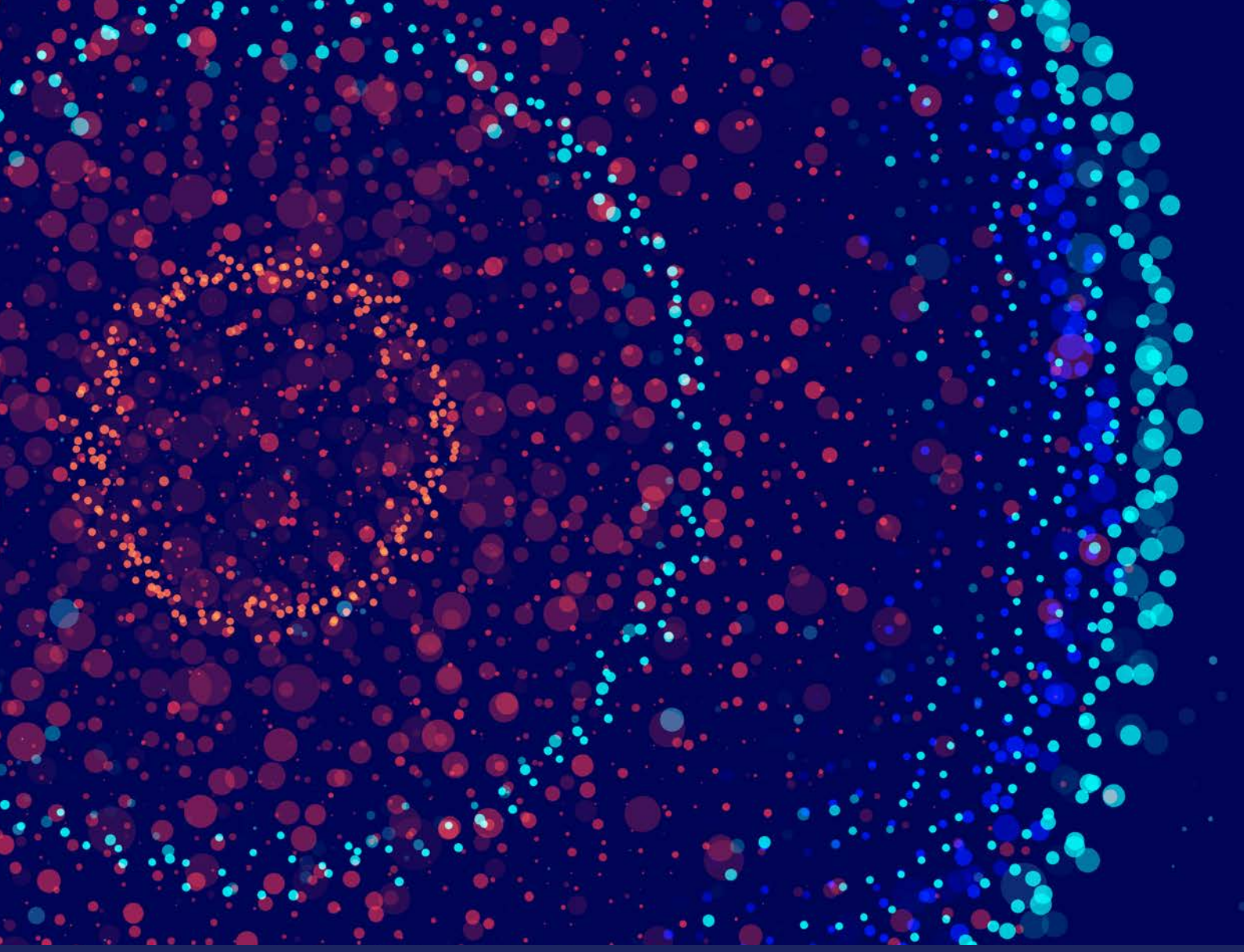

A PROPOSAL FOR A CO-FUNDED EARLY ACCESS PILOT PROGRAMME FOR INNOVATIVE ONCOLOGY MEDICINES

July 2025

This report was commissioned by AstraZeneca Ireland and drafted with support from The Health Policy Partnership. The workshop that informed the development of this report was facilitated by Hanover Communications. This report has been reviewed by AstraZeneca to ensure compliance with relevant Irish requirements.

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CONTENTS

EXECUTIVE SUMMARY

Cancer remains a pressing public health challenge in Ireland, with over 41,000 people diagnosed each year.[1] According to the European Cancer Inequalities Registry, Ireland had the second highest rate of new cancer diagnoses among EU countries in 2022.[2] Cancer is also the leading cause of mortality in the country, accounting for nearly 9,800 deaths annually, which represents 30% of all deaths.[3]

The inequities in access to innovative cancer treatments are widening. People who rely on the public health system face significant delays and barriers in accessing new medicines compared with those with private insurance.[4] This disparity underscores an urgent need for systemic change to ensure equitable access to essential treatments for all people with cancer in Ireland.

AstraZeneca Ireland convened key stakeholders to collaboratively address the inequities in access to cancer medicines. A roundtable held in September 2024 identified the need for an early access pilot programme for innovative oncology medicines to bridge existing access gaps. Following this, a workshop in May 2025 focused on developing the structure of this early access pilot programme, including setting clinical criteria for treatments.

Early access programmes offer an opportunity for policymakers to significantly reduce inequities in the time it takes to access cancer medicines. The Programme for Government has committed to exploring innovative reimbursement methods, including early access programmes.[5] It is imperative that the government fulfils this commitment to ensure people in Ireland are not left behind.

This proposal outlines the key components of a pilot early access programme for oncology medicines in Ireland. AstraZeneca Ireland is committed to collaborating with all stakeholders to create a path towards equitable access to cancer medicines for all patients. While this pilot specifically targets innovative oncology medicines, recognition of its potential applicability to other areas of high unmet need (such as rare diseases) and potentially to all innovative medicines, is essential.

We strongly urge the government to commit to funding this early access pilot programme to ensure timely and fair access to innovative cancer medicines.

FOREWORD

'The inequities that many Irish cancer patients face regarding access to innovative cancer treatments are extremely concerning. People who rely on the public health system face significant delays and barriers in accessing new medicines compared with those who can afford private health insurance.

People living with cancer in Ireland deserve the best possible chance at survival and improved quality of life by having access to the most advanced treatments available, when they need them, regardless of their geographical location or financial status.

There is an urgent need for change in the health system to ensure equitable access to essential treatments for all people with cancer in Ireland.'

Liz Yeates, CEO, Marie Keating Foundation

'Public patients in Ireland wait longer for access to new cancer drugs compared with those treated in private hospitals; these delays mean patients with cancer can miss out on treatments that could potentially extend or improve life. Inequities in access to innovative cancer treatments are developing and widening across our health systems. Ensuring equitable access to new cancer medicines for all patients, regardless of their healthcare setting and while ensuring value for taxpayers' money, is a considerable challenge that is not unique to Ireland – yet it is a challenge that must be addressed.

This report proposes solutions and ideas that are aligned with government policy and calls by patient advocacy groups. Considering solutions that have been implemented elsewhere in Europe and evaluating their suitability for implementation in an Irish setting can provide a framework for collaboration between all stakeholders for the benefit of our patients.'

Professor Maeve Lowery, Consultant Medical Oncologist, St James's Hospital

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INTRODUCTION

Access to cancer medicines: Ireland's two-tier system

People with cancer in Ireland face two very different scenarios when accessing new cancer medicines, depending on whether they access treatment through the public or private health system. Almost half of the population has private health insurance, meaning the other half of the population relies on the public health system.[6] Since 2019, private healthcare insurers have started to reimburse new medicines potentially as early as within one or two months from the date they were clinically approved by the European Medicines Agency (EMA).[7]

Clinicians face telling one in four people with cancer that it is not possible to prescribe the medicines they desperately need due to shortcomings in the reimbursement system.[8] This disparity results in inequities in access to cancer medicines, with people reliant on public healthcare often receiving 'second best' treatment options, while those with private insurance can access newer, innovative therapies without undue delay.[9]

When an innovative medicine is submitted for reimbursement in Ireland, it typically requires a full Health Technology Assessment (HTA, see *Box 1*). Regrettably, this process can take up to 971 days from submission to reimbursement, a time frame that people with late-stage cancer simply cannot afford (*Table 1*).[10] This situation underscores the urgent need for systemic change to ensure equitable access across Ireland.

971 DAYS

is a time frame that people with late-stage cancer cannot afford

If the government fails to take proactive measures against this growing disparity, these inequities will continue to widen as cancer rates rise.[11]

Box 1.

The reimbursement process in Ireland

Once a medicine is deemed safe for human use by the EMA, the Irish public health system requires the Health Service Executive (HSE) to agree on reimbursement. This decision is guided by recommendations from the National Centre for Pharmacoeconomics (NCPE), which assesses the clinical and cost-effectiveness of the medicine through a Rapid Review assessment for all medicines and a full HTA when required.[12] The pharmaceutical company then negotiates a price with the HSE Corporate Pharmaceutical Unit, and an offer will be presented to the HSE Drugs Group for consideration.[12]

Table 1. Time to access for Irish Pharmaceutical Healthcare Association medicines requiring HTA in Ireland, reimbursed from 2022 to 2024[10]

Year	(No. of indications/ medicines)	NCPE assessment	Negotiation timeline	Total access time (average no. of days for HTA)
2022	16	464	397	861
2023	13	587	405	992
2024	18	571	400	971
2022–24				+13%

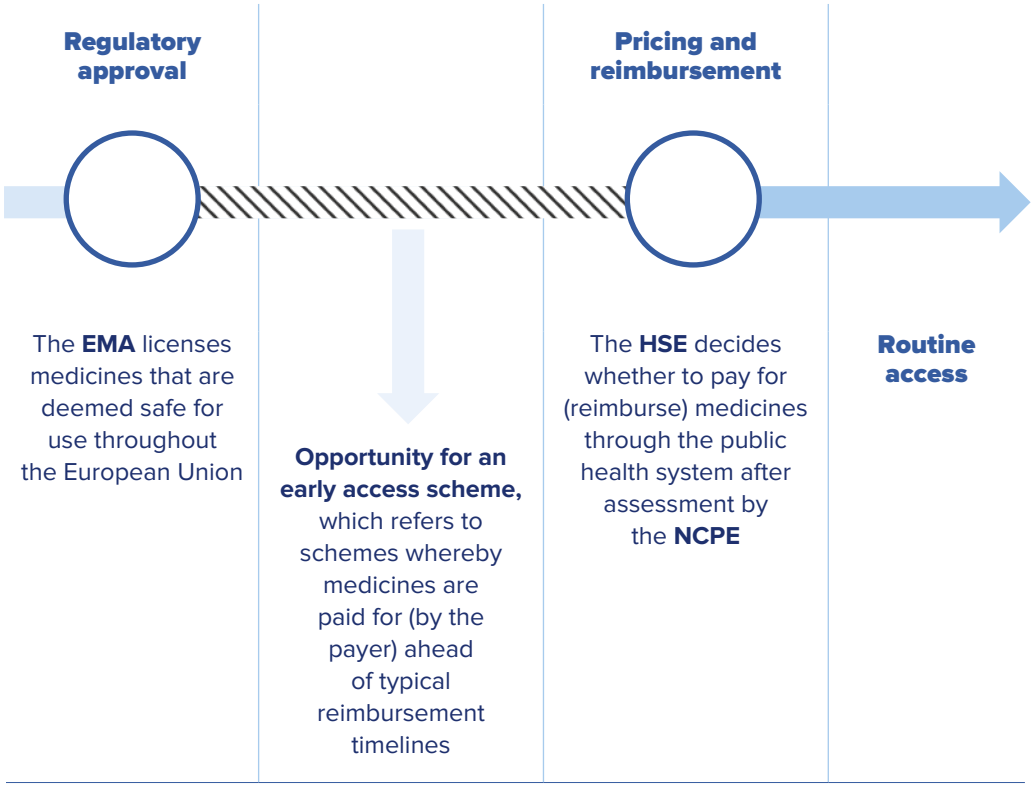
Early access programmes

For people with life-threatening or seriously debilitating conditions, some countries have programmes that allow access to the medicine shortly after regulatory approval. These programmes allow medicines to be co-funded by the payer and industry ahead of typical reimbursement timelines (*Figure 1*). **Such early access programmes offer an opportunity for policymakers to significantly reduce inequities in the time it takes to access cancer medicines.**

These programmes are widespread across Europe; an analysis found that 29 in 35 European countries have an early access programme described.[13] The countries that do not have such a programme include Ireland, Albania, Belarus, Bosnia and Herzegovina, Lithuania and Moldova.

Of these 29 programmes, 11 are government funded.[13] For example, France's 'accès précoce' programme reduces the time to reimbursement for new medicines to 3 months after regulatory approval,[14] compared with an average of 597 days in its standard reimbursement process.[15]

Figure 1. An overview of how early access programmes fit into the typical reimbursement pathway

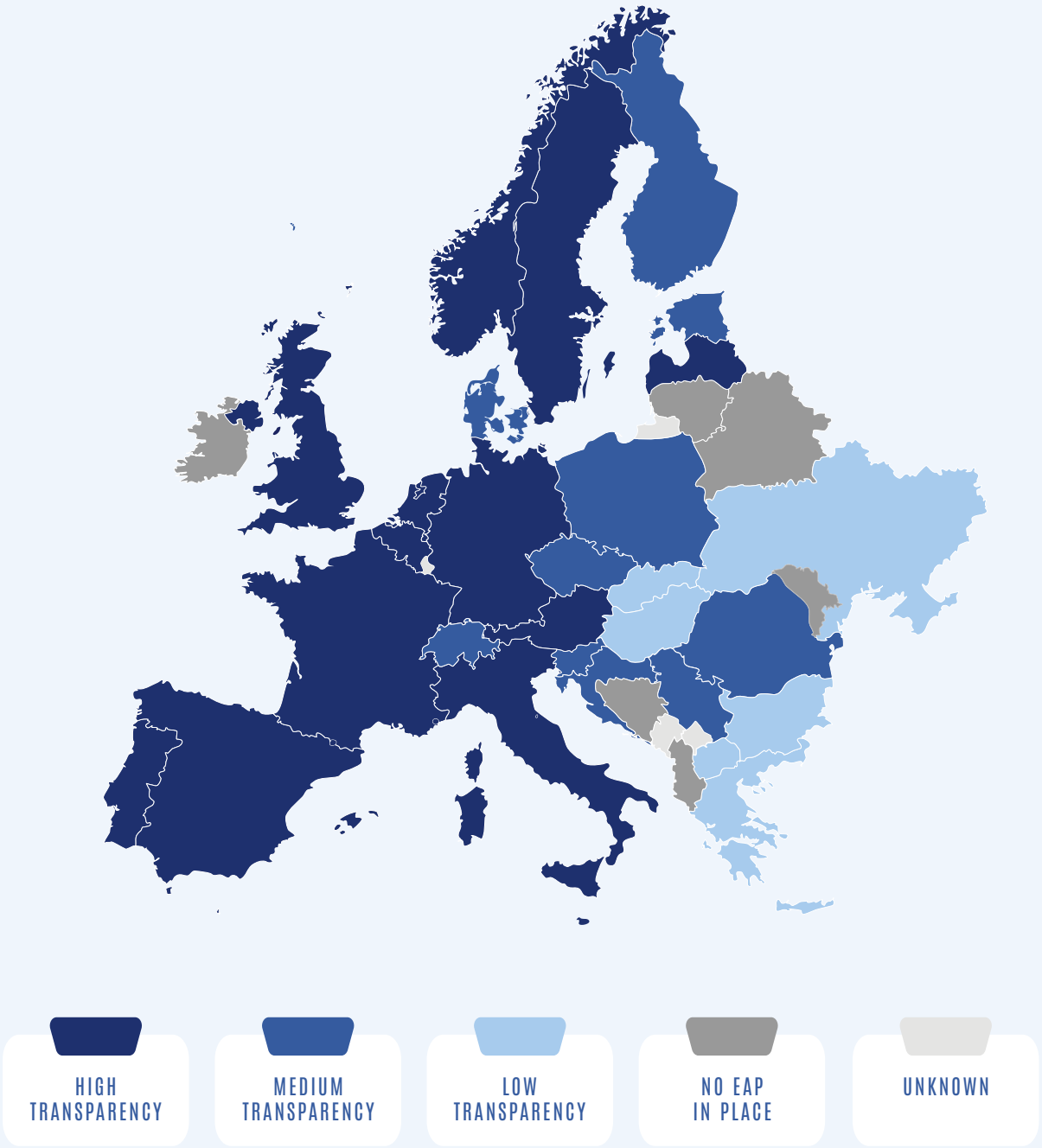


Ireland* is the only country in Western Europe that does not have an early access programme in place (*Figure 2*). This gap must be urgently addressed. The Programme for Government has committed to exploring innovative reimbursement methods, including early access programmes. It is imperative that the government fulfils this commitment to ensure people in Ireland are not left behind. Implementing an early access programme will not only align Ireland with our Western European counterparts but also provide timely access to critical treatments for people in need. We strongly urge the government to commit to funding an early access pilot programme in Ireland.

* Mechanisms for access to unauthorised products exist via the exempt medicinal product scheme or expanded access schemes. However, these tend to be case- and product-specific, and do not meet the definition of an early access programme in this research i.e. a standardised, national programme.

Figure 2. Ireland is one of the few European countries with no early access scheme in place

Adapted from Prüfert *et al.*[13]



Criteria for transparency rating
High transparency: government webpage identified, clear guidelines for manufacturers to follow, information primarily from these sources and confirmed by published sources.
Medium transparency: government webpage etc identified, but information largely supplemented from published sources.
Low transparency: no government webpage etc identified, information from published sources.

AGREEING A WAY FORWARD: BRINGING STAKEHOLDERS TOGETHER TO IMPROVE ACCESS TO CANCER MEDICINES IN IRELAND

Roundtable

In September 2024, a roundtable was held by AstraZeneca Ireland. The roundtable brought together key stakeholders to discuss the inequity faced by people with cancer in Ireland when trying to access new medicines. The purpose of the meeting was to identify a collaborative strategy to address this disparity and improve access to innovative medicines for all people with cancer in Ireland.

The attendees engaged in discussions that led to three key recommendations. One of these was the need to propose an early access pilot programme for innovative oncology medicines, aimed at bridging the existing access gap.

Workshop

As agreed at the roundtable, the next step was for AstraZeneca Ireland to facilitate a workshop to advance the development of an early access pilot programme. The workshop took place in May 2025 and sought to achieve consensus on the structure of a pilot programme, including establishing clinical criteria to define what qualifies as innovative oncology treatment.

Stakeholder engagement

Throughout this process, AstraZeneca Ireland engaged with the following stakeholders:

- Marie Keating Foundation (MKF)
- OvaCare
- Irish Cancer Society (ICS)
- Consultant oncologists.

A PROPOSAL FOR AN EARLY ACCESS PILOT PROGRAMME IN IRELAND

The following proposal is the culmination of the above meetings and discussions. For the purpose of this proposal, 'experts' refers to the attendees of the roundtable and/or workshop.

The experts agreed that the following criteria are the essential components for an early access pilot programme for oncology medicines in Ireland:

ESSENTIAL COMPONENTS

1.	2.	3.	4.	5.	6.
Parties responsible for assessing applications to the programme	Define clinical eligibility criteria	Funding	Data collection requirements	Conversion to regular reimbursement	Estimated budget impact and potential patient benefit

1

Parties responsible for assessing applications to the programme

Responsibility for assessing the early access pilot programme could be integrated within existing HTA bodies. Experts suggest that the implementation of this programme could align with the NCPE's Rapid Review process, which is already established for all new medicines. Through this process, eligibility for a new cancer medicine or indication to enter the early access pilot programme could be determined at the same time as it is recommended for a full HTA.

To streamline administration, pharmaceutical companies would indicate at the time of Rapid Review submission whether they wish their medicine or indication to be considered for inclusion in the early access pilot programme. This submission should occur within two months of the EMA decision for the medicine to be eligible. If a full HTA is recommended, the NCPE would concurrently assess eligibility for early access and make a joint recommendation. The HSE would then have one month to consider this recommendation, allowing the early access pilot programme to proceed if approved.

2

Define clinical eligibility criteria

Early access programmes across Europe typically have broad clinical criteria to assess what is deemed as an innovative medicine. The experts recognised that the proposed programme would take place after regulatory approval (through the EMA), which means important metrics in terms of safety, efficacy and quality of life have already been assessed. This existing validation helps inform and shape more inclusive clinical criteria. Drawing from international models, the experts agreed that the criteria used in the French 'accès précoce' for defining innovation could serve as a helpful framework (see *Appendix 1*).[16] These criteria would include: rare, serious or incapacitating disease; no appropriate treatment available; novel treatment modality; therapeutic emergency; presumed to be efficient, safe and innovative.

3

Funding

Experts broadly agreed that a funding model akin to the one used in Portugal could serve as an effective framework (see *Appendix 1*). In Portugal, this model is anchored to Portuguese law, which stipulates a reimbursement decision timeline of 210 days from the submission of the reimbursement file. During this period, the pharmaceutical company covers the costs, while the Portuguese national health service takes over funding the programme from day 211 onwards.[17]

Considering the Irish Health Act 2013 includes a similar provision, recommending a reimbursement decision within 180 days, it was agreed that an effective co-funding model would involve the pharmaceutical company covering costs for the initial 180 days of the programme (starting from HSE acceptance to programme).[18] Subsequently, the HSE would fund the programme from day 181 until the reimbursement is finalised.

Importantly, the pharmaceutical company would be required to submit an HTA for the indication/medicine within six months of the Rapid Review decision, adhering to all stop-clock timelines during the NCPE's question and factual accuracy check stages.

4

Data collection requirements

Experts noted that data collection in Ireland faces hurdles such as inadequate IT infrastructure and stringent data policies. Nevertheless, clinicians felt there would be value in them collecting data, where possible, on people accessing new medicines through the programme, to assess its impact on patient outcomes. Demonstrating a significant positive impact could justify expanding the programme to other areas of high unmet need (such as rare diseases) and potentially to all innovative medicines, aligning with practices in most other European countries. Collecting data on the overall programme would also be beneficial in validating predicted budget impacts and patient uptake from a broader perspective.

5

Conversion to regular reimbursement

Experts emphasised that it is crucial for a medicine funded through an early access programme to remain available to the people using it (and to be funded) for the entire duration of their care, even if the decision is ultimately made not to reimburse the medicine under common law, similar to the approach in the Portuguese programme.

It was agreed that in the event of a negative reimbursement decision, the HSE and the pharmaceutical company share the costs for any existing patients in the programme on a 50/50 basis, with no new patients allowed to enter the programme. Conversely, similar to the Portuguese example, if a positive reimbursement decision is reached and the newly agreed net reimbursed price results in a larger rebate to the HSE than the pharmaceutical company's 180-day rebate, as if it had been applied from the programme's inception, then the pharmaceutical company will rebate the difference to the HSE.

6

Estimated budget impact and potential patient benefit

In parallel with this proposal, AstraZeneca Ireland, in collaboration with the health economics faculty at the University of Galway, is conducting a retrospective analysis to illustrate the potential budget impact if the proposed early access programme had been in place for all oncology medicines and indications reviewed by the HSE Drugs Group and reimbursed in 2024.

The complete analysis will be published in a peer-reviewed health economics journal. Preliminary findings indicate that an early access programme (if piloted for one year) would typically incur an annualised cost of approximately €21.7 million over a three-year period until reimbursement decision, when accounting for all patients (those with private health insurance and those without).[19] When restricting the analysis to patients without private health insurance, the annualised cost decreases to an estimated €12.9 million. In terms of patient benefit, an early access programme is estimated to provide a lifetime

gain of 1,615 quality-adjusted life years (QALYs) across the entire population. For those without private health insurance, the projected QALY gain is 958. The published full analysis is expected to be available in the near future.

An internal AstraZeneca analysis of all HSE Drugs Group-minutes from 2022 to 2024 suggests that rigorous application of the clinical criteria outlined in this proposal could ensure that very few, if any, of the accepted indications or medicines entering the early access programme would subsequently be denied reimbursement.[20]

The analysis found that 41 oncology indications or medicines were discussed following a full HTA submission. Of these, only nine submissions (22%) were not reimbursed.[20] Notably, the reasons for non-reimbursement included a paucity of clinical data; specifically, two submissions were based on phase-1 or -2 trials, while another two lacked robust comparative evidence against the standard of care. Among the remaining five, value was a concern: one was a combination regimen which was above the cost-effectiveness threshold, and four offered no or only modest improvement in overall survival.

Other considerations

Utilising biomarkers to optimise treatment outcomes

Companion diagnostics for targeted cancer treatment must be considered in funding models and timelines for an early access pilot programme. Some cancer medicines require biomarker testing (tests that identify specific molecular signatures unique to a person's cancer), to ensure the correct targeted treatment is given. It is therefore important that the health system assesses capacity in its biomarker testing facilities to ensure that delays in receiving test results will not be a bottleneck to initiating care. It was discussed that the accelerated access through the pathway be considered as part of the horizon scan process by the national cancer control programme to allow proper time to plan for testing requirements.

SUMMARY

As cancer rates continue to rise, **the disparities in access to innovative treatments will only deepen without action**. By adopting learnings from successful models in other countries, Ireland can ensure timely and equitable access to innovative cancer medicines.

The establishment of an early access pilot programme for oncology medicines in Ireland represents a critical opportunity for the Irish government to address the growing inequities in the current reimbursement system.

We welcome the Programme for Government's commitment to explore earlier reimbursement methods, including early access programmes. By allocating funds to this pilot programme, **the government can ensure timely access to innovative medicines for all people with cancer in Ireland**.

AstraZeneca Ireland is committed to working collaboratively with all stakeholders. **The time is now for decisive action, and it is imperative that we all work together.** People living with cancer in Ireland deserve the best possible chance at survival and improved quality of life by having access to the most advanced treatments available, when they need them, irrespective of their geographical location or financial status.

APPENDICES

Appendix 1. The Portuguese and French early access models for innovative medicines

	Programa de acesso precoce a medicamentos **(PORTUGUESE MODEL)**	Accès précoce **(FRENCH MODEL)**
Parties responsible for evaluating application for early access programmes	Infarmed, National Authority of Medicines and Health Products IP (Infarmed, Autoridade Nacional do Medicamento e Produtos de Saúde IP; i.e. the HTA body)[21]	French National Authority for Health (Haute Autorité de Santé, HAS; i.e. the HTA body)[16]
Clinical eligibility criteria	Life-threatening, or at risk of serious complications with no appropriate treatment available Case-by-case approval[17]	Rare, serious or incapacitating disease; no appropriate treatment available; novel treatment modality; therapeutic emergency; presumed to be efficient, safe and innovative[16]
Application process/ funding duration	Single application required and funding until reimbursement decision	Single application required, reassessed annually until final reimbursement decision[14]
Funding	Cost-sharing agreement (covered by hospitals from day 210 after EMA)[21 22] The price difference between the initial commercialised price and the final negotiated price is paid back by the pharmaceutical company[23]	Financial-managed agreements
Data collection requirements	None	HAS sets data collection requirements (which can include real-world evidence on efficacy, adverse events, real conditions of use and population characteristics) Non-compliance can risk negative reimbursement decision[16]
Conversion to regular reimbursement	Following the final decision, the product is funded through regular reimbursement. In case of a negative decision, people currently on treatment can finish their treatment but no new patients will start[22]	After annual reassessment, the medicine can be reimbursed through common law[14]

Appendix 2. Glossary

EMA	**European Medicines Agency.** This is an EU-wide regulatory body that assesses new medicines to decide whether they are safe for human use and can be marketed throughout the EU. Decisions on pricing and reimbursement are then left to each country to decide with their own HTA bodies.
HSE	**Health Service Executive.** This is the body in Ireland that decides whether to pay for (reimburse) medicines through the public health system.
NCPE	**National Centre for Pharmacoeconomics.** This independent HTA body assesses the clinical- and cost-effectiveness of medicines in Ireland on behalf of the HSE and advises the HSE on its findings.

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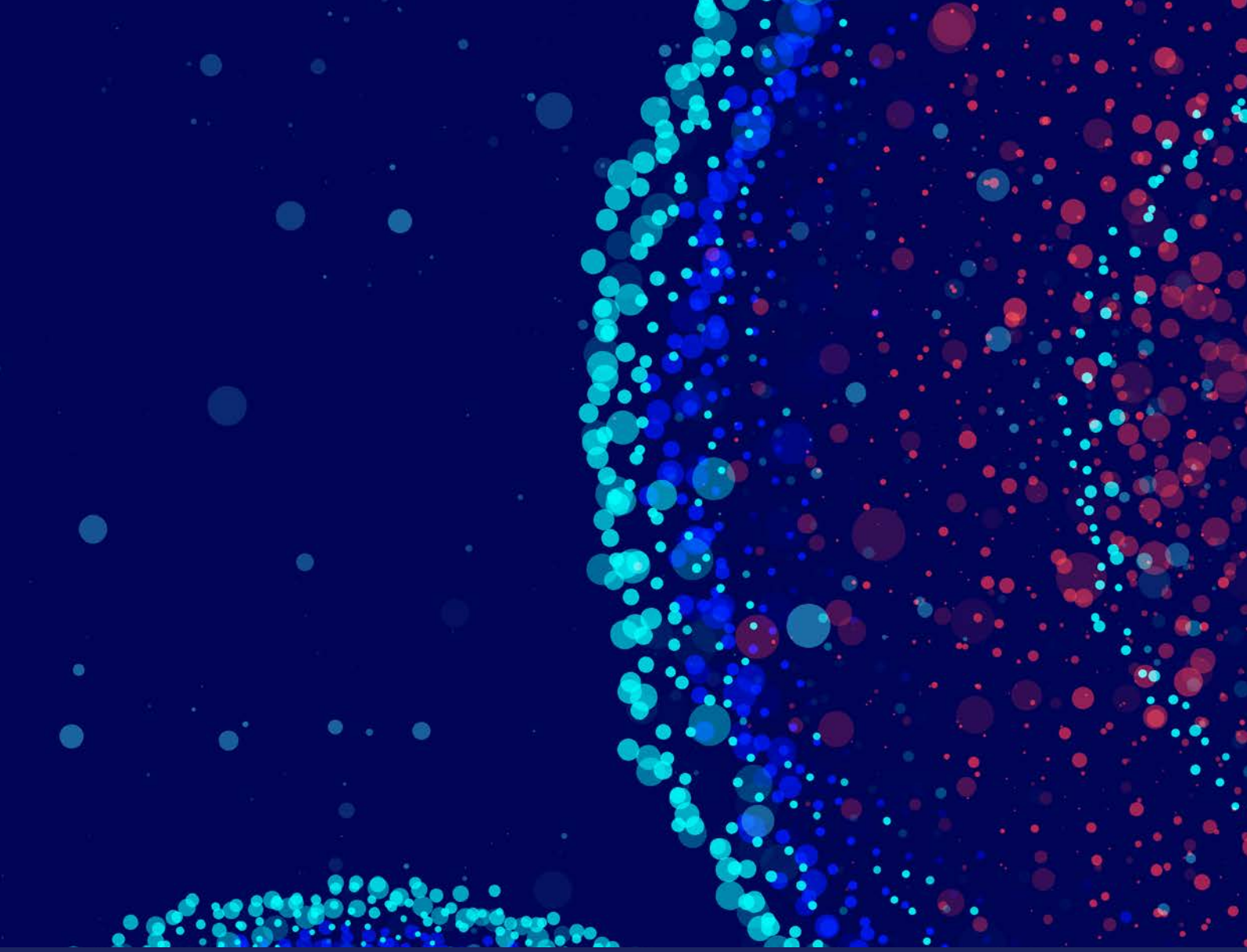

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