12.11 TEMPORARY LISTING OF ENGERIX-B® (ADULT FORMULATION) FOR HEPATITIS B ON THE NATIONAL IMMUNISATION PROGRAM (NIP)

1 Purpose

1.1 To request temporary National Immunisation Program (NIP) listing of Hepatitis B surface antigen recombinant vaccine, Engerix-B (adult formulation), for use in adolescents and adults due to a shortage of the NIP listed adult formulation of H-B-Vax II for the same indication and population.

2 Background

2.1 Engerix-B is a hepatitis B vaccine sponsored by GlaxoSmithKline (GSK).

2.2 Engerix-B is TGA registered for active immunisation against hepatitis B virus infection.

2.3 H-B-Vax II is TGA registered for immunisation against infection caused by all known subtypes of Hepatitis B virus.

2.4 The PBAC has not previously considered hepatitis B monovalent vaccines.

3 Current situation

3.1 H-B-Vax II, sponsored by Seqirus Australia Pty Ltd (Seqirus), is currently NIP listed for adult (H-B-Vax ll) and paediatric populations (H-B-Vax ll paediatric), and is the only hepatitis b vaccine listed for the adult population. Engerix-B is currently NIP listed for the paediatric population only, but is available in both adult and paediatric (Engerix-B paediatric) formulations.

3.2 Merck Sharp and Dohme (MSD), who are the third party providers of hepatitis B vaccines for Seqirus (H-B-Vax ll), is encountering a shortage currently predicted to last until 31 December 2019. [redacted] As a consequence there is expected to be a shortage of adult hepatitis B vaccines until 2019.

3.3 The population impacted by this shortage are catch up cohorts of adolescents aged 10-19 years old and refugees and humanitarian entrants of all ages. There are financial implications for family payments if the adolescent group do not undertake vaccination, and because refugees and humanitarian entrants may come from hepatitis B endemic areas, there are public health implications if this group cannot receive vaccination.

3.4 A vaccination course involves three doses. The Australian Technical Advisory Group on Immunisation (ATAGI) advised that whilst not recommended, the two vaccines (H-B-Vax ll and Engerix-B) can be used interchangeably, implying they are equivalent. There is also published evidence suggesting the two vaccines offer equivalent clinical protection 12 months following vaccination (Vinod *et.al,* 1995)[1].

3.5 [redacted].

3.6 GSK has advised that they have sufficient adult formulation doses of Engerix-B (adult formulation) to meet NIP requirements for 12 to 18 months and that this supply will not impact state programs or the private market.

3.7 GSK have agreed to provide Engerix-B (adult formulation) on a cost neutral basis to the existing NIP listing, $[redacted] GST Excl per dose.

4 Requested PBAC advice

4.1 In June 2018 the Chief Medical Officer (CMO) wrote to the PBAC asking that it consider the temporary NIP listing of Engerix-B (adult formulation) to cover the supply shortage of H-B-Vax II (adult formulation) in adolescents and adults.

5 PBAC Outcome

5.1 The PBAC recommended the temporary listing of Engerix-B (adult formulation) for use in adolescents and adults on the NIP until either the shortage of H-B-Vax II (adult formulation) has been resolved, or 31 December 2019, whichever were to occur first. The PBAC considered that Engerix-B was sufficiently interchangeable with H-B-VAX II as per the advice of the ATAGI, and that the listing would be cost neutral as Engerix-B would be provided at the NIP tendered price paid for H-B-Vax II and would ensure ongoing coverage for the catch up populations that are eligible for the vaccine under the NIP.

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to

[1] Vinod K., Rustgi etc etc etc (1995), *Comparative study of the immunogenicity and safety of Engerix-B administered at 0, 1, 2 and 12 months and Recombivax HB administered at 0.1. and 6 months in healthy adults,* Vaccine, Vol 13, 17:1665-1668

recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

7 Sponsor's Comment

The sponsor had no comment.