11.06 TGA Consultation Paper on Prescription S8 opioid use and misuse in Australia

1 Purpose of Item

1.1 To seek PBAC's advice on:

- whether it wishes to make a submission;
- what the submission will include; and
- which committee members would be required to review this submission before it is submitted, noting the short turnaround time on this paper.

2 Background

2.1 On 19 January 2018, the Therapeutic Goods Administration (TGA) opened public consultation on prescription strong opioid use and misuse in Australia via a discussion paper (Attachment A). This discussion paper covered a range of potential options including several measures through the PBS. The formal consultation period closed on 2 March 2018. The PBAC has been provided an extension on submitting a response until 16 March 2018 to enable consideration by the Committee at this meeting.

3 Current situation/outcomes of the report

3.1 In its consultation paper, the TGA has outlined the context and rationale for the consultation including indication creep. The TGA noted that regulation is one part of a broader process to address misuse of opioids and the TGA options posed in the paper are generally within the TGA's regulatory power.

3.2 In its review of the paper, the TGA Advisory Committee for Medicines (ACM) recommended that further consideration be given to the below items:

- The introduction of smaller pack sizes for strong opioids that may be prescribed when short-term use is required, such as for pain relief after surgery.
- A review of the approved indications for S8 opioid medicines and align them to current clinical guidelines.
- Work with the Health Technology Assessment and Access Division of the Department of Health to consider PBS prescribing restrictions, such as smaller quantities and the requirement for specialist medical review of non-cancer pain patients prescribed opioids for extended periods.
- Work with clinical colleges to educate prescribers on judicious use of opioids, treatment de-escalation and the use of non-opioid pain relievers.

3.3 The paper proposed a range of measures under the headings of:

Option 1: Consider the pack sizes for strong Schedule 8 opioids
Option 2: Consider a review of the indications for strong opioids
Option 3: Consider whether the highest dose products should remain on the market, or be restricted to specialist / authority prescribing
Option 4: Strengthening Risk Management Plans for opioid products
Option 5: Review of label warnings and revision to Consumer Medicines Information
Option 6: Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes
Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong opioids
Option 8: Increase health care professional awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain
Possible role of PBS Prescribing Controls

3.4 Several of these options could benefit from PBAC comment due to implications for the PBS and/or clinician expertise.

3.5 To assist the Committee in developing a submission to the TGA, the Secretariat has outlined potential responses the Committee may consider useful to include under the relevant options (Attachment B).

3.6 If a submission is to be made on behalf of the PBAC, relevant members will provided with a draft submission to review COB Wednesday 14 March 2018.

4 PBAC Outcome

4.1 The PBAC considered the TGA discussion paper and considered it would be appropriate to make a submission based on member input to be provided to the PBAC Secretariat out of session.