A joint submission to

The Health Technology Assessment (HTA) Policy and Methods Review

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This submission has been prepared jointly between Cancer Council Australia (Cancer Council), the Cancer Nurses Society of Australia (CNSA), the Clinical Oncology Society of Australia (COSA), Private Cancer Physicians of Australia (PCPA) and Medical Oncology Group of Australia (MOGA).

Cancer Council is Australia's peak national non-government cancer control organisation and advises the Australian Government and other bodies on evidence-based practices and policies to help prevent, detect and treat cancer.

Cancer Nurses Society of Australia is the peak national body for cancer nursing and strives to promote excellence in cancer care through the professional contribution of cancer nurses.

The Clinical Oncology Society of Australia is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients.

Medical Oncology Group of Australia is the national, professional organisation for medical oncologists and the profession in Australia.

The Private Cancer Physicians of Australia is the peak body for private cancer physicians (Medical and Radiation Oncologists and Haematologists), dedicated to improving outcomes for all cancer patients, but particularly those seeking treatment in the private sector.

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Introduction

Cancer Council, the Cancer Nurses Society of Australia (CNSA), the Clinical Oncology Society of Australia (COSA), the Medical Oncology Group of Australia (MOGA) and Private Cancer Physicians of Australia (PCPA) thank the Australian Department of Health and Aged Care (the Department) for the opportunity to participate in the first consultation of the Health Technology Assessment (HTA) Policy and Methods Review (the Review).

We welcome the opportunity to contribute to the Review to ensure the HTA process continues to provide Australians with access to quality therapeutic products and medical services while being sustainable, adaptable and responsive to changing therapeutic advances in cancer care. The Review is core to shaping the future of Australia's healthcare system and must be a priority for the Australian Government. The HTA plays a critical role in informing government funding of health technologies, including pharmaceuticals, and ensuring that funded technologies are relevant, cost effective, and safe. The HTA review and process also underpin national health policy decisions to ensure the Australian health system is well placed to address current and future demands while continuing to reflect best clinical practice with regard to new medicines and technologies.

The Review's primary aim is to reduce access time for Australian patients, so that they can equitably access new health technologies. This is a vital outcome, via expedited timing and, to ensure the HTA system evolves in tandem with key advancements in medical technology and research.

We note that the Review, the first in almost three decades, has bipartisan support and is a key part of the five-year Strategic Agreement signed in 2022 between Medicines Australia and the Federal Government. While we welcome the Review Committee's anticipated approach to recommend actionable short and long-term outcomes without the requirement for legislative changes, we are of the view that the Review Committee should also make recommendations for significant reform where required to ensure future access to best clinical practice.

Our submission addresses the aim of Consultation 1 to gather evidence or examples in relation to the objectives and Terms of Reference (ToR) of the HTA Review.

While being adaptable to changing clinical environments and patient expectations, the HTA process must remain transparent in its funding decisions and accountability to Australian taxpayers.

The ToR for this Review focuses on medicines. Our organisations suggest that a broader ToR for this Review is required to include all aspects of HTAs, including diagnostic tests, medical devices, implanted protheses, medical procedures and public health interventions.

Cancer is the highest burden of disease illness in Australia (1) and the challenges of sustainable funding and timely patient access to new medical products and services products within our publicly funded health system to respond to cancer are likely to continue. Advances in our understanding of cancer have aided the development of medicines, medical devices (including tests such as genomic profiling), and medical services, to enable the earlier detection of certain cancers and the availability of treatment options, many of which the Australian Government has funded. Although only accounting for 1.7% of all prescription medicines, 41% of the total expenditure on the Pharmaceutical Benefits Scheme (PBS) between 2019-2020 and 2020-2021, was spent on antineoplastic and immunomodulating agents, which includes anti-cancer therapies such as chemotherapy (2). This is likely influenced by the highly specialised nature of newer cancer treatment options.

It is our view that a revised HTA process should:

- Enable the revised National Medicines Policy
- Achieve sustainability for the Australian taxpayer funded health system
- Reduce the financial burden on individual Australians currently required to directly fund their cancer care while waiting for care to be subsidised
- Maintain patient access to best clinical practice
- Streamline and speed up assessment of joint submissions to the Medical Services Advisory Committee (MSAC) and the Pharmaceutical Benefits Advisory Committee (PBAC), where co-dependent technologies, such as tests for cancer targets, are being assessed at the same time as cancer medicines and
- Overall, achieve more timely access to treatments for cancer patients in Australia.

Consultation questions

1. **Elements and features that are working effectively**

The existing HTA process is well designed to assess large, population-wide diseases with large datasets and comparative evaluations. This process has enabled treatments for common cancers such as breast, lung, prostate, colon and melanoma, but is limited in its ability to make these treatments available in a timely way or assess products targeted to smaller disease groups. Rather than treating cancer based on its anatomical location alone, new and emerging cancer medicines target specific markers identified within the cancer. These products benefit a smaller number of people and often at a higher cost which can affect funding decisions. The significant benefits to people affected by cancer offered by these products need to be considered within the HTA assessment. There have been several inquiries and reviews in the past decade into the medicine, medical devices and medical services approval and reimbursement pathways however the same challenges remain and require bold process and policy change.

2. Current or future barriers to earliest possible access

The rise of innovative therapies is putting pressure on the reimbursement process to be more flexible and adaptive to the complexity of more targeted/personalised medicines. Innovative, biological medical products targeting human immune factors are commonly referred to as 'high-cost drugs' because they are complex and costly to develop and typically benefit a small sub-group of people with cancer (amongst other diseases). Their specialised nature restricts the market of patients who will benefit, which impacts the attractiveness of the commercial market to sponsors. These products often provide patients with several benefits in addition to survival such as reduced side effects, leading to better quality of life and greater chance of participating in their usual (pre-cancer) activities. Assessing new and emerging cancer medicines is challenging because the clinical studies accompanying these applications have uncertain data outcomes and may not yet be subject to real-world environments. Traditional comparators are likely older, cheaper cytotoxic medicines which while remaining effective in many circumstances do not work for all patients and introduce undesirable side effects. It is in this context that the HTA processes and policies should be reviewed, providing more specific guidance for applicants and regulators to support the accessibility of clinically effective and patient-focused products earlier, without introducing rigidity into the health system.

In our view, the focus of the HTA Review should be enabling "earliest possible access". Individuals with cancer cannot wait for subsidised access to valuable new medicines which increase the chance of cure, extend survival time and/or improve their quality of life. In June of this year (2023) data will be presented at the American Society of Clinical Oncology annual meeting that demonstrates the use of osimertinib in the adjuvant (after surgical resection) setting substantially improves overall survival for EGFR mutated non-small cell lung cancer. Osmertinib is currently funded in Australia when used as first line treatment for patients with metastatic EGFR mutated non-small cell lung cancer (3). For the adjuvant indication, osmertinib is currently only accessible through a company sponsored program with a cost to the patient of approximately $140,000 for 3 years treatment. Given its effectiveness, the barrier to timely, affordable access will be in the cost negotiation process between the industry sponsor and the Australian Government. To address this, a mechanism for the PBAC to make recommendations for immediate access for medicines that substantially improve survival while the final price is being negotiated between the medicines developer and the Australian Government could be introduced.

Providing the earliest possible access to high-cost products and products where the evidence is still being established requires greater use of risk sharing arrangements, between the product's developer and the Australian Government, such as Managed Access Programs. Such arrangements could see earlier patient access while the product's developer provides ongoing reporting of the product's outcomes. This was recommended by the House of Representatives Standing Committee on Health, Aged Care and Sport in their inquiry into approval processes for new drugs and novel medical technologies in Australia. Recommendation 10. 11:11 of their report states *"the Australian Government amend the National Health Act 1953 (Cth) to give the Pharmaceutical Benefits Advisory Committee the power to authorise Managed Access Programs. The eligibility criteria for these Managed Accessed Programs should be aligned, as far as possible, with the eligibility criteria for the Therapeutic Goods Administration's provisional registration"* (4). For products that aim to fulfill a significant unmet need, and where evidence is promising but remains uncertain, robust, pre-planned post-approval data collection should be implemented with the aim of meeting the evidence requirements for a full PBS listing. In these arrangements, consideration must be given to the implications for withdrawing support where the real-world effectiveness does not demonstrate efficacy. Other risk sharing opportunities between the Australian Government and the product's sponsor should be explored in this Review.

A significant challenge to the HTA process is that the product under review for reimbursement can only be considered for the indication for which it is listed on the Australian Register of Therapeutic Goods (ARTG). There are several products registered on the ARTG for the treatment of cancer and its side effects where their indication for use as best clinical practice is not registered, and therefore the products cannot be considered for reimbursement. This limits timely, affordable access to best practice care for Australians with cancer. Some examples include:

- Dacarbazine is recommended for curative intent treatment of Hodgkin's Lymphoma (5), however the ARTG registered indication is for the treatment of metastatic malignant melanoma and various sarcomas (6).
- Mitomycin C, in combination with radiotherapy and fluorouracil (5FU), is recommended for the curative treatment of patients with anal squamous cell carcinoma (7) and transitional cell carcinoma of the bladder (8). However, mitomycin is registered for the palliative treatment of carcinoma of the stomach, pancreas, colon, lung (non-small cell), breast, cervix, head and neck, liver and bladder (9).
- Olanzapine is an antipsychotic medication registered on the ARTG for the treatment of schizophrenia and related psychoses; short-term treatment of acute manic episodes associated with bipolar disorder; and, preventing recurrence of manic, mixed or depressive episodes in bipolar disorder (10). International guidelines recommend its use in treating refractory anti-cancer therapy induced nausea and vomiting, in addition to appropriate preventive treatment (11-14).
- Infliximab has several registered indications related to the management of inflammatory disease, this does not extend to managing inflammatory toxicity caused by immunotherapy, such as immune checkpoint inhibitor related colitis, as recommended by national and international guidelines (7, 15).
- Zoledronic acid is used to prevent bone metastases in women with early breast cancer who are postmenopausal. MOGA, PCPA and consumers advocated with a generic medicines

company, to make a submission to have the product listed on the PBS, as the patent was expiring. The medication is not high cost, but not being PBS listed means that few hospitals provide it.

- The TGA indications limit permissible combinations of nicotine replacement therapy (e.g. 2mg nicotine gum or 2mg nicotine lozenge together with nicotine patch) and/or restricts dosing of faster-acting formulations when used in combination with the nicotine patch (e.g. nicotine mouth spray max of 32 sprays/day). Therefore, clinical guideline recommendations for using higher strength gum and lozenge (4mg) and other faster-acting formulations (at higher doses) together with nicotine patch may not be aligned with TGA indications and therefore cannot be considered for reimbursement for the optimal indication, limiting consumers access.
- The test for a person's DPYD gene status prior to 5-F fluorouracil (5-FU) based chemotherapy is not funded. 5-F fluorouracil (5-FU) based chemotherapy is used to treat several different cancer types and knowing a person's DPYD status prior to receiving chemotherapy may save a patient serious toxicity including admissions to hospital with severe diarrhoea. This side-effect can be more effectively managed through chemotherapy dosing when DPYD status is known.

These examples demonstrate missed opportunities to ensure optimal and accessible care is delivered in both clinically appropriate and patient appropriate environments.

eviQ provides evidence-based information to support health professionals in the delivery of cancer treatments and underpins how quality cancer care is delivered in Australia. A medicine is often only included within an eviQ guidance and implemented into clinical practice once it is listed on the PBS.

In the short term, the Department and PBAC should be able to request that the TGA review and extend a product's indication where it may address a significant unmet need. Longer term, consideration should be given for a single approval entity or review to facilitate streamlining of approval processes, and processes for extending indications between the MSAC and PBAC processes.

3. Current or future barriers to equitable access

Currently some medical products and services to meet the needs of cancer patients are not funded by the Australian Government, leaving patients and their families to decide between forgoing treatment or paying significant out-of-pocket costs. This is not only a challenge for patients, but also to doctors in presenting the treatment options and the cost of different treatment options to patients and their families who may go into financial stress trying to afford recommended treatment. Cancer medical professionals report feeling uncomfortable discussing unfunded treatment options with their patients and are conflicted about presenting these options to their patients especially when it could cause significant financial strain (16). More than two-thirds of medical and radiation oncologists and haematologists who responded to a survey at the PCPA's Annual Scientific Meeting in May 2023, agreed or strongly agreed with the statement, 'If I think a patient is struggling financially, I don't raise the option of unfunded co-pay programs' (17).

Existing HTA policy enables the process for assessing a product for registration and reimbursement to be conducted in parallel. However, there is currently no obligation or requirement for a co-dependent

technology associated with the effective use of a medicine to be assessed for registration or reimbursement. If a test is not subsidised a patient must pay for this co-dependent test out-of-pocket which can render treatment overall unaffordable and inaccessible. Co-dependent technologies associated with the improved health outcomes should be required to be assessed at the same time as the medicine or medical service for which its use is associated.

Identifying biomarkers assists with treatment decisions and in some circumstances are required to prescribe certain medicines. The use of pembrolizumab for head and neck cancer requires a patient to have a Combined Positive Score (CPS), a more complicated PD-L1 score. While the test for PD-L1 to inform the use of pembrolizumab in head and neck cancer patients is funded, the test for CPS is not funded. While in practice the cost of this test may be being covered by the funded PD-L1 MBS item number, doctors may be reluctant to seek a CPS test because there is no standalone item number.

Separately, while the same molecular target can be detected across different cancer types, current HTA process requires that evidence for effectiveness is reviewed for each indication. For example, pembrolizumab targets the PD-L1 protein and in Australia the test is funded for use only when a patient is diagnosed with non-small cell lung cancer or recurrent or metastatic squamous cell carcinoma of the head and neck (18).

This Review could explore the feasibility of introducing a fast-tracked pathway to assess evidence to extend the use of a targeted medicine. If the indication is subsequently funded, cancer patients would benefit from earlier access to the medicine and without significant financial cost while ensuring funding decisions remain based on critical analysis. This point is similarly recommended within the House of Representatives Standing Committee on Health, Aged Care and Sport's inquiry into approval processes for new drugs and novel medical technologies in Australia that (Recommendation 13, 11.4) *"The Department of Health reform its regulatory and reimbursement processes to enable therapeutic goods to be registered and reimbursed, by molecular indication in addition to by disease indication. This should include legislative change if necessary"* (4).

This Review should consider the feasibility of publicly-funded comprehensive genomic profiling for people diagnosed with cancer. This would provide patients and doctors with information to direct care earlier and avoid the need for single gene tests. This may require HTA processes outside the conventional MSAC or PBAC pathway, similar to the assessment of CAR-T, a cell therapy that was recommended by MSAC but is funded through the National Health Care Agreements. PCPA has several patient stories that demonstrate the impact of genomic profiling on cancer outcomes and experiences which can be provided on request.

Radiation therapy can provide significant benefits to cancer patients and can cost significantly less. It can improve patient outcomes when used alongside other treatments, or as a standalone treatment for some cancers. Radiation therapy advances typically relate to incremental changes in both hardware and software, that is, technology and technique changes but such changes are not well assessed under the current HTA process. Because the changes are incremental the gains are often small, however over time with more and more change the benefit becomes more substantial. This disincentivises the prompt implementation of improved techniques or technology and can mean patient access can be years behind what is optimal. Also, in the current process the defined

comparator technology can become outdated and suboptimal making it challenging to demonstrate a significant gain and cost-effectiveness.

Some radiation therapy requires the use of a prosthesis. In this setting, whether someone has private health insurance and the appropriate coverage, or not, can influence the affordability and accessibility of radiation therapy. The rebate associated with the MBS item number pays towards the proceduralist in a private hospital but then the prosthesis, for example prostate seed implants, or hydrogel to inject into the space between the prostate and the rectal mucosa (to spare the rectum from a high radiation dose), may come under private health insurance. If the patient does not have private health insurance, public hospitals will not pay this cost. This reiterates our earlier point regarding all services and products involved in delivering best care be assessed at the same time.

5. Disincentives

In our view, the most critical and challenging areas of patient access to appropriate medicines and medical devices in cancer, are the lack of commercial incentives for a sponsor to register or apply for reimbursement of their therapeutic product, especially for new indications; and the limited ability for non-commercial sponsors to access the evidence required to submit an application for a medicine, medical device or medical service for reimbursement. Even when a non-commercial sponsor makes an application, price negotiations require the product's developer to agree with the Australian Government on its price. This is another critical point which can limit patient access.

For products with an existing ARTG listing, the PBAC or Department could initiate a review to subsidise products that would fulfill a significant unmet need for Australians. Regulators could therefore play an active, rather than passive role, in enabling Australian's timely and affordable access to safe and effective medicines. It would also address the challenges non-commercial sponsors have in having the expertise and funding to meet ongoing conditions of approval. However, for medicines and medical devices this process still begins with the product's registration.

Although focussed on product registration, suggestions for attracting reimbursement applications identified through the Repurposing of Prescription Medicines consultation conducted by the TGA in 2022 could also direct reimbursement opportunities. The key parameters to include are:

- The sponsor remains responsible for post-market requirements including pharmacovigilance as non-commercial organisations are not likely to have the necessary financial resources, expertise and infrastructure.
- Require the applicant making a submission for registration to also submit to the PBAC to have the product reimbursed.
- Make it an obligation that the medicine's original sponsor submits evidence to extend the indication and subsequent reimbursement as it emerges.
- Initiate a fee relief assessment based on pre-determined criteria.

Reducing reliance on sponsor-initiated applications should be explored by this Review. Policy to enable the Department and the PBAC to proactively identify products for reimbursement is one opportunity. Another is Recommendation 9, 11.10 from the House of Representatives Standing Committee on

Health, Aged Care and Sport's report from their inquiry into approval processes for new drugs and novel medical technologies in Australia which stated *"The Committee recommends that the Australian Government establish a fund to support patients, clinicians and non-profit organisations to sponsor registration and reimbursement applications where there is no realistic prospect of a company serving as sponsor, and where the Department of Health is otherwise supportive of the application."* (4)

6. Areas for further investigation or analysis

As part of the Review, it is important that new concepts are tested for feasibility to ensure that the outcomes and recommendations from this Review do not inadvertently entrench existing inequities and/or lower the value placed on new technologies.

Government expenditure in health and healthcare in Australia must be viewed as an investment. Decisions to make this investment should reflect improvements in clinical outcomes and the outcomes important to Australians. Consideration should be given in assessment processes to the negative impact to patients when decisions are made not to fund technologies or the regulatory hurdles delay patient access.

All submissions for funding of new technologies should demonstrate evidence of clinically relevant benefits and patient relevant outcomes, such as improvement in overall survival and quality of life. Regulators should encourage evidence of additional patient relevant outcomes to be submitted such as patient preferences for one treatment over another (through better integration of the patient perspective and experience in submissions), ability to return to work or other meaningful activity, and beneficial effects on family and/or carers. By better integrating outcomes important to the patient the evidence in favour of funding would be stronger for some interventions. There is evidence that the use of sotorasib to treat advanced/metastatic KRAS G12C mutated non-small cell lung cancer is equivalent to chemotherapy (docetaxel) as second line treatment in terms of overall survival. Ignoring its costs, sotorasib is preferred by patients over docetaxel due to their side effect profiles and improved or maintained quality of life (19). In March 2022 the PBAC considered listing sotorasib but it was not recommended. The PBAC assessed that while it was likely that sotorasib provided some clinical benefit over docetaxel, the magnitude of the benefit was highly uncertain and the proposed price was unacceptably high (20). If the HTA process gave more consideration to patient preferences in the assessment, sotorasib may be an intervention that becomes worthwhile funding.

The PBAC can assess evidence from other sources than randomised clinical trials to inform their recommendation. This could be more explicitly set out in the PBAC guidelines. Section 2 of the existing PBS guidelines currently says, *"Clinical evaluation. Provides the best available evidence comparing the clinical performance of the proposed medicine with that of the main comparator (preferably from direct randomised trials, or, if these are not available, from other suitable trials or studies). Concludes with a therapeutic conclusion stating whether the proposed medicine is superior, noninferior or inferior to the main comparator, taking account of any differences between the trial population and circumstances of use, and those proposed for the listing (applicability)"*(21). This is not well promoted and the process is still not consumer focused. Additionally, applicants could be encouraged and supported to submit patient reported outcomes and experiences.

Similarly, the Review should identify opportunities for patient outcomes from clinical trial data to be presented to the PBAC in a clinically meaningful way. Inviting clinical trial participants to speak directly to the PBAC about their experience may be another option however, this would likely be restricted to commercially sponsored applications, as non-commercial sponsors are unable to access clinical trial participants. Other opportunities to improve patient engagement with the HTA process could include a more person-focused online submission process which has standardised questions to capture the elements of their experience patients want to share to support the PBAC in their assessment. Promotion of the consumer portal to clinicians could increase wide professional views to be considered in the assessment process.

Rare Cancers Australia and Canteen recently undertook an analysis of the broader value of improving survival and quality of life for people living with non-curative cancer, as well as the burden caused by the death of a loved one to cancer (22). It found that over the course of five years, investment in new technologies, therapies, and services to extend the prognosis and quality of life of people with non-curative cancer can return $3.17 billion of social value. The Review should consider how such benefits could be incorporated into the cost-effectiveness assessment.

Resources are needed to address the gap between health technology development and its successful implementation. This includes a coordinated independent national molecular tumour board to discuss complex results from sequencing to guide optimal therapy, to bridge the gap between health technology development and successful implementation. Support for funding of biomarker/Next Generation Sequencing or genomic profiling to guide modern treatment is critical as well as education of clinicians to interpret increasingly complex and multifaceted biomarker panels (panel Next Generation Sequencing, fusion, immunohistochemistry) in tumour and liquid biopsy settings would be of value.

As the Review is exploratory in its approach, the Committee could explore the appropriateness and impact of capped funding programs for certain high-burden diseases such as cancer, and for example the Cancer Drugs Fund in the UK, on aiding timely access to cancer medicines.

7. Other details of importance to the HTA Policy and Methods Review not covered above + document / attachment upload point.

Australia is a party to several international human rights law treaties that impose obligations to advance the right to health which includes access to essential medications, health technologies and services, especially for vulnerable or marginalised groups (23). Australia has also made several commitments under international agreements and frameworks to reduce financial hardship and out-of-pocket costs related to healthcare by advancing universal health coverage (24, 25). Australia has voluntarily committed to comply with these instruments in good faith and to take the necessary steps to give effect to these commitments. The recommendations set out in this submission would help Australia in its commitment to advance the right to health and ensure universal health coverage.

To offset the cost to the health budget of innovative but expensive medicines and other high-cost products, effective policies could be used to drive the uptake of biosimilar medicines including ensuring patients and their healthcare professionals are educated and incentivised to opt for the more

affordable biosimilar medicine, when it is appropriate. The decision of which option to choose must always remain that of the clinician and their patient.

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