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31 August 2015

Pharmaceutical Benefits Advisory Committee Guidelines Review  
Department of Health  
GPO Box 9848  
Canberra ACT 2601  
**Via email to [PBSPostmarket@health.gov.au](mailto:PBSPostmarket@health.gov.au)**

Dear Review Steering Committee,

GSK welcomes the opportunity to make a submission regarding the scope of the Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines Review, and we thank the Government for initiating this important Review. For two decades, Australia has been acknowledged for robust, evidence based health technology assessment (HTA). This Review is a timely recognition by Government that Australia cannot rest on our history as leaders in HTA, but instead we must challenge and strengthen our system.

GSK is a research-based pharmaceutical and healthcare company operating in more than 100 countries around the world. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer. Here in Australia, we have a proud history dating back to the early 1900s. Today, we strive to improve the wellbeing of Australians by delivering high-quality medicines, vaccines and healthcare products.

Medicines and vaccines sponsors are key partners in Australia's PBAC system. After years of research and development and the investment of millions of dollars for each new product brought to market, sponsors contribute much of the data used by the PBAC to make informed reimbursement recommendations. Indeed, the volume and complexity of sponsor-generated data has grown alongside our industry's contributions to medical and scientific advances. It will be important that this Review examines how to make best use of the evidence available while also ensuring that Australia keeps pace with best practice in HTA.

GSK is supportive of the scope of the Review as outlined for this consultation including: the consideration of the PBAC Guidelines alongside comparable international HTA agencies and international best practice; and the preparation of detailed technical papers on areas for Guidelines revisions will be prepared.

While we acknowledge there will be dozens of important technical issues addressed throughout this Review, we would like to highlight particular concern regarding the assessment of vaccines. The modern PBAC system was designed in the early 1990s for robust evaluation of therapeutic pharmaceuticals. Later, in 2005, vaccines were moved into the PBAC system but without fit-for-purpose changes that would stretch the system appropriately to address the unique costs, benefits and attributes of vaccines.

GSK has sponsored a number of submissions for new vaccines or new vaccine indications in the ten years since the PBAC was given responsibility for vaccines reimbursement advice. Through this experience, we have noted with growing concern the system issues which result in undervaluation of vaccines. These include (although not limited to vaccines):

- Discount rates
- Dynamic transmission modelling
- Time horizon expectations for modelling vaccines outcomes
- Indirect costs and benefits for society relating to vaccines
- Quality of life estimates and methods for short term diseases in young children (and their carers)

GSK urges the Steering Committee to closely review these technical challenges and design Guidelines revisions which resolve these issues through this Review. Without Guidelines revisions to ensure appropriate, robust vaccines valuation, GSK is concerned that some new vaccines may not be made available in Australia.

In recent years some new vaccines have been successfully managed within the existing PBAC system through resubmissions and deliberate efforts by sponsors to overcome the obstacles; however, case by case fixes do not serve the Government or taxpayers well. Australia's PBAC system is intended to support the Government in allocating resources to those medicines and vaccines which represent value for money within our health system; where the system provides suboptimal evaluation of vaccines, it is offering suboptimal information to Government on where to direct resources. Ultimately, the patient impact can be long delays, limited access or no access to new vaccines.

GSK notes that international HTA experts have commented on the unique challenges for vaccines HTA evaluation<sup>1</sup>. Furthermore, comparable international HTA agencies in some cases take a different approach to the PBAC, for example on the issue of discounting rates<sup>2</sup>. By referencing international HTA experts and alternative systems, there may be solutions appropriate to the Australian system which can be adopted to ensure timely, appropriate and robust valuation of vaccines are conducted in the best interest of the Australian public.

GSK welcomes the opportunity to make this submission and to engage in the Review process as it moves forward through our industry's peak body Medicines Australia. We encourage the Steering Committee to use the Review as an opportunity to contribute to national and international discourse on HTA, for example by making the technical papers available publicly and by facilitating additional points for broader involvement in the Review. This will ensure the robustness of the Review process and therefore the integrity of the revised Draft Guidelines.

We would welcome the opportunity to discuss these issues with the Steering Committee or the Adelaide Health Technology Assessment.

Yours faithfully,

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Director, Healthcare Environment  
GSK Australia

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<sup>1</sup> Beutels P, Scuffham P, MacIntyre C. Funding of drugs: do vaccines warrant a different approach?. *The Lancet Infectious Diseases* 2008; 8: 727-733.

<sup>2</sup> National Institute for Health and Clinical Excellence. Guide to the methods of technology appraisal 2013. Available from: <https://www.nice.org.uk/article/pmg9/resources/non-guidance-guide-to-the-methods-of-technology-appraisal-2013-pdf>