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Department of Health
GPO Box 9848
Canberra ACT 2601

Via email: PBSpostmarket@health.gov.au

To whom it may concern,

RE: Public Consultation on the Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines Review

Thank you for providing Pfizer Australia with the opportunity to comment on the draft, revised PBAC Guidelines Version 5.0.

Pfizer Australia is one of Australia's leading providers of prescription medicines and consumer health products. We deliver medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives. We are proud of the active role we play in Australia's health system.

Pfizer Australia supports the Government's review of the PBAC Guidelines. Guidelines that remain contemporary, comprehensive and world's best practice ultimately help ensure Australians have timely access to safe, clinically proven and cost-effective medicines, while safeguarding the sustainability of the Pharmaceutical Benefits Scheme so it can benefit future generations.

Pfizer Australia is a member of Medicines Australia (MA), the peak body representing innovative pharmaceutical companies in Australia and was involved in the preparation of MA's submission to this Review. We support MA's submission and encourage the Department of Health to carefully consider the evidence and analysis presented within.

Pfizer Australia's submission (Attachment 1) builds on the key themes outlined in MA's submission. Given the page limitations for submissions, we have chosen to focus on four key areas of concern: choice of comparator(s); disease-specific considerations for vaccines, rare diseases and oncology; evidentiary requirements; and PBAC decision making criteria.

Thank you again for the opportunity to make a submission to this Review. We are available at any time to provide further information, as required.

Yours sincerely,

Louise Graham
Director Access & Public Affairs

ATTACHMENT 1

Submission to the Department of Health's Public Consultation on the draft revised PBAC Guidelines

#	Revision	Description / Impact	Recommendation
Choice of comparator(s);			
1	The revised draft guidelines express a strong preference for the 'least expensive alternative medicine' to be selected as the main comparator.	In line with Medicines Australia's submission, Pfizer Australia does not agree with the interpretation of section 101(3A) of the *National Health Act 1953* outlined in Section 1 of the revised guidance on the selection of the main comparator. Specifically, we do not believe there is a basis in the Act for the Pharmaceutical Benefits Advisory Committee (PBAC) to limit its selection of a main comparator to the least expensive alternative medicine. The least expensive alternative medicine is often one that has been listed on the Pharmaceutical Benefits Scheme (PBS) for a considerable period of time. Its evidence base is usually much older and therefore of relatively poorer quality than that of the proposed new medicine. This asymmetry of evidence will make it very difficult for a sponsor to show that their proposed new medicine is superior or non-inferior. Requiring that sponsors use the least expensive alternative medicine as the main comparator will also make it difficult for sponsors to demonstrate cost effectiveness using a price that is both fair, reflecting the value brought by an innovative new medicine, and sustainable. This requirement is inconsistent with the guidelines provided under Section 2. In particular, Section 2 expresses a preference for direct randomised clinical trials versus the standard of care in clinical practice. The standard of care in clinical practice, however, is not always, by default, the least expensive comparator. If introduced, this requirement could have a significant impact on timely and affordable access to innovative new medicines in Australia by discouraging sponsors to seek reimbursement for some medicines. It is therefore also, by extension, wholly at odds with the Government's stated focus on encouraging innovation in our economy.	• Consider Medicines Australia's detailed commentary on this issue in their submission to this Review. • Revise the guidance in draft Version 5.0 to specify that the main comparator should be the therapy that prescribers would most likely replace with the proposed medicine in practice.

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2	In many cases, sponsors will now be required to provide economic evaluation against a number of comparators.	Requiring sponsors to analyse multiple comparators increases the need for indirect comparisons. This can lead to the amplification of inconsistences between data sets that would have otherwise been relatively innocuous. Ultimately, this increases uncertainty by diluting robust evidence. This requirement adds a layer of complexity that is not always necessary. Pfizer Australian maintains that the use of multiple comparators should be based on evidence and reflect Australian clinical practice.	• Remove the requirement for the inclusion of multiple comparison analyses in instances where there is an obvious medicine that the new medicine is most likely to replace. • Provide clear points to consider on whether multiple main comparators are required; this should be the exception rather than the norm.
3	In some cases, sponsors may be required to account for and analyse "future" comparators (i.e. comparators that are not yet listed on the PBS or Australian Register of Therapeutic Goods [ARTG]).	It is unclear how, under the current system, a sponsor will be able to comply with this requirement because: • Sponsors are not privy to their competitors' registration and listing timelines so will likely be unable to even identify "future" comparators. • Similarly, sponsors are not privy to their competitors' full suite of evidence; they must rely on the evidence available in the public domain. This 'public' evidence may be immature, uncertain or in a patient population that differs from the final ARTG approved indication. • Pricing details for treatments undergoing evaluation by the PBAC are confidential. Without access to the "future" comparators' pricing details, sponsors will be unable to provide an economic comparison. If introduced, this requirement could delay patient access to innovative new medicines.	• Remove the requirement for sponsors to account for and analyse "future" comparators.

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Disease-specific Considerations			
4	The guidelines do not recognise the unique intertemporal features of vaccines, compared to most other health interventions.	Vaccination has several unique features compared to traditional medicine. First, there are often long delays between when a vaccine is administered and when the disease/illness is averted (i.e. when the cost is incurred and the benefit accrues), so benefits are considerably impacted by discounting. Second, vaccines have a number of positive economic and social externalities, all of which have been well-document across the literature. For example, vaccines can provide a wider population with 'herd immunity'. The assessment of cost-effectiveness for vaccines, therefore, requires a considerably different methodology to that used to assess traditional prescription medicines. Though the current guidelines recognise this to some extent, Pfizer Australia maintains there is still much room for improvement.	• Recognise the long term value of vaccines by, for example: (i) reducing the base case discount rate to be consistent with the majority of other HTA agencies; and (ii) allowing for differential discounting for interventions with long-term outcomes. Contemporary literature provides ample evidence to support this. • Allow sponsors to account for the full range of economic and social benefits of vaccines in assessments.* ** In line with Medicines Australia's submission, it is our view that this allowance should not be restricted to just vaccines.*
5	There is no mention of rare diseases in the draft revised guidelines.	It is difficult for rare disease treatments to meet the rigorous evidentiary requirements and [consequently] cost-effectiveness criteria for listing on the PBS. A more flexible assessment process—that takes into consideration the challenges faced by sponsors of rare disease therapies—is therefore crucial to ensuring patients suffering from rare diseases receive timely and affordable access to innovative new medicines. Pfizer Australia had hoped that this issue would be addressed, at least in part, through the Department's post-market review of the Life Saving Drugs Program last year. We, therefore, look forward to the release of the review's findings and final recommendations.	• Consider the analysis and recommendations provided in Optum's submission (on behalf of the Rare Disease Industry Working Group) to this Review.

#	Revision	Description / Impact	Recommendation
6	The draft revised guidelines do not reference the most up-to-date research in the area of crossover in clinical trials, ostensibly for oncology.	Without clear guidance on acceptable statistical adjustment methods (that are based on up-to-date research and international best practice), sponsors may be unable to appropriately value medicines that include crossover as part of the clinical trial design. This can lead to disagreement between a sponsor and the PBAC during negotiations and ultimately delay reimbursement decisions. Pfizer Australia understands that this is an increasingly common scenario across industry.	• Incorporate the outcomes of the 'Challenges of early crossover in clinical trial design for oncology' workshop held in October 2014 into the guidelines. • Provide further detail on acceptable statistical adjustment methods by way of a "points to consider" subsection, which aligns with current best practice. This subsection could be included as an easily editable appendix so that the guidelines can be adjusted regularly and as required to *remain* in line with best practice.
Evidentiary Requirements			
7	Sponsors will now be required to provide a systematic review of the relationship between surrogate outcomes and final outcomes, even where this relationship is already well-established.	This requirement will considerably (and unnecessarily) increase the volume of work and cost associated with developing a submission. It is, in essence, at odds with the Government's stated desire for a more streamlined PBAC submission process. For example, a sponsor could be required to provide a systematic review of the already well-established link between smoking cessation and a decreased risk of cardiovascular disease.	• At a minimum, amend the guidelines such that established surrogate endpoints are recognised and so do not require lengthy and duplicative review.
8	Sponsors will now be required to provide details of the patients to be grandfathered onto PBS-listed medicine supply.	Product Familiarisation Programs (PFPs), conducted in accordance with the Medicines Australia Code of Conduct, are run between a positive PBAC recommendation and PBS-listing. Therefore, patient numbers are usually not known at the time of PBAC lodgement.	• Provide further guidance to sponsors on how to deal with grandfathering in the absence of patient number details.

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9	The draft guidelines recommend that a clinical expert reviews and validates the economic model.	It is unclear how a clinical expert can validate an economic model without also having demonstrated expertise in economic modelling, particularly given the complexities of some economic models (e.g. will a clinical expert without economic modelling expertise be able to advise on transition probabilities or utility measures?). Moreover, this requirement will increase the cost associated with developing a submission.	• Consider removing this requirement.
PBAC Decision Making Criteria			
10	"Patient affordability in the absence of a PBS subsidy" is a new criterion introduced into PBAC decision making.	Pfizer Australia seeks further clarity on this criterion, specifically: • What thresholds will the PBAC use in determining what is "affordable" and what is not? • Does the addition of this criterion represent a change in government policy, such that the PBS is being transformed to a subsidisation scheme for high cost drugs only? If so, how does this align with the PBS's key principle of equity of access?	• Provide further clarity on the intended purpose of this additional criterion, as well as how it will be considered in practice by the PBAC.