APPENDIX 3

Review of Health Technology Assessment in Australia December 2009–Recommendations

1. **That the impact of the proposed changes to the Australian Government Health Technology Assessment (HTA) system approved by the Australian Government be evaluated within three years of the Government's response to this review.**

2. **That the rigorous consideration of evidence be consistently applied across all Australian Government HTA processes to ensure sustainability of the Australian Government's health financing arrangements.**

3. **That the Australian Government HTA system be guided by the vision, goal, objectives and principles articulated in the *Review of Health Technology Assessment in Australia* (HTA Review) Report.**

4. **That DoHA establish a website for Australian Government HTA processes by July 2010 which:**

   a) describes the roles, responsibilities and relationships between the different HTA processes;

   b) facilitates access to all related Australian Government HTA websites to ensure that policy and guidance for all Australian Government HTA processes are easily accessible; and

   c) regularly publishes reports on agreed performance and activity data to clearly demonstrate the performance of the system and focus attention on areas requiring performance improvement.

5. **That the procedural fairness and consistency of Australian Government HTA processes be improved by 2011, by:**

   a) establishing independent review mechanisms and opportunities for re-submissions in a consistent manner for Australian Government HTA processes (where they are currently not available);

   b) updating operating procedures for administering Australian Government HTA processes, including publishing specific milestones and timeframe targets for each individual HTA process;

   c) improving public disclosure of Australian Government HTA processes, including advisory committee membership, performance and activity data, and assessment and appraisal outcomes (including the rationale for those outcomes);

   d) establishing and publicising specified communication points with applicants throughout each process, including providing opportunities for pre-lodgement meetings; and

   e) adopting and implementing transparent and consistent policies and procedures for the management of conflict of interest for all external parties involved in Australian Government HTA processes.

6. **That in order to improve the efficiency of HTA, DoHA establish a single entry point (SEP) by July 2010 to receive applications for subsidy under the Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Schedule (PBS) and Prostheses List. The role of the SEP will be to:**

   a) provide a single point of contact to help applicants throughout the HTA process;

   b) determine the most appropriate advisory committee(s) to appraise the technology;

   c) identify the most appropriate assessment pathway for an application, including maintaining and reinforcing current processes where these are the most efficient for the technologies submitted to a particular process;

   d) conduct an initial risk and impact assessment and determine the most appropriate methodology to be used in assessing the technology;

   e) ensure the timely assessment and appraisal of co-dependent and hybrid technologies, or technologies being assessed concurrently for both public and private reimbursement and coordinate the provision of comprehensive advice to the Minister for Health and Ageing (the Minister);

   f) achieve synergies through sharing and sustaining HTA expertise across the advisory committee secretariats; and

   g) develop and report on the achievement of performance targets for HTA reimbursement.

7. **That applicants have the option of applying to different HTA processes concurrently. Finalisation of each HTA process may be subject to the completion of a critical antecedent process (such as inclusion on the Australian Register of Therapeutic Goods (ARTG) prior to MBS or Prostheses List listing). This will require procedures to be put in place by July 2010 to allow the efficient flow of information between HTA processes (including from the TGA to other HTA agencies, subject to confidentiality constraints).**

8. **That the Therapeutic Goods Administration (TGA), in the context of international harmonisation:**

   a) continue its role as the independent national regulator solely responsible for assessing the safety, quality and efficacy of therapeutic goods for entry on The Australian Register of Therapeutic Goods (ARTG) and marketing in Australia;

   b) respond to the issues raised in consultations regarding third party conformity assessment by July 2010, with a view to implementing changes agreed by government by 2011;

   c) increase the rigour of regulatory assessment of higher risk medical devices by 2011, to ensure an appropriate level of evidential review is undertaken to ensure safety, quality and efficacy of these devices prior to entry on the ARTG and to provide a sound evidence basis for Australian Government HTA processes; and

   d) develop protocols by July 2010 for sharing information with other HTA agencies through the SEP (subject to commercial-in-confidence constraints) on the outcomes of its safety assessments.

9. That by July 2010, MSAC strengthen and streamline its operations and improve the flexibility of its regulatory processes by:

a) providing advice to the Minister based on a critique of an applicant's comparative clinical and economic evaluations, as an alternative to the current process and in the context of agreeing specific timeframes for assessment with the applicant;

b) ensuring that data collection requirements supporting a recommendation for interim funding for a professional service for listing on the MBS are sufficiently rigorous and reliable to provide a sound basis for a final decision on funding;

c) ensuring that its advice to the Minister addresses all aspects of the proposed change to the MBS, especially in regard to the proposed MBS item descriptor and fee; and

d) streamlining current processes for accessing expert advice to improve timeliness of assessment processes and set a target of all advisory panels being established within six weeks of accepting an application.

10. That in order to reduce regulatory costs:

a) the terms of reference for the Prostheses and Devices Committee (PDC) and its subcommittees be revised by July 2010 so that it is clear that its assessments of prostheses only consider clinical effectiveness (including comparative cost and comparative safety); and

b) channels of communication between the TGA and PDC should be formalised to ensure that any concerns the PDC encounters regarding the intrinsic safety of prostheses are immediately referred to the TGA and dealt with appropriately.

11. That the PDC be restructured by July 2010 to ensure that its membership is balanced and:

a) includes individuals with expertise in current clinical practice, health policy and health economics;

b) includes representation from health consumers, health service providers, and the health insurance and health technology industries; and

c) has an independent chair.

12. That the arrangements for the Prostheses List be changed by 2011, with appropriate consultation, to:

a) accept applications on a continuous basis, but still make the Prostheses List every six months;

b) establish and maintain groups of products with similar clinical effectiveness;

c) abolish the negotiation of benefits for individual listed products, and instead establish and maintain a single (benchmark) benefit for the products included in each group, with sponsors being required to accept this benefit in order to be listed;

d) abolish the negotiation, setting or publication of maximum benefits, to eliminate the potential for gap payments for patients who have Private Health Insurance (PHI); and

e) permit the establishment of new product groups (or sub-groups) where a sponsor establishes clear superiority of their product compared to those in an existing group.

13. That, in order to improve the contribution of post-market surveillance to patient safety, the TGA take steps to increase the rate of reporting of adverse events, including by health service providers and consumers.

14. That, in order to improve the contribution of post-market surveillance to the sustainability of the health system and the longer-term regulatory efficiency of HTA processes, DoHA explore options for consideration by government in 2011 to facilitate the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions for devices and procedures.

15. That registers for high-risk implantable medical devices and/or procedures be established, with:

a) key stakeholders such as clinicians, health consumers and industry to participate in governance of and contribution to registries;

b) establishment of mechanisms to apply data from the register to future HTA;

c) the feasibility, benefits and methodologies for data linkage to be explored in a pilot project in regard to a particular device identified by the high-risk implantable devices register;

d) consideration of how developments in e-health and data linkage could improve the efficiency of the post-market surveillance of medical technology more generally; and

e) the development of criteria, the identification of opportunities and the consideration of strategies for improvements in public investment in medical devices.

16. **That the Australian Health Ministers' Conference be asked to consider the need for a national approach to HTA processes, including processes required to evaluate blood and blood products**.