



1140/1647



**THE HON SUSSAN LEY MP
MINISTER FOR HEALTH
MINISTER FOR AGED CARE
MINISTER FOR SPORT**

Ref No: MC16-008376

Dr Dennis Jensen MP
Chair
Standing Committee on Petitions
PO Box 6021
Parliament House
CANBERRA ACT 2600

Dear ~~Chair~~

Thank you for your letter of 3 March 2016, offering me the opportunity to respond to a petition received by the Committee, presented by the Member for Barker, on 2 March 2016 for the inclusion of the Meningococcal B Vaccine on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP). I apologise for the delay in responding.

In general, essential vaccines are subsidised via the NIP and not through the PBS. The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, makes recommendations to the Australian Government about PBS and NIP listings, in accord with the requirements of the *National Health Act 1953*.

The Government does not have the legal power to include any medicine or vaccine on the PBS or NIP without a positive recommendation from PBAC.

The process of considering products for listing on the PBS or NIP is evidence based. The PBAC considers each PBS and NIP listing submission, having regard to the safety, clinical effectiveness and cost-effectiveness (value-for-money) of the medicine or vaccine for the intended use, in comparison with other available treatments. The same evaluation requirements are applied in all cases, as required by the legislation, to ensure consistency and fairness in the listing process.

The Australian Technical Advisory Group on Immunisation (ATAGI) advises the PBAC on matters relating to the ongoing strength of evidence pertaining to existing, new and emerging vaccines in relation to their effectiveness and use in Australian populations.

The PBAC considered the inclusion of a four component meningococcal group B (recombinant, adsorbed) vaccine (4CMenB) (Bexsero®), currently marketed by GlaxoSmithKline Australia Pty Ltd, for the prevention of meningococcal B disease in infants and adolescents on the NIP on three occasions, in November 2013, July 2014 and most recently in July 2015, but did not recommend listing on any of those occasions.

The PBAC acknowledges the clinical need for a vaccine against meningococcal B disease. However, on each occasion it has considered this vaccine for inclusion on the NIP, the PBAC has rejected the sponsor's submission because the cost effectiveness of the vaccine is unacceptably high and uncertain at the price proposed by the sponsor.

In July 2015, the PBAC reaffirmed its November 2013 and July 2014 conclusion that the vaccine is effective in inducing antibodies against the component antigens of 4CMenB. However, in the context of a population-based intervention against invasive meningococcal disease, the Committee considered the clinical claim of superiority over no vaccination in terms of comparative effectiveness with an acceptable tolerability profile in infants and adolescents, was highly uncertain. This is because of the likely short persistence of the antibody response in children, uncertainty about the correlation between antibody responses and protection, the uncertain effect on carriage of the bacteria, the overall uncertain long term protective efficacy against infection and disease, and the unknown influence of projected herd immunity effects on overall disease burden. These issues were not addressed in the July 2015 submission, although the PBAC acknowledged the limitations of the evidence base.

The outcomes of the committee's July 2015 meeting are available on PBS' webpage by entering 'PBAC meetings' in the search bar at www.pbs.gov.au.

The sponsor company can reapply to the PBAC at any time. However sponsors cannot be compelled to lodge further applications.

NPS MedicineWise, which receives funding from the Government, is an independent, not-for profit and evidence-based organisation. NPS MedicineWise provides practical tools, such as medicines lists, evidence-based information and continuing professional development educational activities, with the aim to improve the way health technologies, medicines and medical tests are prescribed and used. NPS MedicineWise has published information to inform medical professionals and members of the community about this and other meningococcal disease vaccines on its website on a number of occasions.

Thank you for bringing this matter to my attention.

The Hon Sussan Ley MP

18 APR 2016