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Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Re: Senate Inquiry into rare and less common cancers, including neuroendocrine cancer

Dear Committee Members

AstraZeneca welcomes the Senate Inquiry into equitable access to the diagnosis and treatment of individuals with rare and less common cancers, including neuroendocrine cancer, and thanks the Committee and the Government for the opportunity to provide our perspectives on the unique challenges cancer patients and their families face. In making a submission, our aim is to ensure every Australian diagnosed with cancer receives diagnosis, treatment and care regardless of their cancer type, age, stage of disease, ethnicity or location.

About AstraZeneca

AstraZeneca is a global biopharmaceutical company that has been operating in Australia for 60 years employing more than 800 people across Australia and New Zealand. Our mission is simple. We are striving to eliminate cancer as a cause of death.

We have over 100 individual medicine indications listed on the Pharmaceutical Benefits Scheme (PBS) and a large pipeline of treatments that will continue to improve the lives of many Australians.

Our oncology medicines include treatments for breast, ovarian, lung, gastro-intestinal, genito-urinary and blood cancers – many for rare cancers, such as biliary tract cancer – an aggressive and incurable cancer in the bile duct, sub-types of cancer such as BRCA-mutated ovarian cancer, and pancreatic cancer.

AstraZeneca is among the largest investors in cancer clinical trials and research in Australia with 96 active trials across 79 sites. We are also one of the largest pharmaceutical manufacturers in Australia with a manufacturing site in North Ryde Sydney employing approximately 300 people and supplying medicines to 18 countries across southeast Asia, Europe, China and Japan

About Our Submission

Despite a decade of advocacy, inquiries and reports, Australians living with rare and less common cancers do not have the same access to diagnosis, treatment and care as those with more common cancers. This can lead to later diagnosis of their disease, poorer prognosis and survival outcomes.

This submission will address:

1. Barriers to accessing screening and diagnosis for patients with rare cancers and rare sub-types of more common cancers
2. Barriers to accessing appropriate treatment and specifically, funded access to innovative cancer medicines

RECOMMENDATION 1

Funded access to comprehensive screening and genomic testing for a broader range of cancers beyond the most common cancers

Symptoms of rare and less common cancers can be unusual or unremarkable and as a result are less well known to doctors than symptoms of more common cancers. Doctors often investigate other causes for the symptoms first, leading to delayed diagnosis and/or misdiagnosis. A patient may need several tests and to see more than one specialist to confirm a diagnosis. For patients with cancer, the right test and the right treatment at the right time are critical to optimal patient outcomes. For example, 95% of people with pancreatic cancer will die of their disease because during the early stages when the disease is most treatable, there are usually no symptoms.

Access to screening and cancer genomics will enable faster and more accurate diagnosis, early intervention and identification of patients who may benefit from targeted therapies. This will ensure more efficient use of medicines by preventing ineffective use of therapies on patients in whom they do not work and overall, will improve outcomes for cancer patients, including those with rare and less common cancers.

This recommendation aligns with the New Frontier report from the '*Inquiry into approval processes for new drugs and novel medical technologies in Australia*' that recommended the Australian Government establish a Centre for Precision Medicine and Rare Diseases within the Department of Health[1].

ACTION REQUIRED:

1. Increase investment in broad and routine screening for a wider spectrum of cancer types. Earlier detection and diagnosis are key to improving survival chances and reducing the future burden of cancer.
2. Streamline PBAC and MSAC processes used to evaluate the co-dependent technologies and diagnostics used to confirm a cancer diagnosis and identify patient sub-types and invest in more qualified resources to undertake the evaluations.
3. Increase access to genomic testing – cancer genomics are a key component of precision medicine providing more accurate clinical information to guide clinicians in their treatment decisions. Investing in a coordinated national approach to genomics in cancer care is critical to improving outcomes for Australian cancer patients.
4. Invest in broad health education for healthcare professionals and the community on the symptoms of rare and less common cancers by providing funding for specialised Health Consumer Organisations to enable them to undertake awareness raising activities.

RECOMMENDATION 2

An alternative methodology for evaluating cancer medicines, as the current criteria disadvantages patients with rare and less common cancers

Securing government reimbursement for medicines targeting rare cancers presents a distinct set of challenges. Limited clinical data due to the rarity of these cancers can hinder the assessment of a

[1]https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Newdrugs/Report/section?id=committees%2freportrep%2f024755%2f77380

treatment's effectiveness, often leading to uncertainty among health authorities. High costs associated with discovery, clinical research and development, coupled with the small patient population, make it challenging to obtain sufficient clinical evidence to prove the efficacy of the medicine, causing hesitancy in reimbursement decisions.

The lack of standardised criteria for evaluating the value of treatments for rare cancers and rare sub-types of more common cancers further complicates matters. Traditional reimbursement frameworks do not adequately capture the unique benefits these therapies offer to patients with limited alternatives. Additionally, budget constraints within the healthcare system may lead to difficult choices regarding which treatments to fund.

The consequence of wrestling with these challenges is time. Australian patients wait too long for access to cancer medicines. People with rare and less common cancers – many of whom are diagnosed with advanced or metastatic disease do not have time on their side. For example, people with advanced biliary tract cancer (BTC) - a rare and devastating cancer with one of the worst survival rates of all cancers in Australia – have a median survival of less than one year, which means they may not live for the time is takes from TGA registration to reimbursement of a medicine that may help them.

The Medicines Australia, Medicines Matter 2022 report indicated Germany, Great Britain, Austria and Japan reimbursed an average of 80.5 more new molecular entities (NMEs) between 2016-21 when compared to Australia, and more than 70% of medicines in Germany, France, Japan, and the UK were reimbursed within six months, compared to only 17% of medicines in Australia.

ACTION REQUIRED:

Establish a dedicated approach within the HTA system for evaluating cancer medicines to deliver faster and fairer access to cancer therapies as the current criteria disadvantages patients with rare and less common cancers because the threshold for proving the clinical benefits and cost effectiveness is too high, making the system inherently inequitable. This must include:

1. Adjusted evidence needs for rare and less common cancers as HTA evidence requirements and methods often do not reflect the data available for these cancers
2. A framework for the use of real-world evidence
3. Broader considerations of value including downstream societal and economic benefits such as workforce participation, productivity and reduced need for social services
4. Increased patient engagement, particularly at early stages of the HTA process
5. Enhanced coordination between TGA, PBAC and MSAC processes
6. Improved risk-sharing between Sponsors and the Government
7. Greater collaboration between Sponsors, evaluators and discussants

RECOMMENDATION 3

Establish an interim cancer drugs fund for medicines immediately following registration with the Therapeutic Goods Administration (TGA) to enable faster access for patients with rare and less common cancers, and those with metastatic disease

As part of reviewing the way cancer medicines are evaluated and accessed, we recommend an interim funding mechanism for cancer medicines in Australia. Such a fund could be similar to the Cancer Drugs Fund in the United Kingdom, which was introduced in 2011 to improve patient access to cancer drugs

prior to the anticipated reform of the country's reimbursement arrangements for branded medicines undertaken at the end of 2013

An interim fund for medicines for high priority cancer patients – such as those with advanced and metastatic disease with poor prognosis, and those for whom there are no other treatment options - offers numerous benefits. The fund would expedite access to innovative treatments for these cancer patients, providing equitable access regardless of a patient's type or stage of disease and ability to pay prior to reimbursement. An interim fund with specific criteria provides consistent and predictable funding for these medicines, reducing uncertainties for clinicians and their patients. Ultimately, it demonstrates a commitment to improving cancer care and aligns with public health goals of providing fair and equitable access to medicines for all cancer patients.

ACTION REQUIRED:

1. Establish a multi-stakeholder working group to propose the funding mechanism and framework, similar to the process established for the first national Australian Cancer Plan. The group would consider a risk-sharing framework and potential risk management plans as part of their proposal.
2. Evaluate dedicated cancer funds being managed successfully by our international counterparts in comparable HTA markets to understand how they address the unique challenges of rare and less common cancers and the measures and safeguards that have been put in place to ensure long term sustainability.

AstraZeneca is grateful for the opportunity to provide our input to this Senate Inquiry. We believe all Australian cancer patients should have fast and fair access to the treatment and care they need to improve their chances of living longer and living well. No patient should be left behind.

We are committed to working constructively with the Government and all key stakeholders to reform our healthcare system for the benefit of the Australian people and society. If you have any questions about our submission or we can be of further assistance to the Inquiry please contact Christine Jones, Head of Corporate Affairs, Oncology on Christine.jones@astrazeneca.com

Yours sincerely,

Benjamin McDonald

Country President

AstraZeneca Australia and New Zealand