

2025-26 PRE-BUDGET SUBMISSION

29 January 2025

AstraZeneca welcomes the opportunity to make a submission to the Commonwealth Government ahead of the 2025-26 Federal Budget.

AstraZeneca is a global biopharmaceutical company employing more than 90,000 people globally and 1,000 people across Australia and New Zealand. AstraZeneca is a science-led and patient-focused company committed to transforming healthcare and contributing sustainably to people, society and the planet.

Our therapy areas are focused on oncology; cardiovascular, renal and metabolism; respiratory and immunology; and rare diseases. AstraZeneca is among the largest investors in clinical trials and research in Australia. We currently have 119 active clinical trials in Australia, involving over 1500 patients and more than 160 sites. We are one of few pharmaceutical manufacturers in Australia, and have been manufacturing in North Ryde, Sydney, for over 60 years.

Focused on the planet, we are taking bold action on climate change with initiatives that include ambitious science-based decarbonisation targets; manufacturing our medicines in a more sustainable and efficient way; and restoring local ecosystems through partnerships.

AstraZeneca believes that healthcare policy reform that ensures earlier, faster and fairer access to medicines in Australia should be considered as a core priority for government. By improving our healthcare system, Australians would be diagnosed earlier and have faster access to treatment and care in a more equitable system, to deliver overall better health outcomes for patients and preventing future costs to the health system.

We have identified three areas of focus and six key recommendations for consideration by the Government that would improve Australia's access to healthcare:

Reforming healthcare to ensure fairer access to diagnosis and therapies:

1. Establish a bridging funding mechanism as recommended in the Health Technology Assessment (HTA) review to bridge the funding gap between registration and reimbursement where there is a time-critical, high unmet clinical need, ensuring Australians have faster access to the best available treatments.
2. Establish comprehensive genomic profiling for all Australians diagnosed with cancer, including a National Test Directory, to enable timely access to precision medicine, and enable equitable access to genomic information by de-linking the funding of testing from treatment.

Transforming health outcomes through earlier diagnosis and faster access through targeted, disease specific initiatives:

3. Develop a national target to test and treat 1 million people at-risk of chronic kidney disease (CKD) by 2030 and increase the diagnosed and treated population from 10% to at least 50%.

4. Develop a National Chronic Obstructive Pulmonary Disease (COPD) Program to provide ongoing support for the implementation, uptake and evaluation of COPD Clinical Care Standards, in alignment with the implementation of Lung Foundation Australia's COPD Blueprint 2022-25¹.
5. Commit to improving psychosocial support for those living with metastatic breast cancer (mBC) and providing greater training and access to the nurses and psychologists providing this care.

Health infrastructure and sovereign capabilities – health sector manufacturing policy and initiatives:

6. Build Australia's economic resilience, competitive edge and security outcomes by developing a unified, cohesive and intentional approach to prioritise the Australian life sciences industry.

RECOMMENDATION 1

Establish a bridging funding mechanism as recommended in the Health Technology Assessment (HTA) review to bridge the funding gap between registration and reimbursement where there is a time-critical, high unmet clinical need, ensuring Australians have faster access to the best available treatments.

Australian cancer patients wait 442 days (nearly 15 months) on average between a potentially life-changing cancer medicine receiving approval from the Therapeutic Goods Administration (TGA), and that medicine being reimbursed through the Pharmaceutical Benefits Scheme (PBS)². This length of time is **two months longer** than the average wait time of 384 days across all 20 OECD countries³.

Many patients do not have this time to wait, as an advanced cancer diagnosis may result in a much shorter prognosis of six months or less. In Japan, registration to reimbursement takes just 102 days, 136 days in Germany and 156 days in Great Britain⁴. This means that Australia's average waiting period is **almost a year longer** than these comparable OECD countries.

Cancer remains the biggest health cost in Australia, and Australia's greatest disease burden with more than 151,000 Australians being diagnosed every year⁵. On average, 135 Australians die of cancer every day, resulting in approximately 49,000 cancer deaths in Australia each year⁶. One million Australians are currently living with, or have previously had, a cancer diagnosis. Demand for basic cancer services (such as access to an oncologist) is increasing and is expected to increase by 50% in the next 20 years⁷.

With a dedicated budgetary allocation, interim government funding would bridge the gap between the time a medicine is registered with the TGA and the time it is reimbursed on the PBS, for medicines where there is a high unmet need and where patients cannot afford the time for the medicine to be listed on the PBS.

Bridging funding would help these time-critical patients gain earlier access to cancer medicines that may save or significantly extend their life at the time of TGA registration, so that they can access the medicines they need as soon as they are deemed safe and effective to use.

¹ Lung Foundation of Australia COPD Blueprint 2022-25 https://lungfoundation.com.au/wp-content/uploads/2022/11/LFA_COPD-Blueprint_Print-V2.pdf

² Medicines Australia. Medicines Matter 2022: Australia's Access to Medicines 2016-2021

³ Ibid

⁴ Ibid

⁵ Australian Institute of Health and Welfare. Cancer in Australia 2021

⁶ Ibid

⁷ Breast Cancer Network Australia. Making Metastatic Breast Cancer Count: No Longer Hidden in Plain Sight

This would ensure Australians receive access to the best available treatments, and that Australian healthcare does not lag behind other OECD countries.

Investing in new cancer treatments as soon as they are approved would deliver significant downstream social and economic benefits, such as higher workforce productivity and reduced need for government-funded support services, as well as cost savings to the health system. Research shows that for every \$1 invested in cancer treatments in Australia, there is \$3.06 of social and economic value created⁸.

Bridging funding is Recommendation 20 of the HTA review report, released in September 2024⁹. AstraZeneca believes bridging funding from the time of TGA registration should be one of the immediate outcomes of this review to enable faster access to medicines that patients need in the face of a cancer diagnosis.

In addition to the HTA review recommendations, broad support for faster access to medicines has continued to gain significant momentum among health, policy and patient experts. The Bridging Funding Coalition – a group of more than 20 oncology experts from across Australia – launched a national consensus statement in support of bridging funding in November 2024. The guiding principles agreed in the consensus statement can be found on the [Bridging Funding Coalition website](#).

RECOMMENDATION 2

Establish comprehensive genomic profiling for all Australians diagnosed with cancer, including a National Test Directory, to enable timely access to precision medicine, and enable equitable access to genomic information by de-linking the funding of testing from treatment.

Australia has been slow to adopt genomic technology as standard of care. Genomic tests that detect subtypes of cancer are currently only evaluated for reimbursement if they are linked to a medicine to treat that type of disease. This limits the ability for patients to seek precision medicine treatments and to understand more about what is driving their disease.

Cancer treatment is rapidly transforming, with technological advances enabling the personalisation of medicines and healthcare

Genomic testing enables rapid diagnosis, early intervention, and targeted therapies for cancer. Genomic testing can provide an accurate cancer diagnosis and predict how cancers may respond to treatment. Genomic testing allows for a more targeted approach in clinical decision making by providing insights into the molecular basis of a patient's disease. Genomic testing provides improved insights to a patient's genetic profile, enabling personalized care that benefits patients while improving the health economic value of the medicines used within the community.

Government-funded genomic testing in Australia is only available for some patients through a limited number of programs or services. Comprehensive genomic profiling would enable fairer access to precision medicines. Undertaking genomic testing for every cancer patient at the point of diagnosis would allow treatments to be optimised (including the monitoring and order of treatments) based on the characteristics of a patient's disease, resulting in more efficient use of medicines.

⁸ Rare Cancers Australia & Canteen, Counting the cost: How we can assess the true value of investing in cancer treatment (Report, 2023), 7.

⁹ <https://www.health.gov.au/resources/collections/hta-review-final-report-collection>

RECOMMENDATION 3

Develop a national target to test and treat 1 million people at-risk of chronic kidney disease (CKD) by 2030 and increase the diagnosed and treated population from 10% to at least 50%.

Chronic kidney disease is one of Australia's biggest health problems and is a silent killer. It affects two million Australians – with only 10% of people with the disease diagnosed. This means an estimated 1.8 million Australians do not know that they are living with CKD¹⁰.

Up to 90% of kidney function can be lost without symptoms¹¹, making CKD a silent disease. This means that many Australians remain undiagnosed with CKD until it reaches a late stage, at which point there are limited treatment options. This late diagnosis not only leads to poorer patient outcomes but also imposes significant financial hardships and restrictions on their work, family, and social life.

Three in four Australian adults are at risk of CKD¹², while one in ten have early biomarkers of the disease. CKD is interconnected with diabetes and cardiovascular disease, and at least 40% of people with diabetes will develop CKD in their lifetime¹³. CKD disproportionately affects Aboriginal and Torres Strait Islander communities and is 2.1 times as prevalent amongst First Nations people¹⁴. Older Australians and those in remote areas are also at greater risk.

In 2022, 22,000 Australians died from CKD¹⁵. 19% of hospitalisations in Australia and 12% of all deaths are kidney related¹⁶, and CKD is estimated to cost the Australian economy \$2.3 billion per year. Late-stage treatment, such as dialysis and renal replacement therapy, cost the health system \$1.9 billion a year¹⁷. Dialysis demand has surged dramatically, more than doubling over the past 20 years, and projected to soar. The prevalence of CKD is anticipated to affect over 3 million people by 2032¹⁸. This growing epidemic is poised to place immense strain on state and federal health systems, stretching health budgets to their limits and impacting communities nationwide.

CKD is detected through a Kidney Health Check which involves a blood pressure check, a blood test, and a urine test. A Kidney Health Check is quick and simple and can be done as part of a regular check-up with a GP. If CKD is diagnosed early, targeted treatments are available on the PBS that may slow the progression of kidney disease.

Early detection and treatment are critical to slow the progressive decline of the kidneys. This is also a lower cost option compared to late-stage treatment, such as dialysis and renal replacement therapy. However, testing rates are low in Australia, and there is no dedicated Medicare reimbursement or incentive for doctors or nurses to undertake Kidney Health Checks for at-risk patients.

¹⁰ Kidney Health Australia and Deloitte Access Economics, *Changing the chronic kidney disease landscape: The economic benefits of early detection and treatment*, February 2023

¹¹ Ibid

¹² AIHW Chronic Kidney Disease, Australian Facts, last updated 24 July 2024

¹³ Alicic RZ, Rooney MT, Tuttle KR. Diabetic Kidney Disease: Challenges, Progress, and Possibilities. Clin J Am Soc Nephrol. 2017 Dec 7;12(12):2032-2045. doi: 10.2215/CJN.11491116. Epub 2017 May 18.

¹⁴ AIHW Chronic Kidney Disease, Australian Facts, last updated 24 July 2024

¹⁵ Ibid

¹⁶ Ibid

¹⁷ Kidney Health Australia and Deloitte Access Economics, *Changing the chronic kidney disease landscape: The economic benefits of early detection and treatment*, February 2023

¹⁸ AF Moura et al, WCN24-1204 Multidimensional Burden of Chronic Kidney Disease in eight countries: insights from the IMPACT CKD study, poster presented at WCN24, Buenos Aires, Argentina, April 2024

By setting national targets to test 1 million people at-risk of CKD by 2030 and to increase the diagnosed and treated population from 10% to at least 50%, the Australian Government could significantly reduce the cost of CKD to the health system. Investment in a targeted early detection program has been estimated to yield a net benefit of \$10.2 billion in late-stage CKD and cardiovascular disease costs over the next 20 years¹⁹.

Earlier detection and treatment of CKD could be achieved by:

1. Setting and tracking a national target to test and treat 1 million people at risk of CKD by 2030.
2. Creating incentives in primary care for nurse-led early detection of CKD with kidney health checks, for targeted early diagnosis and treatment of at-risk patients.
3. Introducing an annual Diabetes-CKD Care Set for at-risk adults at 12-month checkups to increase routine pathology testing in primary care.
4. Utilising MyMedicare chronic disease management to optimise integrated multidisciplinary care for cardiovascular diseases, diabetes and CKD.
5. Adding urine albumin-creatinine ratio (uACR) data collection to the quality improvement measures of the Practice Incentive Program Quality Improvement incentive to improve urine testing and update of Kidney Health Checks in primary care.
6. Introducing a national patient education and awareness campaign in collaboration with Kidney Health Australia and the National Aboriginal Community Controlled Health Organisation, to drive community awareness of kidney health and the need for Kidney Health Checks.

RECOMMENDATION 4

Develop a National Chronic Obstructive Pulmonary Disease (COPD) Program to provide ongoing support for the implementation, uptake and evaluation of COPD Clinical Care Standards, in alignment with the implementation of Lung Foundation Australia's COPD Blueprint 2022-25.

COPD is a condition where the airways or other parts of the lungs are damaged or inflamed. This damage and inflammation can block airflow, making it difficult to breathe. COPD includes emphysema, chronic bronchitis, and chronic asthma. COPD may result from long-term exposure to irritants, including air pollution, cigarette smoke, and occupational hazards.

COPD symptoms often don't appear until significant lung damage has already occurred. While there is no cure for COPD, early diagnosis and intervention can slow progression of the disease and enhance patient outcomes.

In 2022 there were around 638,000 Australians living with COPD²⁰. It is estimated that approximately 1 in 13 Australians over the age of 40 have some form of COPD,²¹ and around 50% of people with COPD do not know that they have it²². COPD is one of the leading causes of premature mortality in Australia, causing more than 7,000 deaths in 2023 (representing 4% of all deaths)²³, and contributes

¹⁹ Kidney Health Australia and Deloitte Access Economics, *Changing the chronic kidney disease landscape: The economic benefits of early detection and treatment*, February 2023

²⁰ AIHW Chronic Obstructive Pulmonary Disease, Australian Facts, last updated 27 November 2024

²¹ Toelle B, Xuan W, Bird T, Abramson M, Atkinson D, Burton D, James A, Jenkins C, Johns D, Maguire G, Musk A, Walters E, Wood-Baker R, Hunter M, Graham B, Southwell P, Vollmer W, Buist A, Marks G. Respiratory symptoms and illness in older Australians: The Burden of Obstructive Lung Disease (BOLD) study. *Med J Aust* 2013;198:144-148

²² Lung Foundation Australia Chronic Obstructive Pulmonary Disease Fact Sheet, updated September 2018

²³ AIHW Chronic Obstructive Pulmonary Disease, Australian Facts, last updated 27 November 2024

significantly to avoidable disease burden in Australia. COPD was estimated to cost the health system \$832 million in 2020-21²⁴, more than the cost of dementia.

COPD patients will often face exacerbations (a sudden worsening of symptoms), which can be severe and require hospitalisation. The lack of understanding of COPD by patients and healthcare practitioners can mean that exacerbations are unrecognized and unreported by the patient. Exacerbations can accelerate the decline in lung function, leading to a worsening of symptoms and longer periods of recovery.

In 2021-22, there were 53,000 hospitalisations with a principal diagnosis of COPD of people over 45²⁵, and over 270,000 potentially preventable hospital bed days²⁶. Approximately 20% of patients hospitalised for an acute COPD exacerbation will be readmitted within 30 days. COPD is the second highest cause of potentially preventable hospital admissions in Australia for people over 65²⁷.

The number and severity of exacerbations may be reduced by identifying at-risk patients and intervening early. Medication reviews conducted by a pharmacist or healthcare provider can ensure proper medication use and appropriate prescribing – including correct inhaler technique; treatment adherence; adjustments to treatment plans to ensure evidence-based medications are used including the correct combination of long-acting beta agonists (LABA), long-acting muscarinic agonists (LAMA) and inhaled corticosteroids (ICS); early identification of worsening symptoms; lifestyle interventions; and pulmonary rehabilitation programs.

Services available for COPD patients vary considerably across Australia, and there is a shortage of respiratory physicians. Hospitals may experience ramping of COPD patients, particularly during winter months. According to the Lung Foundation Australia (LFA), one in four people with COPD say that finding a GP with a good understanding of lung disease is a barrier to effectively managing their condition.

In October 2024 the Australian Commission on Safety and Quality in Healthcare launched COPD Clinical Care Standards to support best practice in the diagnosis and management of COPD to reduce potentially preventable hospitalisations and improve the lives of Australians living with COPD.

These issues highlight the need for a coordinated, national approach to community-based care for COPD patients, which would be achieved through a national COPD program, and through the implementation of the recently launched COPD Clinical Care Standards. Studies have shown that coordinated community-based care programs can reduce hospitalisations, length of stay²⁸, readmission rates, and improve patient outcomes²⁹.

At present, the Australian Department of Health and Aged Care's Quality Use of Diagnostics, Therapeutics and Pathology program funds the Chronic Airways Disease Education Program as part of the Health Professional Education stream. The QUAD – Quality Use of Medicines (QUM) in

²⁴ Ibid

²⁵ Ibid

²⁶ Ibid

²⁷ AIHW Disparities in potentially preventable hospitalisations across Australia 2012-13 to 2017-18

²⁸ Aslam, S., Man, J., Behary, J., Riskallah, J., Ansary, S. and CH Kwan, B. (2016) Outcomes and Cost Effectiveness of a Respiratory Coordinated Care Program in Patients with Severe or Very Severe COPD. *Open Journal of Respiratory Diseases*, 6, 52-57. <http://dx.doi.org/10.4236/ojrd.2016.63008>

²⁹ Spiliopoulos, N., Donoghue, J., Clark, E., & Dunford, M. (2008). Outcomes from a respiratory coordinated care program (RCCP) providing community-based interventions for COPD patients from 1998 to 2006. *Contemporary Nurse*, 31(1), 2–8. <https://doi.org/10.5172/conu.673.31.1.2>

Chronic Airways Disease (CAD) for healthcare professionals – is delivered by the Lung Learning Partnership, led by LFA.

Providing long-term funding to continue the work of the Partnership would provide ongoing evidence-based education to Australian healthcare professionals, enabling Australians living with COPD to receive optimal, best-practice management and care.

It is critical that all stakeholders including Government, healthcare services, healthcare practitioners and industry form a partnership to drive uptake and embed the Standards into all aspects of service delivery and COPD clinical care. Measuring the impact of the Standards through the development of clearly defined national minimum data sets would allow for monitoring and reporting on COPD on a national scale, which would drive best practice clinical care and patient outcomes.

RECOMMENDATION 5

Commit to improving psychosocial support for those living with metastatic breast cancer (mBC) and providing greater training and access to the nurses and psychologists providing this care.

Breast cancer is the second most common cancer among Australians, with an estimated 21,000 people diagnosed and more than 3,300 losing their lives each year.³⁰

Any and every breast cancer diagnosis can bring understandable fear and anxiety. But while early-stage breast cancer has the potential to be cured³¹, this is not the case with a metastatic diagnosis in which breast cancer has spread to other parts of the body.³²

With advancements in treatment, people with metastatic breast cancer are living longer but they do so in deep need of better (or any at all) psychosocial support as they navigate a terminal illness.

World-first data released in October 2024³³ revealed there are many more Australians living with mBC than originally thought, and a report into their experiences revealed there is much more still to do when it comes to supporting those living with metastatic breast cancer, only one in three of whom survive beyond five years.³⁴

International guidelines recommend those with mBC have access to nurses experienced in mBC treatment however this support is not widely available in Australia, especially in rural and regional areas.

Patients with mBC can access just 10 MBS mental health sessions per year, which is insufficient. People living with mBC should be able to access up to 40 reimbursed mental health sessions per year, in line with the support afforded to those who present with an eating disorder.

More comprehensive psychosocial support for those facing the significant pressure of living with metastatic breast cancer amid a constant risk of disease progression would benefit not only the

³⁰ National Breast Cancer Foundation (NBCF) Breast Cancer Stats in Australia. <https://nbcf.org.au/about-breast-cancer/breast-cancer-stats/>

³¹ Hong R et al. Breast cancer: an up-to-date review and future perspectives.

³² Cancer Australia Metastatic Breast Cancer. <https://www.canceraustralia.gov.au/affected-cancer/cancer-types/breast-cancer/metastatic-breast-cancer>

³³ NSW Government Media Release 'NSW first in the world to identify number of people living with metastatic breast cancer' 16 October 2014

³⁴ NBCF Breast Cancer Stats in Australia. <https://nbcf.org.au/about-breast-cancer/breast-cancer-stats/>

patient but also those who care for them as well as those that they care for – which could include elderly parents or young children.

RECOMMENDATION 6

Build Australia’s economic resilience, competitive edge and security outcomes by developing a unified, cohesive and intentional approach to prioritise the Australian life sciences industry.

Australia has many strategic advantages when it comes to domestic advanced manufacturing, including our political and economic stability, our strong cultural ties and trade relations in our region, and our high standards for quality and safety.

The COVID-19 pandemic saw major disruptions to global supply chains, resulting in shortages in pharmaceuticals and essential medical equipment such as PPE. While medicine shortages are not new to Australia, the COVID-19 pandemic highlighted many of the fragilities of Australian supply chains, particularly for medicines.

There are key strategic government initiatives which the government should support in order to make Australia more competitive for domestic manufacturing and to address issues identified in our supply chain. Supporting Australian pharmaceutical manufacturing will help ensure Australia can plan for and secure critical medical supplies in the future, as well as enhancing Australia’s global bargaining power during future supply chain disruptions.

AstraZeneca supports the proposals outlined by [AusBiotech and MTPConnect in their 2025-26 budget submission](#) for the prioritization of the Australian Life Sciences Industry:

1. Developing a national strategy specifically aimed at the life sciences sector, supported by the creation of a national Life Sciences Council;
2. Recognising the Life Sciences Industry as a priority under the Future Made in Australia Act; and
3. Strengthening industry capability through investment in data collection.