Executive Summary

Pathology Technology Australia (PTA) is the peak industry body representing the manufacturers, distributors, and importers of the technology responsible for >95% of pathology testing in Australian laboratories, hospitals and the community. Without this technology, efficient diagnosis, treatment, and monitoring of patients could not happen. Increasingly, our member's technology informs a more predictive, preventative, and personalised approach to healthcare, intended to improve patient outcome at a lower total cost to the healthcare system. In addition, our members partner with clinical and research institutes to develop applications that enhance diagnosis and targeted treatment. As such our membership have a clear view of the technological advancements being developed, and significant experience of the pros and cons of existing HTA approaches as they pertain to diagnostics and supporting technology.

PTA and our member base take note of the recommendations discussed in this Options Paper with some exceptions and recommendations for further consideration as outlined in detail below. We suggest the scope for review of the impact of HTA for access to health technologies be extended to include the full spectrum of diagnostic tools and supporting technology, not just those within the narrow use of medicines.

Our largest concern relates to the suggestion for a single access gateway approach which we believe would contravene the intended goal of identifying high-medical need technologies and reducing time to funded access. We suggest evolution of PICO approaches in recognition that a diversity of tools is required to support a diverse Australian population. And we support reforms that increase public involvement in the HTA process , and reporting tools to inform sponsors prior to, and during HTA application.

1. Scope of the Review and Consultation

While we fully understand the history and rationale for the current Review scope, we remain perplexed by the Terms and Conditions of the Review not considering more extensively the impact of IVD (in vitro diagnostic devices). Over 70% of medical diagnosis and treatment and 100% of cancer diagnoses rely on IVD tests. It seems a missed opportunity that diagnostics and associated technology were not included in the ToRs more extensively.

Rapid advances in genomics, proteomics, biomarkers, point of care testing technology, and digital enablers (including AI), represent significant opportunity to healthcare not yet fully contemplated. We have potential, through IVD and digital innovation, to move from an activity-based healthcare system to a predictive, preventative and personalised system. Other like economies are making these changes and Australia also needs to be re-assessing the way technology regulation and funding impacts our ability to harness the full potential of these healthcare tools.

It has taken 8-12 years from the time an IVD is included on the ARTG to realise funding through the MBS. With 33% of this time spent in sponsor preparation of technical files, there is still significant opportunity to improve upon the time taken in HTA/MSAC and on the Minister's desk. Technology across the diagnostics sector is advancing at a rapid pace where technology may well be superseded by the time it receives funding, leaving patients and the healthcare system lagging behind the rest of the world in access to key developments to support their health. Indeed, several of our major IVD technology suppliers no longer list Australia as a high priority launch country because of the length of time it takes to have new technology funded.

2. Health Technology Funding and Assessment Pathways

We note that the current review is an outcome of a strategic agreement related to the funding of medicines through the PBS. Accordingly, the examination of issues in the options paper relates principally towards obtaining a desired outcome for listing of medicines. This examination implicates diagnostics to the extent that pathology testing helps to determine the choice of medicines optimal for treating a particular disease state, including genetic determinants. However, that logic cannot be extended towards the full range of innovative IVDs. The options fail to account for specific requirements of diagnostics.

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We fully support efforts to accelerate the HTA process and shortening assessment times, however we cannot understand how the suggested single access gateway approach can efficiently achieve these goals. The vast diversity in complexity of technologies and services mitigate against such a strategy. Indeed, similar health economies have moved away from such a concept in favour of sector specific expert panels. These multi-stakeholder groups are responsible for horizon scanning and shortlisting technology that fill unmet healthcare needs or significantly improve existing outcomes.

We respectfully suggest that:

a) lack of relevant technical/clinical expertise is already an issue with our current MSAC pathway - this will be compounded if combining HTA committees across the different technologies.

b) a single gateway model would further extend meeting duration - PBAC meetings take ~3-4 days, similarly for MSAC meetings - what is the planned meeting duration to cover both PBAC and MSAC through a single gateway?

c) consolidation of committees could lead to an increase in evidentiary requirements for IVDs to align with that applied to pharmaceutical products in a streamlined assessment protocol. Given the vastly lower risk factors and completely different cost and price structures for IVDs this would not be justified and would reduce the number of technologies receiving MBS reimbursement and further delay time to reimbursement.

The current expansion of IVD technology into genomics proteomics, biomarkers, point of care technology, and the associated digital enablers, is further evidence against the single gateway concept. It will become exceptionally challenging for a single committee, no matter how competent, to be expert enough to complete even an initial triage of potential high-medical need technology.

While coordination and collaboration across HTA systems is a desirable goal, especially in so far as getting better coordinated implementation between federal and state/territory governments, we suggest this may be achieved through better resourcing processes, rather than trying to consolidate consideration of the variety of expert advisory committees into one committee and, thereby, diluting the evaluative expertise that comes from different HTA committees. We strongly suggest a single front door concept be abandoned in favour of sector specific multi-stakeholder, expert advisory groups of related healthcare professionals, service providers, patient advocacy representatives, and the industry. The EAGs can complete horizon scanning and identify technologies that address unmet healthcare need or improve current outcomes.

Dr Sam Roberts, the CEO of NICE in the UK, shared with us her views on the future of HTA processes, saying for HTA to remain relevant it needs to be more timely, and measure the impact of its decision (for and against funding) on the healthcare system. Dr Robets reports that HTA in the UK has reduced the time for processing simple applications by 50% and all applications by 17% year on year. No such metrics are known for Australia and we are not aware of efforts to achieve improvements in timely path to patient of new technologies.

A further observation relates to companion diagnostics and the dilemma of technology innovation. We have observed instances where a therapeutic was developed, validated and verified (RTCs) against a diagnostic technology which has since been superseded. The subsequent funding for the therapeutic and the obligatory companion test was thus based largely on this superseded technology – often slow, expensive, and offered only in specialised labs. The consequence of this failure is that patients who would benefit often fail to be diagnosed effectively or in a timely way. There needs to be flexibility to more easily change to superior technology as and when it is included on the ARTG.

Similar flexibility and accelerated pathways are needed when evidence arises to enhance the use of an already MBS funded IVD outside of its existing claim. For example, the recent decision to fund one test per year in general practice of NT Pro-BNP for chronic heart failure. Latest evidence developed while this application was being processed through HTA overwhelmingly supports use of NT Pro-BNP as a monitoring test for a new treatment - requiring up to 6 tests within the first year to significantly reduce stage progression of patients at risk of heart failure. A fast-track process to focus examination on new evidence can avoid further, multiple-year delays for clinicians and patients to access advanced understanding and clinical management tools. The MBS Review could be a mechanism for this fast track, if it is appropriately prioritised.

3. Methods for HTA for Australian Government Subsidies

There are some specific points relevant to methods we suggest for consideration.

a) PICO should be agile enough to consider weighted evaluation of each component. For example, when considering an IVD comparator for a point of care test (POCT), it may not be suitable to choose a laboratory test, when in many cases across Australia the real alternative to POCTs is no test at all, as even if a laboratory test could be accessed, results are not timely enough to be effective. We believe the Outcome of PICO needs to be context based. The outcome for difficult to reach populations might be very different to the outcome for populations that can readily access traditional health services.

Use of Real World Evidence is also essential and needs to be fully defined. Economic, timely, and effective applications require communication of acceptable sources and data needs indicated for various target populations vs urban rural and remote, common disorders vs rare, etc.

4. Increased Transparency and Improved Access to HTA Processes and Outcomes

We generally support initiatives to improve public engagement in the HTA process and would support further application of these improvements across HTA for the full IVD sector.

We suggest this approach could inform the inputs of regular impact reviews for HTA decision making. Stakeholder engagement aids understanding and should lead to improved outcomes for patients and the healthcare economy.

The options paper mentions the concept of a processing time clock. It may be possible to model the device used by the USA FDA – our member base report this system is largely working well.