

## 9.04 NATIONAL HEPATITIS C DATA COLLECTION

### 1 Purpose of Item

- 1.1 To update the PBAC on the progress of the National Hepatitis C Data Collection.

### 2 Background

- 2.1 Several new generation direct acting antiviral (DAA) medicines for the treatment of chronic hepatitis C were listed on the PBS from 1 March 2016.
- 2.2 As part of the approval for listing, funding was allocated to develop a national data collection for the ongoing assessment of the cost-effectiveness and health outcomes of the DAA medicines.
- 2.3 At its April 2016 Special meeting, the PBAC recommended a minimum dataset for the data collection. The PBAC considered that surveillance programs funded through the Office of Health Protection may meet the requirements for the data collection.
- 2.4 The 'Real world efficacy of antiviral therapy in chronic hepatitis C' (REACH-C) study, conducted by The Kirby Institute, was identified as capturing the majority of data elements recommended by the PBAC in April 2016.
- 2.5 The Kirby Institute was engaged by the Department of Health in June 2017 to extend the REACH-C study to establish the required data collection for hepatitis C.
- 2.6 PBAC considered the initial data collected from REACH-C at its March 2018 meeting. The data presented was considered to be informative for assessing the real-world treatment response rates across different patient types and in different settings. However PBAC noted there were several limitations with the data, including:
- most of the participants in the REACH-C study were being treated through specialist viral hepatitis clinics. A greater representation of data from non-tertiary clinics was needed; and
  - there were large numbers of treated individuals for whom no data on sustained viral response was available. PBAC noted that follow-up information was not complete for all participants as the study was at an early stage.
- 2.7 The PBAC requested the Department to work with The Kirby Institute to improve the quality of the data collection and increase the representation of data from general practice settings.

### 3 Current situation

- 3.1 As at March 2018, data has been captured for 5,416 participants.
- 3.2 The Kirby Institute has provided a progress project report for participants initiating on treatment from 1 March 2016 to December 2017.
- 3.3 The Kirby report notes that:

- 34% of patients were treated in non-tertiary settings, including general practice, community health clinics, drug and alcohol services and sexual health services (Table 5 p18).
  - The overall loss to follow-up for participants with an unknown sustained virological response outcome (SVR12) was 17%.
  - For the 4,513 participants with a confirmed treatment outcome:
    - 96% achieved SVR12.
    - Of the 184 participants who did not achieve SVR12, the main reasons were virological failure (72%) and did not complete the full treatment course (12%). Reinfection was recorded as a reason for 3 individuals.
- 3.4 The Department has engaged a health technology evaluator to assess the suitability and reliability of the current data to examine the cost-effectiveness of the DAAs in practice. The Department is also undertaking a procurement process to identify other potential suppliers for the data collection.
- 3.5 The Department requested data from the National Prescribing Service (NPS) MedicineInsight program on the general practice management of patients with hepatitis C.
- 3.6 The NPS report notes that:
- Reliable assessments could not be made from MedicineInsight on achievement of sustained virologic response, cirrhotic status, referrals to specialists and liver fibrosis.
  - Only 54.2% of patients had a HCV genotype test recorded before their DAA prescription.
  - The HCV genotype testing rate was similar whether the patient was prescribed a genotype specific DAA regimen or pan-genotypic DAA regimen.
  - For patients prescribed a DAA between 1 March 2016 and 31 December 2017, 7% were subsequently re-treated at the same practice.

## **4 Requested PBAC actions**

- 4.1 That the PBAC note:
- a) The progress report on the current data captured for 5,416 individuals.
  - b) The findings from the NPS report based on MedicineInsight data.
  - c) The activities in relation to assessing the suitability of the current data collection and identifying other potential suppliers.

## **5 PBAC Outcome**

- 5.1 The PBAC noted the provided REACH-C study progress report and the NPS Report.

- 5.2 The Committee recalled when it first considered the data that had been captured from the REACH-C study at its March 2018 meeting that the data had been limited by missing follow-up information due to the immaturity of the data at that stage.
- 5.3 The PBAC noted the REACH-C study had experienced a 17% loss to follow-up and noted that most of the data (~66%) was being captured from tertiary settings with the remainder from non-tertiary settings. The Committee considered that for the data to be more representative of current prescribing there was a need to capture more information from general practice and other community-based settings. The PBAC also considered the cohort in the study was outdated with the last patients initiating in December 2017.
- 5.4 The PBAC also noted the report provided by the NPS MedicineInsight Program and considered it was informative, with data obtained from 359 general practitioner sites. The Committee considered the analyses for an early-initiating cohort versus a later, younger cohort (with less cirrhosis) and analyses for Aboriginal and Torres Strait Islander populations were informative. The PBAC noted the approximate 7% rate of re-treatment and considered that was not unexpected based on the data upon which it had originally recommended the listings of the direct-acting antiviral regimens for the treatment of hepatitis C. The PBAC noted that sustained virological response (SVR) rates could not be reliably assessed from the MedicineInsight data and the relatively low number of recorded genotypes (54%) in the NPS data, irrespective of whether patients had been initiated on pan-genotypic or genotype-specific treatments.

**Outcome:** Noted