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PHARMAC
Pharmaceutical Management Agency

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PBS Post-market review team
By email: PBSpostmarket@health.gov.au
AUSTRALIA

Dear Post-Market Review Team,

PBAC Guidelines Review

This letter responds to your public invitation to comment on the scope of the PBAC Guidelines Review.

PHARMAC takes a strong interest in the PBAC Guidelines and is very pleased to be able to contribute to their further development. We also note that many sponsors coordinate their submissions to Australia and New Zealand and there could therefore be benefit from closer alignment of the assessment methods used in the two countries.

PHARMAC has recently published an update to its *Prescription for Pharmacoeconomic Analysis*[1] and *Guidelines for Funding Applications to PHARMAC*[2]. We have also started an internal review of the PFPA with a view to publication of an update after 2016. That review has identified several issues that the PBAC Guidelines Review may wish to consider.

- Definition of "main comparator" (Section A4 of PBAC Guidelines v4.4). We suggest that the Guidelines Review consider whether to change the main comparator from "the medicine that is prescribed on the PBS" with "medicines that are now prescribed or are likely to be prescribed on the PBS". The reasons for a change would be to take account of pending price changes, trends in volume, and expected use of other therapeutic options.
- Choice of HR-QOL measure (Appendix 7 of PBAC Guidelines 4.4). It would be useful to consider the differences in HR-QOL that can be expected to be reported by different populations, for example reports by trial participants compared to reports from people who have not experienced the condition,
- Measurement and consideration of health-related benefits to people other than the person receiving or using the funded product. Key examples are people at risk of infection; people benefiting from contraception; and family or caregivers whose health-related quality of life is indirectly affected by the treated person's health condition. The Guidelines Review could consider what types and level of evidence for such benefits could be considered in economic evaluations.
- Guidance for use of lower-quality evidence in the economic evaluation, when it is unlikely that high-grade evidence will be available in a timely fashion
- Consideration of alternative approaches to discounting, such as hyperbolic discounting; application of discounting to HR-QOL measures elicited through Standard Gambles or time-tradeoff methods that include a time or risk dimension.[3]

PHARMAC staff would be very happy to discuss any of these points further with the review team.

1 http://www.pharmac.health.nz/economic-analysis

2 http://www.pharmac.health.nz/new-funding-applications/

3 Buckingham KJ, Devlin NJ. A note on the nature of utility in time and health and implications for cost utility analysis. Social science & medicine. 2009 Jan;68(2):362-7.

Yours sincerely,

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