AstraZeneca

An Interim Cancer Fund in Australia

Green Paper
March 2024

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Executive Summary

Cancer remains a major health priority for the community and government. This is evident through the recent launch of the Australian Cancer Plan. The Plan aims for world-class cancer outcomes and experiences for all Australians.

Beyond the Cancer Plan, there is a growing push to improve patient access to potentially life-saving cancer treatments. As the number of innovative medicines in industry research pipelines continues to increase, existing models for medicines funding need to evolve to ensure timely and equitable access to new cancer treatments.

Australian cancer patients wait, on average, **442 days** 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).[1]

The average time from a medicine's registration to its reimbursement for all 20 OECD countries is **384 days**.[2] The average time from a medicine's registration to its reimbursement is **102 days** in Japan, **136 days** in Germany, and **156 days** in Great Britain.[3] Australia's average waiting period is almost a year longer than these comparable OECD countries.

> In Australia, the average number of days taken for oncology medicines to be reimbursed on the PBS after TGA registration is 442 days.

When cancer treatments with high added therapeutic value (HATV) and high unmet clinical need (HUCN) are deemed safe and fit for purpose by the TGA's rigorous approval process, rapid access to those treatments is critical for Australian cancer patients, who may otherwise have limited treatment options. Some patients will pass away while they are waiting for treatments to be funded through the PBS. Others crowdfund to meet private treatment costs. Some must seek treatment overseas.

In response to this issue, conditional approval for reimbursement is a widely utilised approach to manage the uncertainty associated with funding emerging health technologies,[4] facilitated through strategic agreements between payers and sponsors. As noted in the **Health Technology Assessment (HTA) Consultation Options Paper**, *"such agreements are referred to as managed entry agreements (MEAs), managed access programs or pathways (MAPs), and coverage with evidence development approaches (CEDs)."*[5]

[1] Medicines Australia, *Medicines Matter 2022* (Report, 2022) 11.
[2] Ibid, 9.
[3] Ibid.
[4] Health Technology Assessment Policy and Methods Review Reference Committee, *Health Technology Assessment Policy and Methods Review Consultation Options Paper* (Report, 2024) 12.
[5] Ibid.

Australia currently operates several early MEAs or pathways, including the Managed Access Program (MAP). However, as noted in the HTA Consultation Options Paper, *"While there are approaches to addressing clinical and economic uncertainty within the system, particularly in the form of MAPs, they tend to be underutilised."*[6] The Paper addressed contributing factors to this issue, including *"a conservative stance in relation to how uncertainty is viewed in the current system,"*[7] a lack of *"significant data collection infrastructure and governance,"*[8] and low prices.[9] These factors frequently result in the global headquarters of sponsors rejecting MAPs, due to the value of the medicine not being realised by the Government.

An evidence-based access scheme in the form of an **Interim Cancer Fund (ICF)** in Australia would ensure timely access to treatment options expected to provide a substantial and clinically relevant improvement to patient outcomes over existing therapies.

This finite fund would deem medicines eligible for interim funding between TGA approval and PBS reimbursement while further economic data is being collected, to help patients gain earlier access to cancer medicines that may save or significantly extend their life. An ICF is an opportunity to reframe and reinvigorate Australia's approach to funding advanced health technologies.

Investing in new cancer treatments as soon as the regulator approves them would deliver substantial social and economic benefits for Australia – such as higher workforce productivity, improved health equity, and a reduced need for government-funded support services, whilst also giving patients more time with their loved ones and the opportunity to contribute to their community.

For every $1 invested in cancer treatments in Australia, there is **$3.06 of social and economic value created**.[10] 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**.[11] As such, this policy merits consideration and evaluation.

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$1

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$3.06

of social and economic value is created.

[6] Health Technology Assessment Policy and Methods Review Reference Committee, *Health Technology Assessment Policy and Methods Review Consultation Options Paper* (Report, 2024) 130.
[7] Ibid, 131.
[8] Ibid.
[9] Ibid, 130 - 131.
[10] Rare Cancers Australia & Canteen, *Counting the cost: How we can assess the true value of investing in cancer treatment* (Report, 2023), 7.
[11] Ibid.

An Interim Cancer Fund in Australia

Purpose

The purpose of an Interim Cancer Fund is to provide patients with faster access to innovative cancer treatments that may save or significantly extend their lives. The Fund would expedite access to innovative treatments for these cancer patients, to provide equitable access regardless of a patient's ability to pay before reimbursement. An interim fund with specific criteria provides consistent and predictable funding for these medicines, reducing disparities in access 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.

The Existing System and Opportunities for Change

There is a widely recognised need to strengthen and expand provisional subsidised access to medicines currently provided through managed access programs.[12] The HTA Options Paper describes the Australian MEA system as follows,

"Australia currently operates several early MEAs or pathways, including the Managed Access Program (MAP) to provide access to products with High Unmet Clinical Need (HUCN) but which have been identified by the PBAC/MSAC as having otherwise unacceptable clinical or economic uncertainty. PBAC and MSAC may also recommend that specific products be subject to financial-based MEAs (such as discounts, rebates, and volume/expenditure caps) or performance-based MEAs (typically Coverage with Evidence Development (CED) or payment-by-result/Pay-for-performance) within a risk-share arrangement context. MEAs can be considered within the usual PBAC/MSAC pathways and/or within the pathways of MAPs and the LDSP."[13]

Relative to other national jurisdictions, uptake of MEAs through Australia's MAP has been low. It is difficult for pharmaceutical companies to guarantee access to medicines through MAPs because of the delays in reimbursement in Australia. Reasons for this were outlined in **Paper 6 – Funding and purchasing decisions and Managing Uncertainty**, a Paper commissioned by the Australian Government Department of Health and Aged Care to inform the Health Technology Assessment Methods and Policy Review.

[12] House of Representatives Standing Committee on Health, Aged Care and Sport (Cth), *The New Frontier – Delivering better health for all Australians* (Report, 2021) 130 at 6.69.
[13] Health Technology Assessment Policy and Methods Review Reference Committee, *Health Technology Assessment Policy and Methods Review Consultation Options Paper* (Report, 2024) 130.

- *"Administrative burden associated with monitoring, data collection and analysis, and review;*
- *Lack of nationally consistent governance and administrative arrangements, and requisite information technology infrastructure to support ongoing monitoring as set out in the MEA;*
- *Perceived risk associated with future changes to the PBS listing due to changed HTA outcomes upon review, especially as early and managed access arrangements do not have clear 'interim' status in legislation;*
- *Lack of clear exit strategies for disinvestment in cases where medicines do not meet clinical and/or cost-effectiveness outcomes upon review (a risk to both payer and sponsor)."* [14]

In **Medicines Australia's 2024/25 Pre-Budget Submission**, two main issues slowing down access to new medicines were identified, that a provisional pathway and bridging fund would address:[15]

1. **Data Issues** *(e.g., where Phase II clinical trial data has been accepted and Phase III data is still required); and*
2. **Administrative Issues** *(e.g. where a new therapy would be delayed because there are complex funding negotiations with the states and territories.*

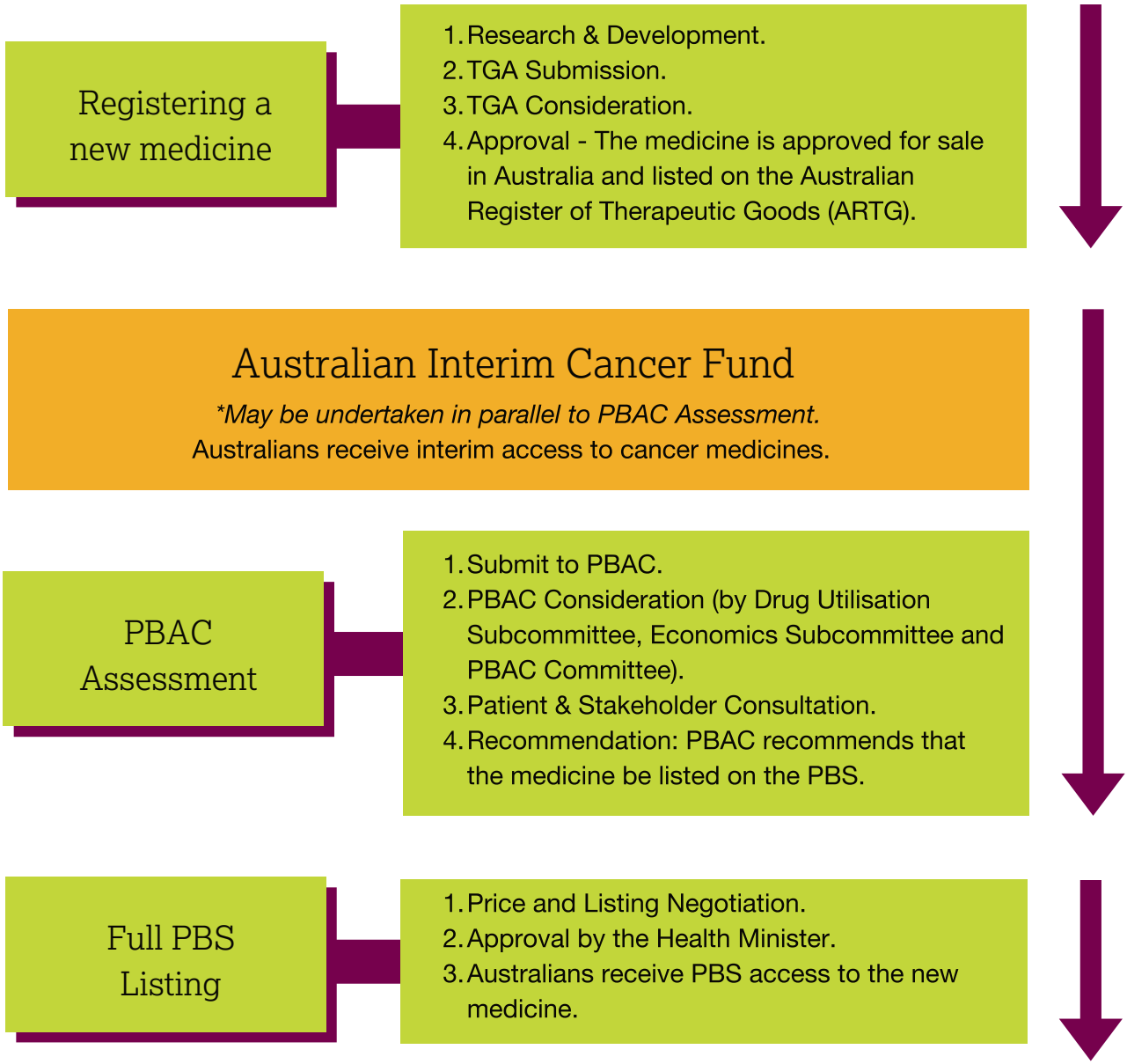
Additionally, delays to reimbursement in Australia often occur due to cost-effectiveness analyses (CEA). Cost-effectiveness analyses evaluate whether a new health technology provides value relative to other existing health technologies.[16] To secure reimbursement, sponsors must lodge major cost-effectiveness submissions to PBAC. **From 2010 to 2018, the average number of submission attempts required to obtain a PBAC recommendation for applications that include a cost-effective analysis was 2.35 attempts**.[17] Often, this process can take more than 12 months from the first reimbursement submission.

Cost-effectiveness submissions involving novel oncology therapies are typically rejected by the PBAC at the time of first submission because of limited data at the time of assessment. This includes overall survival (OS) data, which is considered essential to determining the cost-effectiveness of a medicine. This data takes longer to generate than other evidence-based indications of clinical benefit, such as progression-free survival (PFS). The suitability of the approval process for therapies for aggressive cancers could be evaluated, given the impact the delay has on patients whose prognosis is very poor.

> An Interim Cancer Fund presents an opportunity to address the gap between regulatory and reimbursement approvals, and better support the medicines access needs of Australian cancer patients.

[14] University of Technology Sydney, *Australian Health Technology Assessment Methods and Policy Review – Paper 6 – Funding and purchasing decisions and Managing Uncertainty* (Draft Paper, 2023) 169 – 170.
[15] Medicines Australia, *Medicines Australia 2024-25 Pre-Budget Submission* (Submission, 2024) 3.
[16] Joore M., Grimm S., Boonen A., *et al.* Health technology assessment: a framework. *RMD Open* (2020) 6(3) 2.
[17] Lybrand S. & Wonder M., *Analysis of PBAC submissions and outcomes for medicines (2010-2018). International Journal of Technology Assessment in Health Care* (2020) 36(3) 228.

Figure 1: How an Interim Cancer Fund could fit into the Australian medicines funding framework



Assessment and Criteria for Interim Funding

The criteria governing the implementation of an Interim Cancer Fund (ICF) should be clear, transparent, and balanced to address the expectations of various stakeholders. Crucially, eligibility requirements should be conducive to uptake and positive impact. Medicines eligible for reimbursement may align with existing criteria utilised by the PBAC to identify high-priority medicines, namely:

- *"The medicine […] addresses a high and urgent unmet clinical need; and*
- *"The medicine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies."* [18]

Compatible criteria for Interim Funding could also be developed based on:

- *Agreed requirements for evidence development within a set time period to further inform cost-effectiveness evaluation, including any ongoing clinical trials, progression-free survival, RWE reporting by patients, clinicians and sponsors, and, where possible, overall survival;*
- *Agreed processes for price reviews and/or rebates based on outcomes;*
- *An agreed maximum number of patients the medicine is administered to per annum;*
- *An agreed limit on the total financial exposure for the Government;*
- *An agreed system for continuous evaluation of an Interim Cancer Fund;*
- *Agreed requirements for disclosure before prescribing eligible medicines to patients; and*
- *Community, consumer and clinician engagement in development and implementation.*

'Innovative medicines' may already be registered and reimbursed for other cancer indications.

Risk-Sharing Arrangements

An appropriate risk-sharing arrangement between the sponsor and the Government is imperative to the success of an interim funding mechanism. Risk-sharing agreements are intended to help maintain the appropriateness and cost-effectiveness of listed medicines. Industry and government should work together to identify opportunities to streamline this process.

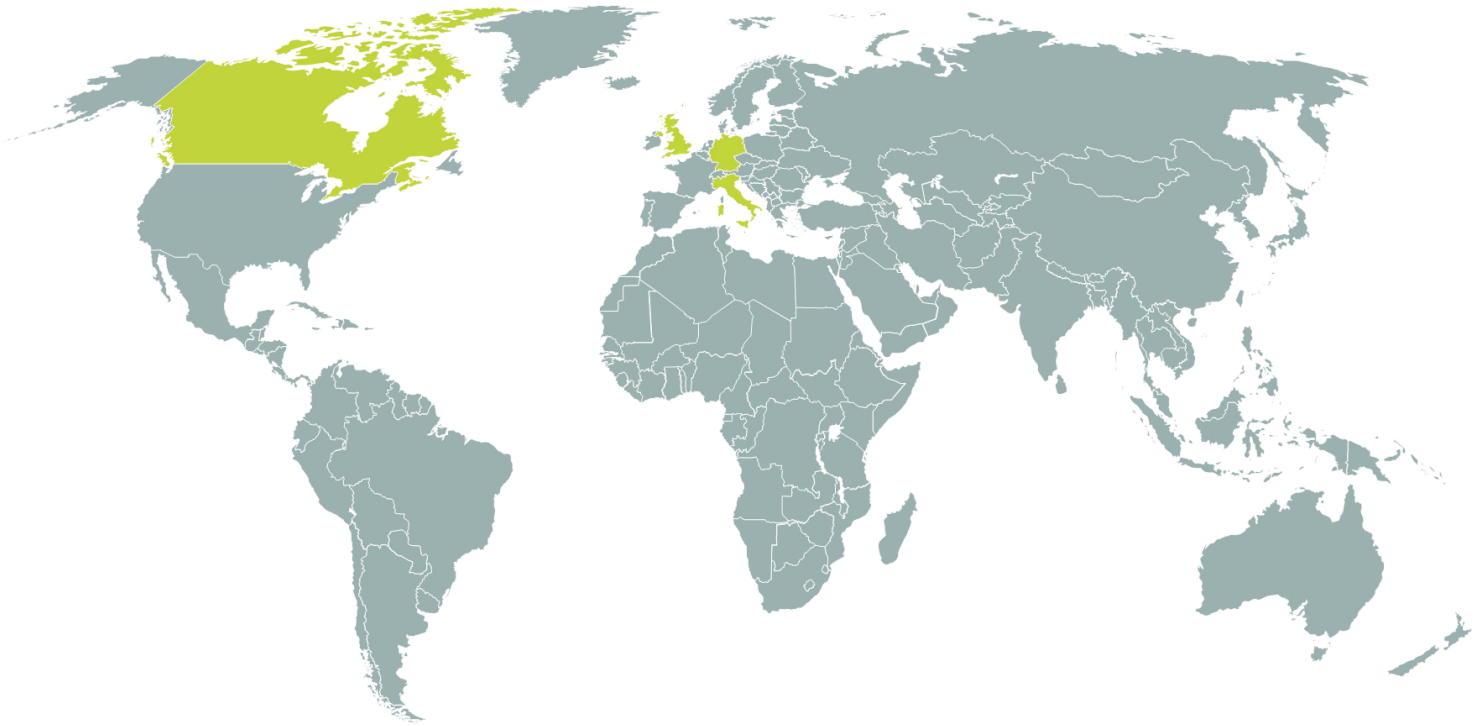
[18] 'Pricing Pathways', The Pharmaceutical Benefits Scheme (Web Page) <https://www.pbs.gov.au/pbs/industry/listing/procedure-guidance/8-procedures-positive-recommendation-list/8-1-price-agreement>.

International Approaches

Numerous Organisation for Economic Co-operation and Development (OECD) governments have implemented interim access to cancer medicines.[19] It is imperative to extract insights from international approaches to reimbursement.

International Health Technology Market Approval, Funding and Assessment Pathways (2023) was commissioned by the Australian Government Department of Health and Aged Care to inform the Health Technology Assessment Policy and Methods Review.[20] It offers a highly comprehensive assessment of international HTA processes.

Outlined below are **four case studies** (the United Kingdom, Germany, Canada and Italy) that illustrate the application of reimbursement pathways and varying frameworks that facilitate them.



[19] Deloitte Access Economics, *A Collaborative Assessment of Access to Cancer Medicines in Australia* (Report, May 2017) 44.
[20] Laka M., Carter D., Gao Y., Tamblyn D. & Merlin T., *Australian Health Technology Assessmenty Methods and Policy Review – Paper 1 – International Health Technology Market Approval, Funding and Assessment Pathways* (Draft Paper, 2023) 2.

The United Kingdom

As noted in **Funding and purchasing decisions and managing uncertainty**, a Paper commissioned by the Australian Government Department of Health and Aged Care to inform the Health Technology Assessment Policy and Methods Review in 2023, *"The Cancer Drugs Fund serves as an exemplar of a CED scheme integrated within a national HTA process, ensuring that patients have access to promising cancer drugs while generating additional evidence to address uncertain clinical effectiveness."*[21]

The **Cancer Drugs Fund (CDF)** was established in 2010 in the United Kingdom in response to criticism over the timeliness of access to new cancer medicines, which were not appraised by the National Institute for Health and Care Excellence (NICE) or had not been recommended for routine commissioning.

According to NHS England, the CDF provides:

- *"An early funding source, via Interim Funding Agreements (IFA), for treatments that receive a provisional positive recommendation from the National Institute for Health and Care Excellence (NICE), without them having to wait for NICE final guidance to be published and subsequent entry into the routine commissioning system.*

- *A source of funding, via Managed Access Agreements (MAA), for treatments that show clinical promise and where further data collection is needed to resolve uncertainty around their effectiveness."*[22]

Initially established in 2010, the Cancer Drugs Fund was reformed in 2016 to operate under renewed parameters, including straightforward entry and exit criteria and a more clearly defined data collection and reassessment process. These were implemented to ensure longer-term sustainability following higher than anticipated expenditure in its first years of operation. Key to the success of this reform was bringing the CDF under the remit of NICE.

The **Innovative Medicines Fund (IMF)** was established in 2021 to extend funded managed access to non-cancer conditions, separately.

The CDF and IMF both operate on a fixed budget under an expenditure control mechanism. **The total CDF Budget for 2023-24 is £340m.**[23] The total IMF Budget is also £340m. Expenditure is managed using a combination of confidential discounts in commercial agreements; and rebates across the entire fund at the end of the year if the budget cap is exceeded.[24]

[21] University of Technology Sydney, *Australian Health Technology Assessment Methods and Policy Review – Paper 6 – Funding and purchasing decisions and Managing Uncertainty* (Draft Paper, 2023) 156.
[22] 'Cancer Drugs Fund activity update Q2 2023-24', NHS England (Web Page, 2023) <https://www.england.nhs.uk/long-read/cancer-drugs-fund-activity-update-q2-2023-24/>.
[23] 'Cancer Drugs Fund', NHS England (Web Page) <https://www.england.nhs.uk/cancer/cdf/>.
[24] Medicines Australia, *Funding Innovative Medicines* (White Paper, 2023) 37.

The CDF accounts for **less than 2% of the overall NHS medicines, appliances, and medical devices budget**. The total cost to NHS commissioners for medicines, appliances, and medicines devices in 2022/2023 was **£18.5bn**.[25] (This figure includes a deduction of £674m for central rebates, including those negotiated to commission treatments in the CDF and in routine commissioning. Without central rebates, the total cost was **£19.2bn**.)[26]

> The CDF accounts for less than 2% of the overall medicines, appliances and medical devices budget in the United Kingdom.

NHS England and NICE work in partnership with pharmaceutical companies to address uncertainty about the effectiveness of new cancer treatments. This involves collecting additional data during a managed access period, including real world evidence (RWE) and data from ongoing clinical trials. Data collection is designed to address key areas of uncertainty highlighted by NICE in a preliminary appraisal and is then utilised in full appraisal for routine commissioning.[27] The additional data helps NICE to decide whether a new treatment should be routinely funded.[28]

As of 21 December 2023, *"Since the new approach to funding cancer drugs began in July 2016, approximately 96,100 patients have been registered to receive treatment with 103 drugs treating 261 different cancer indications. Of these patients, over 21,300 have benefited from earlier access to treatments through Interim Funding Agreements (IFA). In addition, over 59,500 patients have been able to access new treatments because of MAA [NHS England has] negotiated with companies, at significantly discounted prices to the NHS, whilst further data is collected. This data informs a future NICE technology appraisal."*[29]

Since the United Kingdom's new approach to funding cancer drugs began in July 2016 (as of 21 December 2023),

~21,000

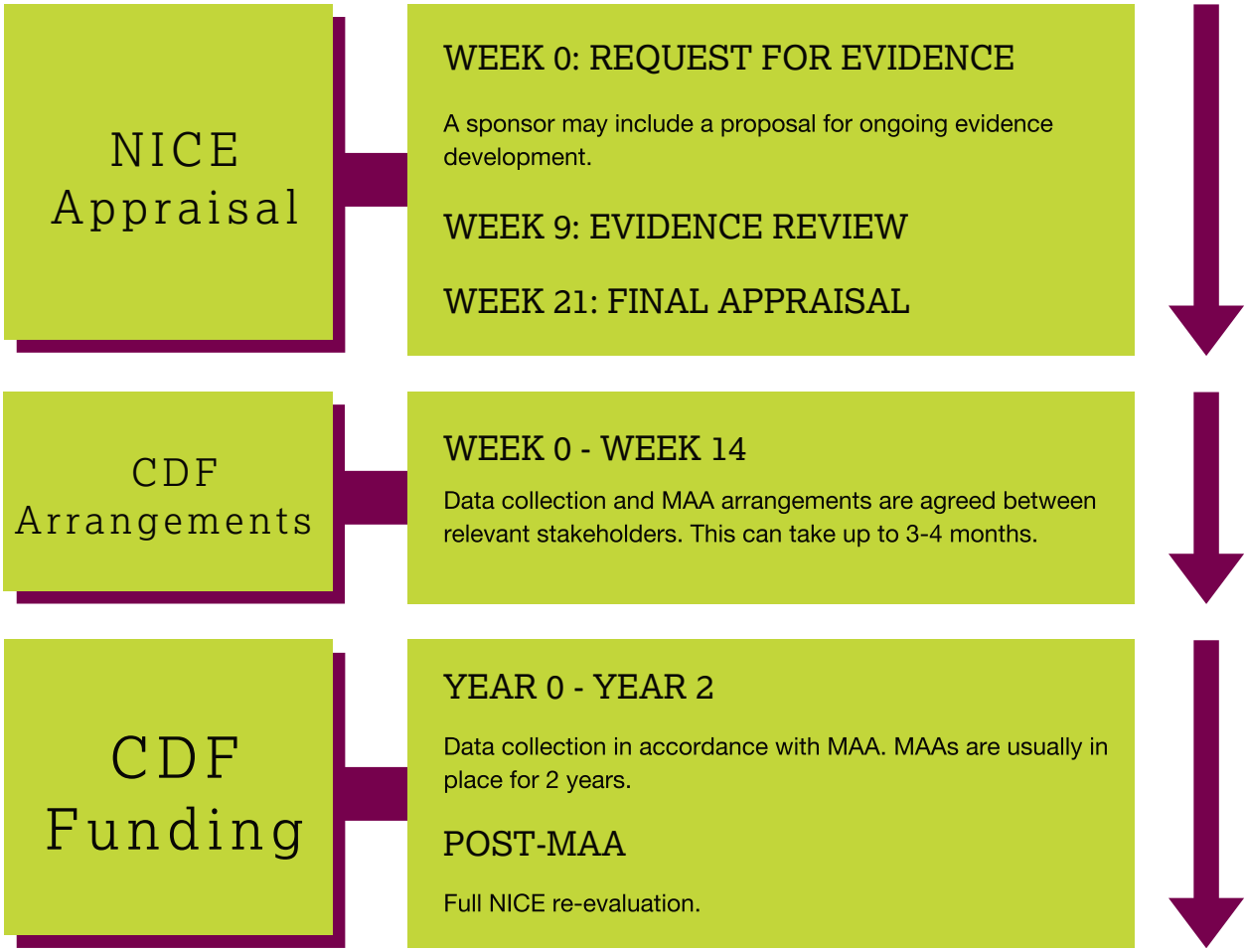
Patients have benefited from earlier access to treatments through Interim Funding Agreements.

~59,500

Patients have been able to access new treatments because of negotiated Managed Access Agreements.

[25] 'Prescribing Costs in Hospitals and the Community', NHS Business Services Authority (Web Page, 2023) <https://nhsbsa-opendata.s3.eu-west-2.amazonaws.com/pchc/pchc-2022-2023-narrative-v001.html>.
[26] Ibid.
[27] Medicines Australia, *Funding Innovative Medicines* (White Paper, 2023) 37.
[28] 'Cancer Drugs Fund activity update Q2 2023-24', NHS England (Web Page, 2023) <https://www.england.nhs.uk/long-read/cancer-drugs-fund-activity-update-q2-2023-24/ >.
[29] 'Cancer Drugs Fund', NHS England (Web Page) <https://www.england.nhs.uk/cancer/cdf/>.

Figure 2: Overview of the Cancer Drugs Fund (CDF) Listing Process[30]



[30] Medicines Australia, *Funding Innovative Medicines* (White Paper, 2023) 37.

Germany

In Germany, legislation regulating the reimbursement of new, innovative medicines (new therapeutic entities) within the statutory healthcare system (Arzneimittelmarkt-Neuordnungsgesetz, 'AMNOG') was introduced on 1 January 2011.[31]

The AMNOG process affords German patients rapid, reimbursed access to new therapies.

The German process enables automatic listing of new therapies, following receipt of marketing authorisation from the European Medicines Agency (EMA) and while HTA and pricing negotiations are completed. Newly authorised active pharmaceutical ingredients can be prescribed immediately upon market launch and are thus available to patients right away.[32]

Upon market entry, the Federal Joint Committee, or Gemeinsamer Bundesausschuss (G-BA) commences an early benefit assessment. The early benefit assessment must be completed within six months after it is launched.[33] The G-BA's subsequent benefit decision is also guided by the Institute for Quality and Efficiency in Healthcare (IQWiG) which independently assesses the medicine. The IQWiG submits an evidence-based expert report to the G-BA, with a recommendation regarding the additional patient-relevant benefit of the medicine.[34]

The medicine is paid at the list price during the first year of assessment and negotiations. The reimbursement price is determined in the second year of launch. It is determined depending on the outcome of the benefit decision. If the medicine has an additional benefit, the reimbursement price is determined by compulsory rebate negotiations between the National Association of Statutory Health Insurance Funds, or GKV-Spitzenverband (GKV-SV) and pharmaceutical companies. If the medicine has no additional benefit, it is assigned a reference price, which is continually reviewed by the GKV-SV.[35]

According to the Commonwealth Fund, *"Manufacturers can withdraw their product from the German market if the resulting price is so low as to undermine prices that can be charged elsewhere. In practice, manufacturers continue to see the German market as important and financially attractive and have not withdrawn any drugs that were shown to offer incremental clinical benefit over their closest comparators."* [36]

Additionally, the G-BA may remove a medicine from reimbursement or restrict the medicine's reimbursed status.[37]

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[31] Gandjour A., Schüßler S., Hammerschmidt T. & Dintsios C., Predictors of negotiated prices for new drugs in Germany. *The European Journal of Health Economics* (2020) 21 1049.
[32] Gemeinsamer Bundesausschuss, *Information brochure of the Federal Joint Committee* (Brochure, 2022) <https://www.g-ba.de/downloads/17-98-3768/2022-09-30_G-BA-Infobroschuere_EN_bf.pdf> 17.
[33] Ibid.
[34] Theidel U. & von der Schulenburg J., Benefit assessment in Germany: implications for price discounts. *Health Economics Review* (2016) 6 4.
[35] Medicines Australia, Submission No 141 to House of Representatives Standing Committee, Parliament of Australia, Inquiry into Approval Processes for New Drugs and Novel Medical Technologies in Australia (2020) 54.
[36] Robinson J., Ex P & Panteli D., 'How Drug Prices are Negotiated in Germany' (*The Commonwealth Fund*, Web Page, 2019) <https://www.commonwealthfund.org/blog/2019/how-drug-prices-are-negotiated-germany>.
[37] Medicines Australia, Submission No 141 to House of Representatives Standing Committee, Parliament of Australia, Inquiry into Approval Processes for New Drugs and Novel Medical Technologies in Australia (2020) 54.

The New Frontiers Report noted that the German model for provisional access drew support during consultation. The following excerpt from New Frontiers briefly evaluates the German model:

"[Better Access] claimed that 'the German reimbursement process does not come at the cost of a rigorous value assessment,' it merely means that 'the negotiation of prices does not… stand in the way of access for patients.' It did however concede that the system 'has faced fiscal challenges with some companies overpricing and failure of the system to clawback excess from use beyond indication, or failure to achieve health outcomes in real world application versus clinical trials.' It argued that: Australia's experience in the utilisation of Risk Share Arrangements and improving data accessibility through electronic health records places us well to modify a system with suitable 'carrots and sticks' to get the balance of access, affordability and transparency right." [38]

Figure 3: Overview of the German approach to negotiating prices for new medicines [39]

[38] House of Representatives Standing Committee on Health, Aged Care and Sport (Cth), The New Frontier – Delivering better health for all Australians (Report, 2021) 133 at 6.77.
[39] Medicines Australia, Funding Innovative Medicines (White Paper, 2023) 36.

Canada

To separate the evaluation of cancer medicines from the common drug review process, the pan-Canadian Oncology Drug Review (pCODR) was established by the provincial and territorial Ministries of Health in 2007. In 2014, it was integrated into Canada's Drug and Health Technology Agency's (CADTH).

As part of CADTH's reimbursement review process, the pCODR Expert Review Committee (pERC) makes reimbursement recommendations for oncology medicines to the participating federal, provincial, and territorial publicly funded drug programs.[40] Committee meetings are held 12 times a year.

In Canada, if the medicine demonstrates added comparative clinical benefit, but the cost-effectiveness is not at an acceptable level, the medicine may be reimbursed on the condition that there is a price reduction.[41]

pERC's well-defined deliberative framework is evidence-based. The Committee considers a variety of criteria, including medical and scientific knowledge, current clinical practice, economics, ethical considerations, and patient and public impact.[42]

Deloitte Access Economics, in partnership with Medicines Australia, described the Canadian system in their 2017 report, **Collaborative Assessment of Access to Cancer Medicines in Australia**:

"The purpose of the pCODR process is to bring consistency and clarity to the assessment of cancer drugs. Following approval by the national regulator, Health Canada, pCODR makes recommendations on the reimbursement of cancer medicines. Similar to Australia, a parallel regulatory and reimbursement submission process is available to sponsors to shorten the time between decisions.

Interestingly, Canada has also established a systematic approach to clinician-led submissions in addition to manufacturer-led submissions. This is a novel approach to the challenge of market failures arising from the challenges of data collection for less common cancers." [43]

Moreover, the pCODR framework incorporates clinical advisory input. In assessing a medicine's value, the pCODR considers evidence from various sources, including patient groups, drug manufacturers, clinician-based tumour groups, and the pCODR Provincial Advisory Group.[44] Clinical guidance panels consider outcomes broader than overall survival (OS), such as including Progression-Free Survival (PFS) and ease of symptom burden.[45]

[40] 'The pCODR Expert Review Committee (pERC)', Canada's Drug and Health Technology Agency (Web Page, 2024) <https://www.cadth.ca/pcodr-expert-review-committee-perc-0>.
[41] Laka M., Carter D., Gao Y., Tamblyn D. & Merlin T., *Australian Health Technology Assessment Methods and Policy Review – Paper 1 – International Health Technology Market Approval, Funding and Assessment Pathways* (Draft Paper, 2023) 94.
[42] 'The pCODR Expert Review Committee (pERC)', Canada's Drug and Health Technology Agency (Web Page, 2024) <https://www.cadth.ca/pcodr-expert-review-committee-perc-0>.
[43] Deloitte Access Economics, *A Collaborative Assessment of Access to Cancer Medicines in Australia* (Report, May 2017) 46.
[44] Ibid 49.
[45] Ibid.

Italy

Italy's value-based pricing framework and reimbursement pathway is a notable case study in **Paper 6 – Funding and purchasing decisions and Managing Uncertainty**:

"In 2017, Italy introduced the assessment of 'innovation status' for medicinal products as part of the pricing and reimbursement (PR) decision process. As outlined in the 2017 Budget Law, applications are made for innovation status according to **specific criteria of unmet need, added clinical value and the robustness of available clinical evidence.**

[Agenzia Italiana del Farmaco] AIFA evaluates the therapeutic indication and rates it on a five-point innovation scale. This assessment is based on criteria considering clinical need and added therapeutic value to determine a score from 'no innovation' to 'high innovation.' Additionally, a four-point 'GRADE' score for the quality of evidence is used to ascribe temporary/conditional or 'fully innovative' status.

Benefits of the 'fully innovative' status include:

- *Recognition and differentiation: The assessment of innovation status allows for the identification and recognition of innovative medicinal products. This helps distinguish these products from conventional therapies and highlights their potential to bring significant advancements in patient care.*
- *Improved patient access: Innovative medicinal products recognised as innovative gain enhanced access to the market. They are included in a dedicated cancer or other innovative medicinal product fund, each amounting to a total of €500 million. Inclusion facilitates patient access by providing funding support and ensuring availability on regional therapeutic formularies. The duration of innovation status is set at maximum of 36 months, providing a significant period for treatments to have a sustained period for access and reimbursement."* [46]

"Overall, AIFA and its registries play a vital and increasing role in pharmaceutical regulation and reimbursement in Italy. Efforts are being made to address challenges related to administrative burden, data quality and patient access, with a focus on implementing innovative approaches that leverage RWE and value-based pricing." [47]

International approaches to interim funding demonstrate the need for robust and transparent criteria to ensure timely patient access and sustainable policy. The assessment of the value and productivity of cancer medicine should be dynamic and adapt to information that may better inform its use. As innovation becomes more nuanced, the methods for defining and valuing innovation have evolved.

[46] University of Technology Sydney, *Australian Health Technology Assessment Methods and Policy Review – Paper 6 – Funding and purchasing decisions and Managing Uncertainty* (Draft Paper, 2023) 158 – 159.
[47] Ibid, 161.

Key Australian Perspectives

Interim funding for cancer medicines has been a recurring consideration for policymakers and key parliamentary stakeholders in Australia for more than a decade.

For a comprehensive recount of expert perspectives on Interim Funding Agreements, please see the **Supporting Document** to the Green Paper. Key stakeholders include:

- The Senate Community Affairs References Committee;
- The Pharmaceutical Benefits Advisory Committee;
- The House of Representatives Standing Committee on Health, Aged Care and Sport;
- The Centre for Health Economics Research & Evaluation (CHERE);
- The Australian Government; and
- The Reference Committee for the Health Technology Assessment Policy and Methods Review ('HTA Review').

2015

The **Senate Community Affairs References Committee** noted strong support for the introduction of an interim specialist cancer drug fund, following the *Inquiry into the availability of new, innovative and specialist cancer drugs in Australia*.

2021

In their Submission to the *Inquiry into Approval Processes for New Drugs and Novel Medical Technologies in Australia* in 2021, the **Pharmaceutical Benefits Advisory Committee** provided formal input on early access programs for promising new medicines.

2021

Recommendation 10 of *The New Frontier - Delivering Better Health for all Australians* Report by the **House of Representatives Standing Committee on Health, Aged Care and Sport** pertained to the PBAC and Managed Access Programs.

2023

The Centre for Health Economics Research and Evaluation's *HTA Review Consultation 1: Report*, which synthesises all submissions to Consultation 1 of the HTA Review, raised an interim listing process as an option to enhance timeliness and agility.

2023

In 2023, the **Australian Government** provided a whole-of-government response to the 2021 Report *The New Frontier - Delivering Better Health for all Australians*.

2024

In Chapter 4.1 of the **HTA Review Reference Committee**'s *HTA Consultation Options Paper*, options for revised MAPs to accelerate funding for therapies that qualify as High Added Therapeutic Value (HATV) with High Unmet Clinical Need (HUCN) are provided.

Next Steps

Australian patients with no other treatment options wait, on average, 442 days between a potentially life-changing cancer medicine receiving TGA approval, and that medicine being made available on the PBS.[48] For these patients, time is of the essence.

A study released in 2019 showed that **44% of the increase in the survival rates for cancer patients in Australia from 2001–2005 to 2011-2015 were attributed to the availability of new cancer medicines.**[49] The launch of these new cancer drugs was also responsible for almost half (48%) of the 2008 to 2018 increase in mean age at death from cancer.[50] Innovative cancer treatments must be included as part of a holistic approach to addressing the burden of cancer.

This Green Paper aims to launch a more comprehensive consultation and evaluation of an **Interim Cancer Fund (ICF)** in Australia.

A **formal working group** should be established to facilitate discussion on an ICF in Australia. The working group should be a collaborative endeavour between **government, patient groups, clinicians and industry**.

A formal working group should consider alignment on:

- Development of a potential funding mechanism/model, including risk-sharing arrangements between pharmaceutical companies and the government.
- Practical implementation of an ICF within the current HTA system, including co-design for potential legislation.
- Development of criteria for access.
- The relevance and desirability of international interim funding mechanisms, including lessons to be learned from other jurisdictional approaches.

A formal working group should be established to discuss the opportunity to deliver earlier, faster and fairer access to cancer medicines for Australians by establishing an Interim Cancer Fund.

[48] Medicines Australia, *Medicines Matter 2022* (Report, 2022) 11.
[49] Lichtenburg F. R., Measuring the Impact of Pharmaceutical Innovation in Australia 1998-2018 (2019) 7.
[50] Ibid.

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'Assessing Value in Cancer Care', American Society of Clinical Oncology (Web Page) <https://old-prod.asco.org/news-initiatives/current-initiatives/cancer-care-initiatives/value-cancer-care>.

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