted that the PBS is a demand-driven program with an uncapped appropriation. However, the PBAC did not accept that the absence of a cap meant that the costs of the PBS could increase significantly without impacting other Government investment, including on health. The PBAC noted that the practice of accounting for social time preference (through discounting) in economic evaluations for health and other interventions is in recognition that additional expenditure in one area displaces expenditure in other areas in an overall Government budget.
- 5.24 The PBAC agreed with the ESC that even if a decision were made to change the standard discount rate, it would still need to consider other factors. In particular, approaches for evaluating economic uncertainty arising from value attributed to future and extrapolated benefits should be adjusted to ensure it is fully captured and considered in decision making.
- 5.25 The PBAC noted the ESC’s advice that if the discount rate were changed, a mandatory 5% discount rate sensitivity analysis would need to be conducted for purpose of being explicit about the impact on opportunity cost and overall budget, and to ensure consistency with prior decisions.

***Stakeholder feedback about the PBAC’s discount rate***

- 5.26 The PBAC acknowledged concern from several stakeholders that the base-case discount rate leads to under-valuing of the longer-term benefits of vaccines, preventative therapies, and cures, and disadvantages submissions for these therapies. The PBAC affirmed its strong view that it was important that its Guidelines and methods allowed appropriate attribution of value to longer-term benefits of any therapy including vaccines, preventative therapies, and cures.
- 5.27 The PBAC also acknowledged Medicines Australia’s statement, in its pre-PBAC response, that pharmaceutical companies consider policy settings in each country when deciding whether to bring new medicines.
- 5.28 The PBAC observed that many stakeholders who made submissions had interpreted its Guidelines as not allowing flexibility in discounting methodologies or interpretation of resulting ICERs. The PBAC also noted a recommendation from the ATAGI that the PBAC consider having some flexibility in the discounting rate for vaccine submissions.

- 5.29 The PBAC clarified that it implicitly considers the impact of different discount rates in decision making through the requirement that sponsors provide sensitivity analyses using discount rates of 3.5%, and 0% per year (applied to both costs and outcomes, see paragraph 2.3). The PBAC also emphasised that section 3A.1.5 of its Guidelines contains the following instruction for sponsors: ‘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’.
- 5.30 The PBAC recalled specific examples where a lower discount rate was explicitly used in calculating the ICER for decision making. For example, a submission seeking NIP listing of multicomponent meningococcal group B vaccine (Bexsero®) for active immunisation against invasive meningococcal disease caused by *Neisseria meningitidis* group B strains. The PBAC recalled that Bexsero received a positive recommendation for listing. The PBAC confirmed that it has and will continue to welcome justified alternative discounting methodologies if relevant, consistent section 3A.1.5 of its Guidelines.
- 5.31 While the PBAC was of the view that these examples, among others, demonstrate it is already able to appropriately recognise the value of preventative therapies and cures through existing flexibility (in discounting methods and ICER acceptance), it was concerned that in several submissions to the stakeholder consultation, stakeholders appeared to be unaware that this flexibility existed and/or held the perception that this flexibility was not applied in decision-making.
- 5.32 The PBAC noted that NICE in the United Kingdom uses two different discount rates: a standard 3.5% rate; and a non-standard 1.5% rate used in special circumstances. The NICE discounting method is set out in Section 4.5 of the National Health and Care Excellence health technology evaluations: the manual (published on 31 January 2022 <https://www.nice.org.uk/process/pmg36>), which states:
- 4.5.1 Cost-effectiveness results should reflect the present value of the stream of costs and benefits accruing over the time horizon of the analysis. For the reference case, costs and health effects should be discounted at the same rate of 3.5% per year.
- 4.5.2 Alternative analyses using rates of 1.5% for both costs and health effects may be presented alongside the reference-case analysis, in specific circumstances.
- Non-reference-case discounting*
- 4.5.3 The committee may consider analyses using a non-reference-case discount rate of 1.5% per year for both costs and health effects, if, in the committee's considerations, all of the following criteria are met:
- The technology is for people who would otherwise die or have a very severely impaired life.
  - It is likely to restore them to full or near-full health.
  - The benefits are likely to be sustained over a very long period.
- 4.5.4 When considering analyses using a 1.5% discount rate, the committee must take account of plausible long-term health benefits in its discussions. The committee will need to be confident that there is a highly plausible case for the maintenance of benefits over time when using a 1.5% discount rate.
- 4.5.5 Further, the committee will need to be satisfied that any irrecoverable costs associated with the technology (including, for example, its acquisition costs and any associated service design or delivery costs) have been appropriately captured in the economic model or mitigated through commercial arrangements.

- 5.33 The PBAC considered whether it should define certain circumstances in which a lower non-standard rate should apply; similar to the guidance used by NICE. The PBAC also considered that this might introduce unnecessary complexity, noting that the PBAC already has the flexibility to consider justified alternative discounting methodologies.
- 5.34 The PBAC noted claims from stakeholders including Medicines Australia that the PBAC's 5% base-case discount rate may have contributed to rejections by the PBAC and subsequent delays in access to therapies in Australia. The PBAC did not accept these claims. The PBAC noted that the discount rate is only one factor amongst many that the PBAC considers in its decision making. It further noted that, as it does not work to a fixed ICER threshold, it has flexibility to consider all the relevant factors in its decision making.
- 5.35 The PBAC also noted claims from stakeholders that reducing the discount rate, and by implication accepting higher prices, would allow Australians to gain faster access to medicines. The PBAC did not agree that this was guaranteed, particularly if sponsors interpreted a reduction to the discount rate as an increase in willingness to pay. The PBAC agreed with the ESC that this would reduce the likelihood that submissions would be accepted as cost-effective at the time of initial consideration.
- 5.36 The PBAC noted suggestions from stakeholders that the PBAC consider the use of differential and time-variable discounting. The PBAC noted advice from the ESC that empirical support for discounting of costs and benefits differently (differential discounting) was increasing but that it can create other complexities and is infrequently used. Consistent with most common international practice, the PBAC reaffirmed that equal discount rates for costs and health outcomes should be maintained in the base case.

### ***Broader consideration of the HTA Review***

- 5.37 The PBAC noted the ESC's advice that the discount rate is one of numerous parameters in economic evaluations that impact the calculation of ICERs, which are used in Australia as a measure of the cost-effectiveness of new health interventions.
- 5.38 The PBAC agreed that discounting is a tool used to improve decision-making by estimating the present value of future streams of costs and outcomes and that no matter how the discount rate is derived, it cannot say what a society's preferred outcomes and investment priorities should be from an ethical perspective.
- 5.39 The PBAC noted the ESC's advice that the PBAC may wish to consider whether it is appropriate to change the discount rate in isolation and whether there is an urgent need for change ahead of the broader HTA Review which is to be undertaken in the 2022-23 financial year. The PBAC acknowledged that the Minister had requested, per clause 5.2.1(b) of the Strategic Agreement with Medicines Australia, that it incorporate any recommended change to the base-case discount rate into its Guidelines by July 2022.

*For more detail on PBAC's view, see section 6 PBAC outcome.*

## 6. PBAC Outcome

- 6.1 The PBAC welcomed the request for advice on whether the base-case discount rate at 3A.1 of its guidelines aligns with international best practice. The PBAC agreed that the request provided a useful and important opportunity to assess the role of discounting in informing decision making about subsidy of health interventions. The PBAC considered that the significant stakeholder input, along with the generated reports, enabled a useful and focused discussion on the role and impact of discount rates in HTA processes.
- 6.2 The PBAC agreed that, notwithstanding this early consideration, discounting would also be an important area of discussion with the broader HTA review, alongside other relevant factors in decision making.

### ***Response to request for advice on whether the base-case discount rate at 3A.1 of its guidelines aligns with international best practice***

- 6.3 The PBAC advised that while it is widely accepted that costs and benefits in economic evaluations should be discounted to account for social time preferences for costs and benefits now relative to the future, there is no academic, professional, or international consensus on what is a 'best practice' discount rate for the purposes of an economic evaluation in the HTA setting.
- 6.4 The PBAC advised that its use of a base-case discount rate of 5% remains within similar range as that used by HTA bodies in other countries, and that section 3A.1 of the PBAC Guidelines already requests submissions examine the impact of different discount rates (including 3.5% and 0%) and allows flexibility in the discounting methodology used where justified.
- 6.5 The PBAC advised that adoption of a 1.5% base-case discount rate for all medicines (as recommended by Medicines Australia) would make it an outlier, as 1.5% is the lowest discount rate used in all countries surveyed by both Medicines Australia and CHERE and is only used as a standard discount rate by one other country (Canada).
- 6.6 The PBAC advised that while discounting is an important part of economic evaluations, it is not determinative on its own in PBAC considerations. The PBAC advised that it was already able to appropriately recognise the value of preventative therapies and cures through flexibility to consider many factors in decision making and to allow different discounting methodologies, and through routine consideration of the impact of different discount rates (including 3.5% and 0%).

### ***Advice on whether the base-case discount rate should be changed***

- 6.7 The PBAC did not recommend a stand-alone change to the base-case discount rate in its Guidelines. The PBAC recommended that, given the range of factors, in addition to the discount rate, that contribute to the assessed value of a medicine or vaccine, any policy decision on a general reduction in the standard base-case discount rate for health interventions should be assessed alongside other relevant factors in decision making as part of the broader HTA review.
- 6.8 To provide further clarity and education on discounting, the PBAC agreed that it would review the wording of its Guidelines on discounting to make it clearer to all

stakeholders that it does consider the impact of different discount rates, and to clarify the circumstances under which this is likely to be particularly important.

6.9 The PBAC recommended that should the Government make a broader policy decision to change the standard base-case discount rate for economic evaluations of health interventions after considering cross-portfolio implications and the HTA Review:

- the base-case discount rate should be no lower than 3.5% - 4% per year
- approaches for evaluating economic uncertainty arising from value attributed to future and extrapolated benefits be adjusted to ensure the uncertainty of future costs and benefits is fully captured and considered in decision making
- equal discount rates for costs and health outcomes should be maintained, consistent with most common international practice
- a mandatory 5% discount rate sensitivity analysis would need to be conducted for purpose of being explicit about the impact on opportunity cost and budget, and to ensure consistency with prior decisions by allowing advisory committees to compare ICERs for new listing requests with previously considered items based on the 5% rate
- implementation should be monitored and reviewed during and after the first 12 months.

**Outcome:**

Advice Provided

## **7. Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.