

- 3.3 On 15 January 2016 the sponsor acknowledged the aforementioned options and requested changing the current Section 100 Highly Specialised Drug Programme public hospital listing for simeprevir to an Authority Required (telephone) listing.

4 PBAC Outcome

- 4.1 The PBAC recommended to the Minister (delegate) to change the current Section 100 Highly Specialised Drug Programme public hospital listings for simeprevir (treatment naïve and treatment experience patients) to Authority required (telephone).
- 4.2 The Committee noted that at the November 2015 meeting the PBAC recommended simeprevir for use in combination with sofosbuvir, but that the listing conditions have not yet been agreed between the Department and the sponsor.
- 4.3 The PBAC reiterated its previous advice that at its current list price, simeprevir would not be considered a cost-effective treatment for Hepatitis C, following the recent listing of interferon-free oral treatment.
- 4.4 The PBAC also noted that a telephone Authority would be consistent with other oral treatments that would be listed for interferon-free regimens.

Outcome:

Recommended

5 Recommended listing

- 5.1 Amend the restriction method for PBS items 10197Q and 10200W to Authority Required – telephone.

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 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.