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RCPA
The Royal College of Pathologists of Australasia

22 February 2024

To: Department of Health and Aged Care
HTA Engage
Via Email: htareviewconsult@health.gov.au

Dear Department of Health and Aged Care,

RE: HTA Policy and Methods Review Consultation 2 – HTA Review Options Paper

Thank you for your email to the Royal College of Pathologists of Australasia, seeking our feedback on the Options Paper in Consultation 2, to inform the Reference Committee's final recommendations and report.

The HTA Review remains a medicine-centric document. Whilst there are common elements with the HTA MSAC/MBS process, the review remains focussed on the PBAC/PBS process. The College would welcome an overarching review of HTA in Australia that is inclusive of all health technologies, in particular diagnostics, but including devices, procedures and newer technologies such as cellular therapies and digital technologies.

Please see below our comments on different sections.

Transparency and communication of HTA pathways, processes, and decisions
Although the options are PBAC-centric, the College agrees that there could be improvements on the HTA webpage, which is often out of date. Searching the MSAC applications page is difficult and cumbersome to navigate.

First Nations people involvement and consideration in HTA
The first goal of the reform is stated as "deliver Australians equitable, timely, safe and affordable access to a high-quality and reliable supply of **medicines** for all Australians"; however, we believe that this should read "deliver Australians equitable, timely, safe and affordable access to a high-quality and reliable **healthcare**". This is especially relevant when the paper discusses access to medicines for First Nation Peoples. Equity of access of rural and remote individuals to all health technologies is an issue in Australia.
We agree with a First Nations Advisory Committee – data on need in Aboriginal and Torres Strait Islander peoples, where there may be the greatest need, is often missing in applications.

State and territory government collaboration in HTA
The College would welcome the development of a central standardised data-sharing system for utilisation and outcome data. We are often asked for data to support applications that are simply not accessible across jurisdictional boundaries, and between the public and private systems.

Streamlining and aligning HTA pathways and advisory committees
Unified HTA pathway for all health technologies with Commonwealth funding
This appears to be a sound idea; however, our concern is that it might add another layer of

complexity to an already long and complex process. MSAC takes an average of 2 years from submission date to MBS item number.

Development of a disease specific common model (reference case) for disease areas with high active product development

It would be beneficial to see this developed from a diagnostics/co-dependent point of view, especially in the cancer/genomics space. Genomic applications are currently submitted variant-by-variant or indication-by-indication, for example, BRCA variants in breast and prostate cancer, or numerous variants in non-small cell lung carcinoma. This approach is extremely time-consuming for applicants, the Department, the MSAC and HTA agencies, as well as consuming limited healthcare resources. A streamlined process to 'future-proof' new item numbers should be developed, making the addition of new variants easier and faster, negating the need to 'reinvent the wheel' with an HTA every time a new variant is identified.

This would be similar to the discussion in Item 3.2 *Clinical Evaluation Methods* "*Develop a guideline on the assessment and appraisal of tumour-agnostic therapies*".

Case manager

This is a terrific idea, however, staff turnover in the Department is an issue. There is a need for consistency in approach and advice.

Clinical Evaluation Methods

Pharmacogenomic technologies

Consideration needs to be given for pharmacogenomic applications that are applying for molecular testing for established drugs – not co-dependent applications – when diagnostic technology has "caught" up with the drug. For example, HLA sensitivity testing for carbamazepine – an established, old drug where a new molecular test is essential for patients exposed to it for the first time.

Selection of the comparator

Once more, with the PBAC-centric nature of this review, there is no mention of technologies that have no comparator. Genetic testing often meets an unmet clinical need in patients where no other testing options exist, and therefore there is no relevant comparator. There may be pathology tests listed on the MBS that may "point" to a potential issue in a patient, but when used in isolation would not lead to a definitive diagnosis and cannot be considered a true comparator.

4.3. Understanding the performance of health technologies in practice

The reimbursement of new and innovative technologies may be associated with significant risk because of uncertainty around the clinical evidence, cost-effectiveness, budget impact, price or the eligible patient population. To overcome these issues, many countries, including Australia, have adopted the use of managed entry or risk-sharing arrangements to expedite access primarily to pharmaceuticals, with final funding decisions contingent on the gathering of real-world evidence, and real-world data. This approach is rarely used for diagnostic testing however it was used to gather information about PET scanning when PET was first introduced into Australia.

Embracing interim funding or coverage with evidence decisions for health technologies other than pharmaceuticals would expedite patient access to diagnostic testing, improve equity of access and provide real-world Australian data (often lacking) around uptake and usage.

Therefore, the proposed Development of Guidance framework for the use of RWE/RWD would be welcomed. There is a plethora of peer-reviewed papers advocating the use of CED

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for diagnostics and devices.

5. Futureproofing

Establishment of horizon scanning programs

Australia had an active Horizon Scanning program for 14 years that was used to inform all the jurisdictions and the Commonwealth of potentially disruptive health technologies entering the health system. This program did not include a Horizon Scanning capacity for drugs, as it was felt that submissions to PBAC were timely. It did, however, inform the jurisdictions on new diagnostics, devices and procedures that could have a financial impact on the jurisdictions or deliver improved patient outcomes.

Horizon Scanning can also be used to inform on new and emerging, innovative health technologies but can identify new uses for existing technologies, as well as identify obsolete technologies. Additionally, it also responds to demand signalling by actively identifying the needs and key priorities/challenges of a health service, especially scanning and mapping groups of technologies in a clinical care pathway rather than just single technologies. Horizon Scanning feeds into managed entry agreements or accelerated access, where often the technology appears to be beneficial to patients, but robust evidence is lacking to support its full introduction into the health system.

5.5. Capacity and capability of the HTA system

The College would welcome initiatives to increase HTA capacity in Australia, especially a specialised HTA unit in the DoH.

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Sincerely,

Dr Debra Graves OAM
Chief Executive Officer