# LIST OF RECOMMENDATIONS

**Recommendation 1**

**6.40 The committee recommends that the Australian Government initiate a comprehensive review of the system for the registration and subsidisation of medicines. The review should examine:**

- **all available pathways for the registration and listing of new medicines, or new indications for medicines already registered on the ARTG and listed on the Pharmaceutical Benefits Scheme, including making provision for utilisation of assessments conducted by comparable overseas regulators; provision for clinicians and/or patient groups to apply for an extension of existing registrations to additional indications, managed access programs and risk-sharing, and the adoption of more flexible evidential requirements;**
- **options for improving the operation of assessment processes including:**
    - **enhancing engagement with sponsors and other stakeholders to better tailor their applications to the requirements of the PBAC, including consideration of pre-application planning meetings;**
    - **applying tiered assessment processes as a means of matching resources to the complexity of applications;**
    - **encouraging greater cooperation between the PBAC, the TGA and the Medical Services Advisory Committee, including examination of options for enhancing the operation of parallel processing arrangements; and**
    - **ensuring greater transparency throughout the assessment process;**
- **options for expanding the post-market review of medicines;**
- **enhancing and formalising mechanisms for consumers and clinicians to play a more central and substantial role in the evaluation of new medicines and new indications for already listed medicines, including:**
    - **consideration of options for expanding consumer and clinician representation on the PBAC;**
    - **enhancing existing avenues for stakeholder input, including the use of consumer and patient hearings; and**
    - **avenues for incorporating public perspectives on overarching moral, ethical and opportunity cost considerations into PBAC decision making processes, including consideration of models employed by comparable overseas regulators; and**
- **options for ensuring that the necessary administrative and technical resources are available to support the implementation of an enhanced PBAC system.**

**Recommendation 2**

**6.41 The committee recommends that the Australian Government commission a review of current data collection mechanisms for cancer medicines, including identification of:**

- **obstacles to the integration of existing databases and potential avenues for addressing these;**
- **opportunities to incorporate data from post-market evaluations; and**
- **avenues for capturing data relating to the off-label use of cancer medicines.**

**Recommendation 3**

**6.42 The committee recommends that the Australian Government establish a Steering Committee to examine the feasibility of establishing a national register of cancer medicines.**