



# Health Technology Assessment Policy and Methods Review Reference Committee

## Communique – 14 July 2023 meeting

The Health Technology Assessment (HTA) Policy and Methods Review (Review) Reference Committee (Committee) met by video conference on 14 July 2023.

Members from the Life Saving Drugs Program (LSDP) Expert Panel, two medical officers from the Department of Health and Aged Care (Department), the Chair of the HTA Consumer Consultative Committee and a representative from the Department's Consumer Evidence and Engagement Unit were invited to speak to the Committee. Support staff from the Review Secretariat in the Department attended.

### **What did the Committee discuss?**

#### **Discussion with members of the Life Saving Drugs Program Expert Panel**

The Committee had a discussion with members of the LSDP Expert Panel (EP) on how the LSDP operates, the role of HTA in the LSDP and the challenges inherent in assessing and subsidising medicines for ultra-rare diseases. Representatives from the Department's LSDP EP Secretariat were also present to support the discussion.

The Committee heard that eligible listings on the LSDP are treatments for ultra-rare (prevalence of 1:50,000 people or fewer) and all currently listed medicines are for single genetic disorders. The Committee heard that many of these treatments are complex biological molecules for which sponsors indicate high costs for both research and development and manufacture. The Committee noted there are treatments for ultra-rare diseases listed on the PBS and that the PBAC has recommended the transition of a LSDP medicine onto the PBS as part of its consideration of a new treatment for the same indication for the PBS and re-evaluation of the LSDP medicine's cost-effectiveness. It was further noted that the LSDP EP recently determined a condition no longer met the LSDP ultra-rare disease criterion and that the PBAC subsequently recommended an associated LSDP medicine for listing on the PBS. The Committee noted that a number of issues in relation to the LSDP were raised in the House of Representatives Inquiry into approval processes for new drugs and novel medical technologies in Australia. Issues and potential options for reform in assessment of ultra-rare diseases discussed will be considered further through the planned Consultation 2.

#### **Presentation on International Collaboration Initiatives**

The Committee heard from Departmental medical officers regarding opportunities and challenges to international collaboration in the assessment of new medicines, particularly the collaboration between comparable overseas regulators (such as ORBIS and the Access Consortium) through the TGA. The Committee also reflected on the shared clinical

evaluation development under EUnetHTA (replaced by a permanent system of HTA collaboration in Europe under the European Regulation on HTA, HTAR, on 16 September 2023) and whether similar work sharing opportunities can be incorporated into HTA. However, no specific options for reform were proposed and potential HTA collaboration will be discussed in more detail at a future meeting.

The Committee heard that while there was now an agreement between HTA agencies or equivalent in the UK, Canada, Australia and NZ to progress collaboration in HTA, the working details of such arrangements were still under negotiation. The Committee was informed all the agencies party to the agreement acknowledged that any collaborative work would not breach commercial-in-confidence agreements between sponsors and individual agencies.

### **Presentation and Discussion on the Conversations for Change Report**

The Committee had a discussion with Ms Jo Watson and a representative from the Department's HTA Consumer Evidence and Engagement Unit on the key messages from the Conversations for Change consultations. The Committee noted that patients and consumers would like to actively participate throughout the HTA process and would like more resources to support their participation. The Committee also noted that patients and consumers would like to be able to participate in the HTA process as early as possible. Issues and potential options for reform discussed will be considered further through the planned Consultation 2.

The Committee thanked the representative from the HTA Consumer Evidence and Engagement Unit and Ms Watson and looked forward to seeing future work in this space.

### **Other Business**

The Committee discussed a number of administrative matters regarding the operation of the Committee.

### **Meeting close and next meeting**

The Committee noted the next meeting will be held on 24 July 2023.