Irish Pharmaceutical Healthcare Association

THE CASE FOR *Fairer* AND *Faster Access* TO MEDICINES

IPHA Position Paper on the 2025 Programme for Government Commitments

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Foreword

"This Government is committed to ensuring that patients have access to new innovative medicines and treatments as quickly as possible"

– **Programme for Government**, January 2025

The Programme for Government represents a significant opportunity for the new Government and Minister for Health to make significant health impacts by making new innovative medicines available to patients in Ireland as quickly as possible. A vital step on that road, can be improving the output from partnership with the pharmaceutical industry via supply agreements.

The Framework Agreement on the Pricing and Supply of Medicines ("the IPHA Agreement") contributes to and articulates the policies and procedures of the pricing and reimbursement system for new medicines set in law and operated by the Health Service Executive (HSE) under the 2013 Health Act. It can and should be designed and implemented in full compliance with the Act with healthcare benefits to patients at its core, making good on 2025 Programme for Government commitments.

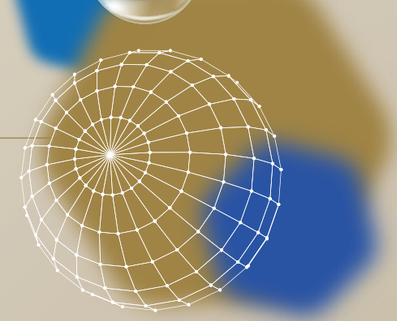
Like all health policies, these benefits to patients are to be delivered within national economic affordability and efficiency parameters, and with the interacting stakeholders accepting and delivering on their responsibilities in the process. Given the pattern of current medicines expenditure, this Framework Agreement with the State is essentially about the uptake of, and expenditure on, innovative medicines within the overall provision of, and expenditure on, medicines by the State. The Framework Agreement is not a cost control framework to manage the entirety of State medicines expenditure. For example, it has no role in relation to State schemes that subsidise wholly or partly the cost of medicines for patients, a key driver of overall medicines expenditure; nor does it contain measures in relation to rates of utilisation or prescribing of any medicines; nor the costs of distribution and dispensing of medicines. With its pricing measures for innovative medicines up to and including 'loss of exclusivity', when competing products are available, the Agreement demonstrably contributes some valuable cost control for the State; but the underlying objective is to enable the continuous flow of new, innovative medicines for patients.

Seen in this light, the Framework Agreement is also consistent with the Department of Health's stated goal of faster and fairer access to care (Statement of Strategy, 2023 to 2025). Medicinal products are the most common therapeutic intervention in the Irish healthcare system. Access to the most recent innovations available that demonstrate value for money and improve the standards of care and patient outcomes in specific therapeutic areas is an essential part of developed health systems, such as Ireland's. This is expected by all stakeholders and is much sought-after and worked towards by national leadership, clinical teams, HSE management and IPHA member companies alike. We propose how a new Framework Agreement will contribute to this ambition and the commitments made in the Programme for Government.

Acronyms and abbreviations

AI	Artificial Intelligence
AIDS	Acquired immune deficiency syndrome
CLL	Chronic lymphocytic leukaemia
CNM	Commercial negotiation meeting
CPU	Corporate Pharmaceutical Unit
DoH	Department of Health
DPS	Drugs Payment Scheme
DG	Drugs Group
EFPIA	European Federation of Pharmaceutical Industry and Associations
ELS	Existing Level of Service
EMA	European Medicines Agency
EMT	Executive Management Team of the HSE
FAR	Factual accuracy response
GMS	General Medical Service
HIQA	Health Information and Quality Authority
HIV	Human immunodeficiency virus
HSE	Health Service Executive
HTA	Health Technology Assessment
IPHA	Irish Pharmaceutical Healthcare Association
IVF	In vitro fertilisation
MAP	Managed access protocol
NCPE	National Centre for Pharmacoeconomics
NICE	National Institute for Health and Care Excellence
ODMS	Oncology Drugs Management System
OECD	Organisation for Economic Co-operation and Development
P&R	Pricing and Reimbursement
PCRS	Primary Care Reimbursement Service
PRQ	Preliminary review questions
PS	Pre-submission
QALY	Quality adjusted life year
RR	Rapid Review
TTA	Time to access
UK	United Kingdom
VAT	Value-Added Tax
W.A.I.T.	Waiting to Access Innovative Therapies

Executive summary



Access to new and innovative medicines is a crucial part of any modern, effective health system. Pharmaceutical innovation has radically changed the trajectory of many diseases from HIV and AIDS, depression, life-threatening cancers, rare diseases, Parkinsons and many others. On their own or when combined with other health advances, medicines can radically change the prognosis for many patients, enhancing our society and economy while enable healthy living, healthy aging and advance life expectancy.

However, delays in accessing new treatments can result in avoidable health losses or foregone health gains, particularly when timely treatment is critical for chronic and life-threatening conditions. Access to medicines, particularly new, innovative medicines, is closely co-related with increased life-expectancy. Every health system has to manage its expenditure on medicines to ensure it delivers clinical effectiveness, value for money and is sustainable within the affordability of its economic environment.

In this paper, we examine Ireland's pricing and reimbursement system from the perspective of timely access, as defined under Irish law. Section 18(2) of the Health Act 2013 (referred to in this paper as 'the Act' or 'the Health Act') obliges the HSE to make decisions of applications for reimbursement of new medicines within 180 days, exclusive of when information is requested from companies ('clock stops').

Under the 2021 IPHA Framework Agreement on the pricing and supply of medicines, the HSE further commits firmly to implement its decisions on reimbursement within 45 days, albeit within overall 'guidance' and 'endeavours'. By combining these two time-points, we assess whether the timelines as mandated by the Oireachtas, and further committed to in the Agreement, are currently being met in the processing of new medicine applications. In effect, time to access new medicines for patients that exceeds 225 days of HSE time from application can reasonably be judged not to be in compliance with the Act, or with the HSE's commitment or intention to implement reimbursement within 45 days, or both. This is the only available standard and is based on law and HSE commitments and/or stated intentions.

Measured against this standard, IPHA's research in relation to 88 reimbursed medicines shows that over a three-year period from 2022-2024:

- The HSE's processes took 426 days on average for all medicines analysed, exceeding the standard measure by 89%, (225 days + 201 days) (n=88).
- Medicines requiring a full HTA exceeded the allowed time for the HSE by 164%, (225 days + 368 days) (n=44).
- All Orphan medicines (n=17) took 225 days + 242 days, with all oncology medicines (n=45) taking 225 days + 267 days, taking over double the standard timeline measure for the HSE time.
- It took 408 days of HSE time, to commence pricing discussions, where a medicine required a HTA assessment (n=44).
- Where a price was agreed with a supplier in one meeting (n=53), it took 391 days of HSE time to reach patients, 74% (225 days + 166 days) above the timeframe.
- It took on average five months (n=88) from the final price offer being proposed to the medicine reaching the patient.
- Pharmaceutical companies were responsible for approximately 15% of the total time to access from application with a further 16% of the timeline uncategorised due to a lack of publicly available information.

The HSE's current reimbursement system is not, and has not been, designed, resourced, operated or governed to enable the HSE to make decisions within the legislative time-period, given the predictable volume of new medicines that are submitted for reimbursement. To do so falls to the HSE and ultimately to the Minister for Health. In the last two years the Minister for Health has promoted and brought forward the use by the HSE of 'indicative timelines' for the reimbursement process. This has been a welcome step and there is now a commitment to progress this in the HSE Service Plan 2025.

As clinicians have stated, the protracted timelines of the reimbursement process entail significant health cost to patients, especially those with time sensitive and chronic conditions. The lengthy timelines contribute to lost workdays, increased hospitalisations, lower standards of care and reduced quality of life for patients and lost life. It further widens disparities in care standards between public and private healthcare and with other European peer countries. This directly contradicts the Sláintecare vision of healthcare for Ireland.

The reimbursement system should be a collaborative process between industry (the applicant) and the State (the assessor/payer), working efficiently and effectively together while adhering to clearly defined process steps. However, when political or public debate on this matter arises, there is an inevitable tendency to seek to attribute responsibility for protracted timelines that do not meet the Government's commitment to make new medicines available 'as soon as possible'. As outlined, the process as it currently functions does not meet legislative timelines; to understand why this is occurring it is important that all currently available data is collated and analysed. By doing so each stakeholder can understand their role in potential delays, and most importantly understand how this can be improved. By publishing this paper, IPHA seek to provide the data that is currently available to them through public sources in addition to further data supplied by members. The purpose in doing so is to thoroughly analyse each step within in the process, clearly identifying which timelines fall within State time, and which timelines fall within industry time. Our aim is to make clear, data driven recommendations on how this process can ultimately be improved, acknowledging the role of all stakeholders.

This research combined with previous experience will inform IPHA's approach to this year's pricing and supply agreement. IPHA fully recognises that State expenditure on medicines has increased to record levels and that new medicines are indeed being reimbursed and made available to patients in the public health system every year. IPHA are partners in the process. Partnership impels us to advocate for change that is in the interests of enhancing patient care in Ireland and that makes good on the Programme for Government and on the requirements of the 2013 Health Act.

Pricing agreements with the pharmaceutical industry go back to the 1970s in Ireland. A new Agreement is to be negotiated for October 2025 onwards, it is now time for the system to be designed, operated, resourced and governed to comply with the Health Act 2013 and meet the goals of faster and fairer access to medicines. Mutual commitments in the Agreement can be linked to achieve these goals. IPHA members will also honour their responsibilities for timely access to new medicines for patients.

We ask the new Minister for Health, with Government support, to work with us to base the next Agreement on these ideas and the following five key principles. We believe these will find support from all key stakeholders – patients, clinicians, management, Oireachtas members.

1. **Ensuring patients in Ireland have access to a steady stream of pharmaceutical therapeutic advances within clear policy-driven timing after authorisation.**
2. **Predictability and stability in medicines expenditure.**
3. **Process transparency and communication.**
4. **Financial measures linked to process efficiencies and accelerated patient access.**
5. **Regular dialogue scheduled between industry and the Agreement parties.**

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Chapter 1

Fairer and Faster Access to Medicines in Ireland

1.0 Introduction - A policy perspective on Access Timelines

This paper sets out to examine the timeliness of patient access to new medicines in the context of the state's legal commitments. These aligns to the Government's commitment in its Programme 'to ensur[e] that patients have access to new innovative medicines and treatments as quickly as possible'. The law governing the timeliness of access and reimbursement of new medicines by the HSE on behalf of the State of new medicines is the Health Act, 2013 ("the Act"). A key factor in timely access for patients is the State's adherence to the provisions of Section 18(2) of the Act for prescription pharmaceutical medicines to be made available to patients via the public health system in Ireland. This provision requires the HSE to make reimbursement decisions within 180 calendar days of receipt of an application, exclusive of written information requests sent to the applicant pharmaceutical company (known as a 'clock stop'). The authors have examined the timelines to decision exclusive of such clock stops. The research is based primarily on publicly available information, principally from the websites of the National Centre for Pharmacoeconomics (NCPE) and the HSE, as well as survey data obtained from IPHA member companies and clinical and policy sources.

As stated in the Executive summary, the paper and IPHA fully recognise that the cumulative timeline of access for patients to newly authorised medicines (by the European or national regulatory authorities) is what matters to patients and clinicians and ultimately for timely care. This cumulative time includes steps that are the responsibility of pharmaceutical companies and steps that are the responsibility of the HSE. Time periods for which pharmaceutical companies are responsible include, the time taken between market authorisation and an application for reimbursement to the HSE, the time taken for pharmaceutical companies to respond to written requests for further information (clock stops), and[3] time taken to propose and agree prices in negotiations with the HSE. IPHA member companies are committed to minimising these timings. IPHA also notes recent comments on behalf of the HSE urging pharmaceutical companies to make applications for all authorised medicines. In the context of European policy, IPHA members are certainly disposed to this and look forward to discussions with the Department of Health and HSE on how to give effect to applications being made for all medicines to be assessed in a timely manner as proposed in this paper.

The provisions of the Act in relation to 180-day timing relate to HSE actions and therefore the question of formal legal compliance with this timeline falls to the HSE. Effectively, there is a heavier legal burden on the HSE, and Industry, as a key stakeholder in this process, seek to support the HSE in meeting that requirement. The paper has analysed carefully the timing data on recent medicines' reimbursements, so that the respective responsibilities of the HSE and companies can be seen. However, fulfilling the Government's Programme for Government commitment to access 'as fast as possible' falls to both pharmaceutical companies and HSE working together collaboratively, with Government support, in a framework that is designed, resourced, operated and governed to meet that goal in a sustained way.

1.1 Why does speed of access to medicines matter?

The importance of access to innovative medicines has been clearly summarised and articulated by the Chair of the National Institute for Clinical Excellence (NICE) in the UK, the body tasked with assessing pharmaceutical reimbursements in England, Wales and Northern Ireland who stated:

"Speed matters most because the opportunity cost of delay is not zero. Patients are waiting on life-saving treatments and innovative medicines to make a difference to their lives."

– **Sharmila Nebhrajani**
(speaking at Kings Fund online event, July 17, 2023).

The logic of this in an Irish context is set out by HSE senior leadership in a note to the Department of Health on October 6th, 2023, where it is stated:

"It cannot be denied that access to new medicines represents an important part of any modern health system and that small incremental benefits which arise with some medicines can over time when combined with other treatment advances significantly change prognosis for patients,"

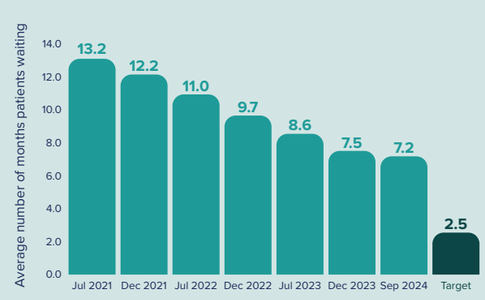
It goes onto say:
"The responsibility of the Health System has to be to ensure access to a steady stream of therapeutic advances whilst ensuring as far as possible the best value for money is achieved. New medicines will and should always represent an area of investment subject to robust assessment."[1]

There are also a significant number of peer reviewed studies that show speed of access to healthcare is fundamental to health outcomes and how this logic applies to pharmaceutical innovation. A brief overview of such research is outlined in Appendix 2.

The Department of Health's current Statement of Strategy 2023-2025 outlines how to 'Make Access to Healthcare Fairer and Faster' (See Figure 1.1). The Statement details how, in many areas, significant progress is being made with data published against priorities such as average appointment waiting times and reduced diagnostic waiting times (See Figure 1).

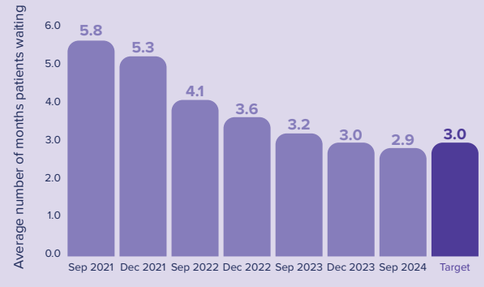
Figure 1. Average waiting times published in the Department of Health's current Statement of Strategy

Average waiting time for an outpatient appointment almost halved



Source: Department of Health

Average waiting time for a GI Scope reduced by half



Source: Department of Health

1 Briefing on New medicines funding, HSE note to Department of Health obtained through a Freedom of Information request
2 https://www.gov.ie/en/organisation-information/38cca-department-of-health-statement-of-strategy-2023-2025

Figure 1.1

Make access to healthcare fairer and faster

What does this strategic priority mean?

- A whole-of-system approach to support better health outcomes through the right care delivered in the right place at the right time.
- Maintaining our focus on fundamental health inequalities to ensure equitable access to health and social care services based on need, and not on ability to pay. We will build on the significant progress we have made, including the expansion in eligibility, abolition of public in-patient hospital charges, reduction in the number of patients on waiting lists and increased hospital bed capacity.
- A new approach to service planning that is informed by the health and social care needs of regional and local populations.

Why is this a priority?

- The Programme for Government commits to providing fairer and more affordable care, promoting women's health and a range of initiatives targeting marginalized groups to ensure our services meet everyone's needs.
- Improving timely access to care and addressing health inequalities are two key Sláintecare Reform Programmes under the Sláintecare Implementation Strategy and Action Plan 2021-2023.

Source: (Page 15 of Department of Health Statement of Strategy 2023 to 2025)

However, even though medicinal products are the most common form of therapeutic intervention in the Irish health system there is limited evidence, based on the timelines and steps outlined earlier, that any progress on speed of access has taken place since 2020. This is in part why former HSE Director General described the operation of the pricing and reimbursement system as creating a 'hidden waiting' list is costing lives[3].

We can see from the timelines outlined below, that despite increased investment by the State in the provision of new medicines, there was only a marginal decrease in access timelines for Rapid Review only medicines and a 13% increase in the average timelines for HTA medicines. When you categorise the medicines into those for oncology and those for orphan treatments, the timeline becomes starker.

3 https://www.businesspost.ie/analysis-opinion/our-hidden-waiting-list-of-delays-in-access-to-medicines-is-costing-lives

1.2 What does the legislation state?

The Health Act 2013 provides for decisions on reimbursement applications to be taken by the HSE within 180 days of the application. This timeframe does not count the time to which industry must submit responses to requests for information.

Section 18 of the Act states:

*"Where the Executive receives an application…(sic) it shall, before the expiration of a period of 180 days from the day on which it received the application or such **longer period** as may be required by the operation of subsection (3), determine the application."*

The Act outlines that the 'longer period' is allowable for requests that are unable to be determined because it requires additional information from the applicant, it states:

"The Executive shall give notice in writing to the applicant specifying the additional information that it requires from the applicant in order to so determine the application and the running of the period of 180 days referred to in subsection 2, is upon giving notice of referred to into the applicant."

Such periods as those referred to above are known as 'clock stops'. In order to operate in accordance with the legislation, applicants must receive requests for information in writing, otherwise it cannot be considered a clock stop.

Chapter 2

Timelines to Access in Ireland: An Analysis

2.0 Introduction

There are limitations when it comes to defining and measuring timely access to medicines in Ireland. The date of applications and decisions by the HSE are not published or available. The date upon which a Rapid Review is commissioned by the HSE is published as is the date it is added to the national reimbursement list or when the medicine is accessible. For the purposes of examining timelines, it is necessary to consider the 180 days to decision *requirement* on the HSE alongside 'HSE guidance' in Schedule 1[4] of the 2021-25 Framework Agreement. Within the HSE's endeavours and guidance, clause 11 of the Schedule commits the HSE to implement a decision to reimburse a medicine within 45 days.' To be clear, this is not a legal requirement such as in the Health Act, but whether described as a commitment or an intention of the HSE, it is a clear indication of a reasonable standard timeline for access to new medicines for patients after a HSE decision to reimburse that medicine.

Table 1: Standard of Timeliness from Legislation & IPHA Agreement

Source	Timeline
Legal Obligation Section 18(2) of the Health Act 2013 (HSE to make a decision on reimbursement within 180 days excluding clock stops.)	"where the Executive receives an application…, it shall, before the expiration of a period of 180 days from the day on which it received the application or such longer period as may be required by the operation of subsection (3) [requests for further information, 'clock stops'], determine the application… "
Operational Commitment Schedule 1, Clause 11 of the IPHA Framework Agreement, 2021-25 'Notes and Guidance' (HSE to implement a decision to reimburse within 45 day of that decision)	"Where the HSE approves an application to reimburse a medicine, reimbursement will be implemented within 45 days. " [emphasis added]
Standard Measure of Timely Access for Patients	**HSE has 225 days post the application to decide and implement decisions (excluding clock stop)**

4 The language in this Schedule has varying degrees of definitiveness. Everything in the process is described as a commitment to 'endeavour', yet there are distinctions within the provisions. It states "The following sets out HSE guidance on how the HSE and related bodies will endeavour to engage with Companies submitting applications for reimbursement. It does not purport to be an exhaustive description of the entire processes applicable (which are at all times subject to the 2013 Act, where appropriate, and HSE discretion)" Yet Clause 9 of this section refers to the HSE endeavouring to make a decision 45 days after a Drugs Group recommendation while Clause 11 more definitively states that the HSE will implement a decision to reimburse 45 days after that decision. Perhaps this is a distinction without a difference, but it has a relevance to expectations of timelines to access for patients.

In effect, where patient availability occurred within 225 days of Rapid Review commissioning, we can infer that these decisions are compliant within the Act and the HSE's operational commitment or intention. Thus this paper combines both the legislative timeline with the HSE operational commitment as the standard against which current timelines can be assessed.

2.1 Methodology

IPHA researchers built a database of pharmaceutical application and reimbursement timelines based on publicly available information on the websites of the NCPE and HSE. The HSE Drugs Group meetings identified reimbursement recommendations at monthly meetings. The NCPE, the HSE Oncology Drug Management System (ODMS) and Primary Care Reimbursement Service (PCRS) lists identified reimbursement dates between 2022 and 2024. The specific data points analysed are seen in Table 2 and the timepoints represent the period of operation of the IPHA Agreement.

This was augmented by primary research gathered via survey from IPHA member companies where key timepoints were recorded by IPHA companies (See Appendix 1). Results were then aggregated and categorised by assessment type (RR only or HTA), medicine type (e.g. orphan, oncology) along with other milestone points in the process, such as number of commercial negotiation meetings per application and how many Drugs Group meetings a medicine needed. Other information obtained from IPHA members was time it took to get first commercial negotiations meeting and the time from final price agreed offer to reimbursement.

Different timepoints in the process were then categorised based on whether the step met the terms of Section 18(2) of the Health Act 2013, namely, whether information was being requested in writing from an applicant company.

2.2 Limitations

This analysis is of IPHA member medicines only (those who responded to a survey request) and not all medicines added to the reimbursement list in 2022-2024. Nonetheless, it constitutes the experience of members in respect of HSE decisions on 88 medicines which represents 93% of IPHA medicines reimbursed in the survey period (2022-2024), approximately 63% of all medicines reimbursed (including non-IPHA).

A number of limitations with the public information should be noted. The date of company submission is not publicly recorded and available, therefore the earliest publicly available start time is the date of Rapid Review commissioning (while in terms of the Health Act, the legal start time is the date an application is received by the HSE). Similarly, the date of decision on reimbursement by the HSE is not publicly available, therefore as alluded to earlier, 225 days post Rapid Review commissioning is the timepoint that could be considered the period that would meet publicly verifiable expectations of time to access for patients. Compliance with the terms of the legislation may be reasonably inferred but in practice currently can only be known to the HSE. Compliance with the HSE's commitment or intention to implement a reimbursement decision within 45 days after a reimbursement decision can be known by the HSE, and by the company, where the HSE provides it with the exact date of decision to reimburse.

Despite these limitations, the findings are consistent with previous research in this area as published (See Appendix 5) in terms of overall time to reimbursement and the division between assessment and commercial negotiation phase.

2.3 Categorisation of clock stops

This analysis endeavours to segment each step of the process into HSE time, which includes assessment and commercial negotiation time, and industry time. To be consistent with the Health Act 2013, application assessment and commercial negotiation time, are combined into 'State time'. The legislation specifies the HSE as the responsible authority of the State in respect of the reimbursement process, assessment and decision; the NCPE acts with a high degree of expertise as an agent of the HSE in carrying out RRs and HTAs as part of the process if needed; thus the legal responsibility is always with the HSE. Therefore, State time is HSE time.

Table 2. Categorisation of clock stops

Source	Clock Stop Yes/No	Reason for Y/N
Submission by company	No	Not public information.
Time for Rapid Review assessment	No	Assessment is ongoing
Time to pre-submission to NCPE meeting	No	Described on NCPE website as a 'Mandatory' step. Information is not being sought from companies pending a meeting
Time to submit HTA	Yes	Applicant to submit HTA template in compliance with Act
Time to preliminary review questions (PRQ)	No	Part of the assessment by State – time being used by NCPE to draft and send PRQs
Time to response to PRQ	Yes	Applicant receives written request for information in compliance with Act
Time to factual accuracy check	No	Assessment by NCPE
Time to response to factual accuracy check*	Yes	Applicant is to respond to an information request
Remainder time for completion of assessment	Undefined	
Time to 1st commercial negotiation meeting with the HSE	No	No written information being sought
Time from final price offer to Drugs Group (DG) meeting	No	No information being sought
Time from DG positive recommendation to reimbursement	No	No information being sought
Time from final written price offer to reimbursement	No	No information being sought
HSE decision time from final written price offer to reimbursement	No	No information being sought

State time Industry time

For the purposes of analysis, the medicines were examined and categorised according to these process categories:

1. Overall time to access
2. Rapid Review only time to access
3. Rapid Review + HTA time to access
4. With a further examination of medicines based on the number of negotiation meetings that took place.
5. In addition, the time to access was also examined through the categories of oncology and orphan medicinal products.

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2.4 Access Timelines: Key Findings

The following datasets demonstrates that the 'timely processing' of applications is not occurring. By way of illustration, the timing of various steps in the process highlight how there are significant periods during which applications are not being progressed, this could be referred to as a period within the pricing and reimbursement system which results in potential lost opportunities for better healthcare outcomes for patients.

Figure 2. P&R process flowchart for RR only and HTA medicines

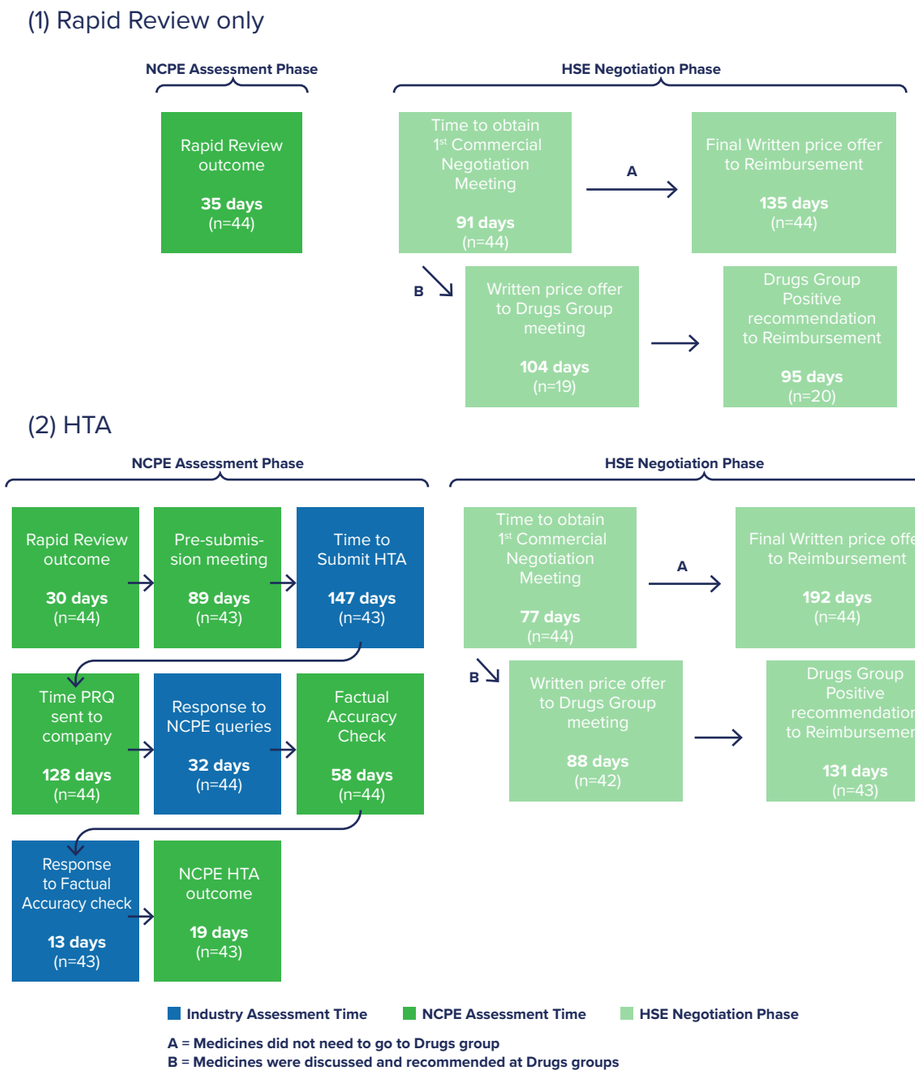

Figure 3. Division of time from application to patient access

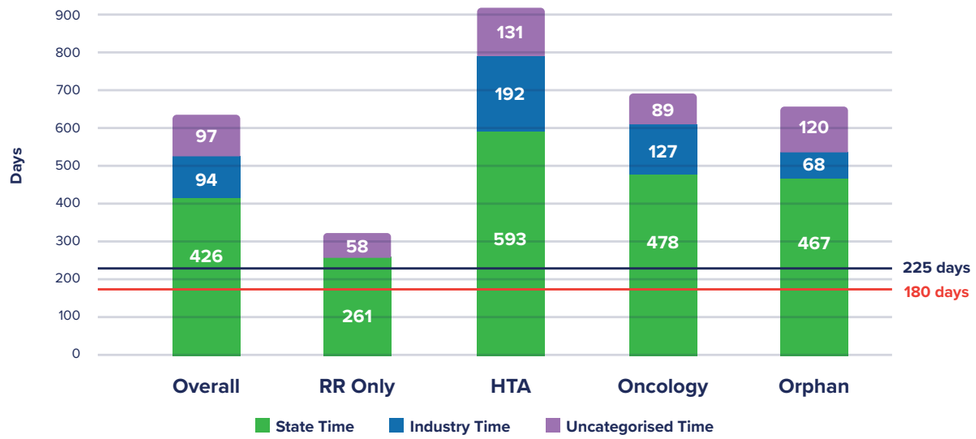

Table 3. State Times for medicines percentages at various timepoints

Category TTA	State time > 180 days	State time > 225 Days	State time > 450 days	State time > 675 days
Overall	92%	86%	56%	28%
RR only	84%	73%	18%	7%
HTA	100%	100%	93%	50%
One CNM	87%	77%	45%	15%
Orphan	100%	88%	71%	24%
Oncology	98%	96%	71%	33%

TTA: Time to Access, CNM: Commercial Negotiation meeting

Table 4 breaks down the number of days and percentage of the overall time to patient access accounted for by each step.

Table 4. Stages of the P&R process for Rapid Review (RR) only medicines (n=44) from 2022 - 2024

NCPE assessment	RR outcome	Post NCPE assessment	Days from RR completion to 1st commercial negotiation meeting	Days from final written price offer to reimbursement	Remainder of time	Total
	35		91	135	58	**319**
	11%		29%	42%	18%	

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In a Rapid Review only application (Table 4), IPHA members stated it took 91 days on average for a meeting to be arranged between the company and the HSE. It took 135 days from the final written price offer for the patient to receive the medicine. The remainder time is likely accounted for by time between commercial negotiation meetings, but this information is not publicly available. **The total timeline of 319 days, State time accounts for 261 days which exceeded the 225 days by 36 days (16%).**

Table 5. Stages of the P&R process for HTA medicines (n=44) from 2022 - 2024

State Time							
RR outcome	**RR complete to PS meeting**	**Full HTA submission to PRQ's**	**PRQ response to Factual accuracy sent**	**Remainder of time for NCPE assessment completion**	**HTA completion to 1st commercial negotiation meeting**	**Final written price offer to reimbursement**	**Total**
30	89	128	58	19	77	192	**593 / 916**
3%	10%	14%	6%	2%	8%	21%	**65%**

PS = Pre-Submission, PRQ = Preliminary review questions

Table 5 outlines the various steps for a medicine where a HTA has been required. To note, the HSE remains legally responsible for the whole process as the commissioner of assessments. It took 128 days to receive a response after a HTA submission, 77 days to secure a meeting with the HSE and 192 days from final written price offer to patient access. **This constitutes 65% of the overall timeframe (916 days) to access a HTA medicine. State time of 593 days exceeded the 225 days by 368 days (164%) during the surveyed period.**

Table 6. Stages of the P&R process for HTA medicines (n=44) 2022 - 2024 regarded as stop clocks

Industry Time			
PS meeting to HTA submission	**PRQ response**	**FAR response**	**Total**
147	32	13	**192 / 916**
16%	4%	1%	**21%**

PRQ = Preliminary Review Questions
FAR = Factual Accuracy response

Table 6 outlines the steps of the reimbursement process where stop clocks are initiated under the Act. We can see that companies typically take on average 147 days to submit HTAs. Companies have a commercial incentive to ensure replies are as prompt as possible therefore the extended timeline is indicative of the robustness of the reimbursement process. **Industry is responsible for 21% of the timeline associated with patient access for HTA medicines.** The remainder of the time 14% (131 days) is likely accounted for in process steps that are not publicly documented or available. These could include, but not necessarily limited to additional meetings to negotiate a price.

The above data, based on a combination of information publicly available on the NCPE and HSE websites, along with responses by IPHA members to survey questions, clearly demonstrates that the pricing and reimbursement system is not operating to the 180-day timeline set in law. As IPHA approach the next agreement, it is reasonable for IPHA members, and for patients and clinicians, to expect that the State would design, resource, operate and govern the pricing and reimbursement system in line with the underpinning legislation. IPHA and its members stand ready to contribute to this process and to play their part in making time to access new medicines as fast as reasonably possible, as per the Programme for Government commitment.

The timelines to patient access of IPHA members' medicines shown below demonstrate that despite additional funding over the period, the time-to-access for RR-only medicines and HTA medicines increased from 2022 to 2024. A similar pattern is repeated when examining orphan and oncology only medicines.

Table 7. Time to access for IPHA medicines requiring only a RR, timelines from 2022 – 2024

Average RR (Days)	(n=)	NCPE assessment	Negotiation timeline	Total Access time
2022	29	34	310	344
2023	10	40	347	387
2024	9	30	350	380
2022 – 2024				**+10%**

Table 8. Time to access for IPHA medicines requiring HTA, timelines from 2022 – 2024

Average HTA (Days)	(n=)	NCPE assessment	Negotiation timeline	Total Access time
2022	16	464	397	861
2023	13	587	405	992
2024	18	571	400	971
2022 – 2024				**+13%**

Table 9. Time to access for Oncology IPHA medicines from 2022 – 2024*

Average (Days)	(n=)	NCPE assessment	Negotiation timeline	Total Access time
2022	17	234	452	686
2023	14	383	268	651
2024	16	481	289	770
2022 – 2024				**+12%**

* Includes medicines that required a RR only and ones that needed an HTA

For oncology medicines of IPHA members, there was a 12% increase in the timelines for patient access with applications taking an average of 704 days between 2022 and 2024.

Table 10. Time to access for Orphan IPHA medicines from 2022 – 2024*

Average (Days)	(n=)	NCPE assessment	Negotiation timeline	Total Access time
2022	8	266	345	611
2023	4	250	508	758
2024	6	336	382	717
2022 – 2024				**+17%**

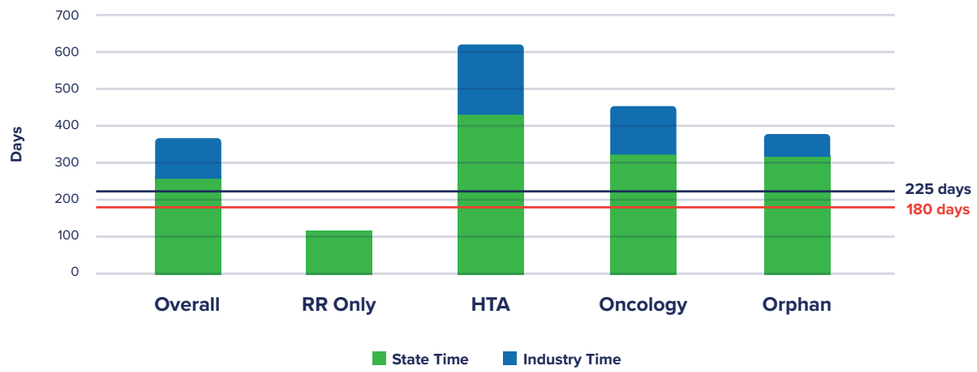
* Includes medicines that required a RR only and ones that needed an HTA

For medicines with an orphan designation, there was a 17% increase in the time to access for orphan treatments taking on average 679 days between 2022 and 2024.

Price Negotiations

From application, it took the State **just under a year on average** to discuss price with industry, in relation to all medicines reimbursed from 2022 to 2024 (n=88) industry was responsible for 26% of this time, the State 74%.

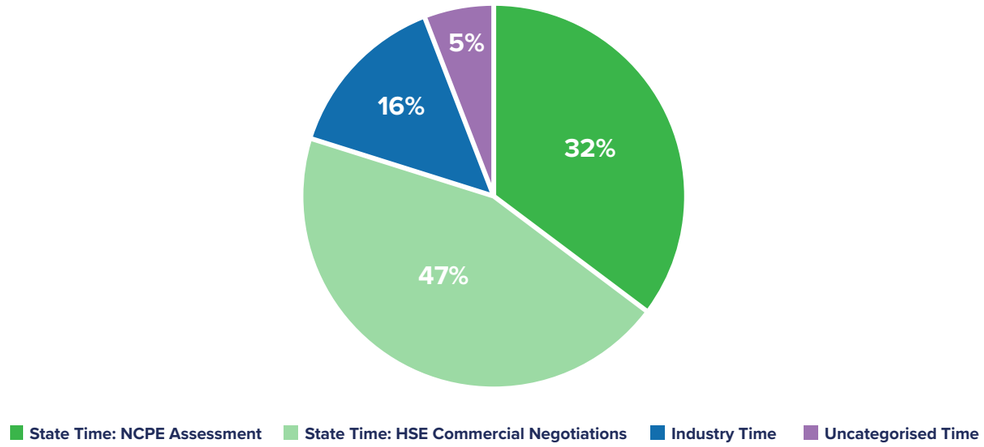
Figure 4. Division of time from application to 1st price negotiation meeting



On average, it took 1.7 meetings to negotiate price for HTA medicines (n=44) and 1.3 meetings if the medicine only required a Rapid Review (n=44).

When a medicine needed only one commercial negotiation meeting to agree a price (n=53), it took on average 495 days from time of application to patient access. State time, 391 days, accounted for 79% of the overall time. It would be reasonable to expect that where pricing negotiations needed just one meeting, the timelines would be much shorter and compliance with the 180-day limit could be more easily achieved. This did not happen on average. An overall breakdown of the share of time in these cases is illustrative in Figure 5.

Figure 5: Breakdown of overall time if only one Commercial Negotiation meeting occurred



Managed Access Protocol (MAP)

The time from a positive Drugs Group recommendation to the implementation of a Managed Access Protocol (MAP),[5] where the medicine became available to patients was on average 338 days (n=14). Some of this time is between the Drugs Group review and the HSE Executive Management Team's formal decision to reimburse; the rest – we assume the majority – arises after a decision to reimburse, when the details of the MAP are then addressed.

If the HSE decides a MAP is to be put in place for a particular medicine, i**t is taking on average over 11 months** from the time the medicine is recommended at Drugs Group to when it is available to the patient (Table 11), representing 30% of time to access (1139 days).

In comparison, medicines which did not require a MAP (n=50) took 2.2 months to receive a formal reimbursement decision by the HSE after a positive recommendation at Drug Group. Therefore, MAP medicines on average took nearly nine months longer for patient access. This, and any other process that influences time to availability for patients after a formal HSE decision to reimburse, is not within the scope of the 180-day requirement in the Act. However, in Schedule 1 of the 2021-25 Framework Agreement, setting out HSE guidance that the HSE will endeavour to implement, the HSE says that where a decision is made to reimburse a medicine, 'reimbursement will be implemented within 45 days' (para 11) [emphasis added] and earlier, (in para 9) that the HSE will endeavour to make a decision within 45 days of a Drugs Group recommendation. Accordingly, a reasonably expected timeline for actual reimbursement (where a decision has been positive) and consequent availability to patients from the HSE Drugs Group meeting can be 90 days; and more definitively, 45 days after a formal HSE decision. No distinction between medicines deemed to require an MAP or otherwise is made in the Agreement Schedule. Clearly the intended, endeavoured or expected 45-day timeline to reimbursement after HSE decision is not being meet in relation to MAP medicines. It has to be recognised that the HSE has legal discretion to decide if a medicine requires a MAP or not and what the MAP should contain. Notwithstanding commitments or intentions expressed in Schedule 1 of the Framework Agreement, the exercise of this discretion, how long it takes to set a MAP and the consequences including timeliness of access to the new medicine for the patients concerned, remains the responsibility of the HSE.

5 Managed Access Protocols (MAP)s enable access to drugs for patient cohorts with greatest unmet need, while providing oversight, governance and budgetary certainty to the payer. Source: https://link.springer.com/article/10.1007/s40258-024-00904-1

Table 11. MAP Timelines 2022 – 2024 Reimbursements

Time from Positive Drugs Group Recommendation to Patient Availability				
Brand	**Positive Drugs Group Recommendation**	**MAP in place**	**Days from positive Drugs Group recommendation**	**Time above 90 days**
Vyndaqel	29/06/2021	01/03/2022	245	155
Dupixent	08/03/2022	01/05/2022	54	0
Xarelto	09/02/2021	01/10/2022	599	509
Saxenda	14/09/2021	01/01/2023	474	384
Vitrakvi	13/12/2022	01/06/2023	170	80
Luxturna	12/07/2022	23/08/2023	407	317
Evrysdi	14/02/2023	01/09/2023	199	109
Sativex	08/11/2022	01/10/2023	327	237
Dupixent	11/10/2022	01/11/2023	386	296
Nustendi	12/09/2023	01/09/2024	355	265
Nilemdo	12/09/2023	01/09/2024	355	265
Evenity	22/08/2023	01/11/2024	437	347
Bylvay	12/03/2024	01/12/2024	264	174
Rukobia	12/09/2023	09/12/2024	454	364
Average (n=14)			**338**	**248**
Median (n=14)			**355**	**265**

2.5 Potential Impact of Delayed Access to new medicines

Higher Treatment Costs Due to Disease Progression
Delayed access to effective treatments often leads to disease progression, necessitating more intensive and costly interventions. One study[6] assessing the impact of systemic delays in access to oncology drugs found that such delays adversely affect clinical outcomes, including overall survival and progression-free survival. The study emphasizes the need for timely access to improve patient outcomes and reduce healthcare costs.

Reduction in Health Gains and QALY Losses
Timely access to medications is crucial for maximising health benefits. A study published in the Medicine[7] journal highlights that high medication and healthcare costs constitute financial burdens, leading to unmet healthcare needs and suboptimal health outcomes. This underscores the importance of fair pricing and timely access to medications to prevent health disparities and loss of QALYs.

Increased Burden on the Healthcare System
Delays in treatment can lead to increased hospital admissions and long-term care needs. The same study examines[8] how high healthcare costs can lead to financial burdens on governments, as more resources are needed to care for a population with suboptimal health outcomes.

Economic Burden on Patients and Society
Delayed access to medications can lead to cost-related medication non-adherence, adversely affecting health outcomes and increasing overall healthcare costs. A survey study published in JAMA Network Open[9] found that cost-related medication non-adherence is prevalent among adults aged 65 years and older, highlighting the need for better access to affordable medications.

6 https://www.mdpi.com/1718-7729/31/3/110
7 https://journals.lww.com/md-journal/fulltext/2021/08060/a_comparison_between_the_effects_of_drug_costs_and.78.aspx
8 ibid
9 Dusetzina SB, Besaw RJ, Whitmore CC, et al. Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022. JAMA Netw Open. 2023;6(5):e2314211. doi:10.1001/jamanetworkopen.2023.14211

Budgetary Impact and Inefficiencies in Healthcare Spending
Delays in medicines reimbursement and approval processes can lead to inefficiencies in healthcare spending. A study in Health Economics Review[10] assessed the impact of negotiation situations for life-extending pharmaceuticals on societal outcomes, highlighting how delays can affect the cost and availability of medications, leading to broader economic implications.

The direct impact of the timelines on the health service in Ireland can be seen in many instances, with an emerging divide between medicines available publicly and privately as well as disparities in care standards between Ireland and comparator countries in Europe.

2.5.1 Public Private emerging divide

Several clinicians are now reporting a disparity between the timing and availability of new medicines for public patients, and those which private patients can access via private health insurance coverage or by their out-of-pocket payments. Private patients can often access new medicines once authorised by the EMA through their health insurer, typically as part of private hospital-based care. On the other hand, public patients typically have to wait for the medicine to be assessed and reimbursed by the HSE before being able to access it and, as has been demonstrated, this can take months or years beyond reasonable expectations. Oncology clinicians are reporting more referrals to private clinics and increasingly having to ask their patients if they have access to health insurance to determine which course of treatment they can provide[11].

2.5.2 Disparities between access to care improvements in Ireland and comparator countries.

The EFPIA Patient W.A.I.T. indicator[12] reliably and consistently shows patients in Ireland receive later access to innovative treatments than European countries. This is a survey based on publicly available information. The significant learning for the Irish health system is that over the last decade, the study has demonstrated much slower rates of availability of medicines and slower access times for patients in Ireland, as measured from the time of central authorisation by the EMA/European Commission.

It is important to note that according to the EFPIA Patient WAIT indicator, 372 medicines were approved by the EMA from 2014–2022. From this cohort, applications for 71% of medicines were submitted by companies for reimbursement in Ireland. From the 106 medicines without an application, IPHA member companies only account for 29 medicines (27%).

Furthermore, the current EFPIA Patient WAIT indicator found that there are more newly authorised innovative medicines available in similar markets such as Scotland, Luxembourg, Bulgaria, Greece, Slovenia, Norway and Iceland than in Ireland. Therefore, the time it takes to process applications in Ireland may well be as much a factor in the timing of a decision to apply for reimbursement as relative market size.

In the context of continuing considerations of the proposed revisions to the EU's General Pharmaceutical Legislation, EFPIA members (including parent companies of IPHA members) have committed to make applications for reimbursement for any or all medicines that individual EU Member States request.

As discussed below, the rate of availability and time to availability shown in EFPIA WAIT data is a function both of company decisions to apply for reimbursement and of State reimbursement processes.

10 https://healtheconomicsreview.biomedcentral.com/articles/10.1186/s13561-020-00267-y?utm_source=chatgpt.com
11 https://www.irishexaminer.com/news/spotlight/arid-41363710.html
12 2024 Patient W.A.I.T. Indicator https://efpia.eu/news-events/the-efpia-view/efpia-news/new-data-from-efpia-reveals-multiple-factors-leading-to-unequal-access-to-medicines-for-patients-across-europe/

Figure 6. EFPIA Patient W.A.I.T. Indicator (2019 - 2022) for Time to availability for oncology medicines

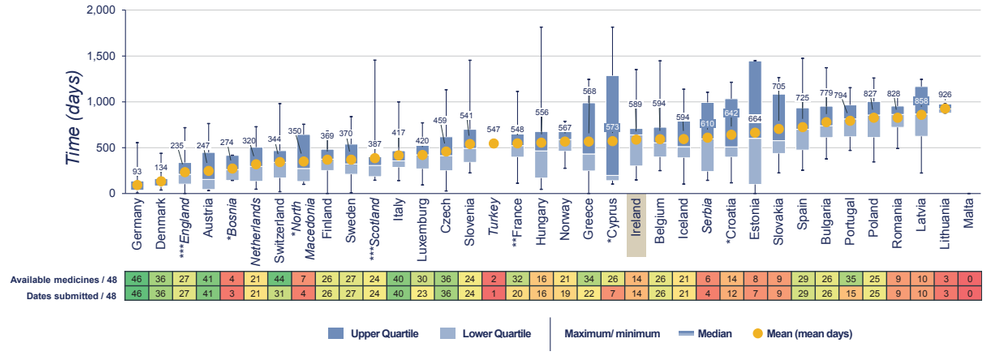
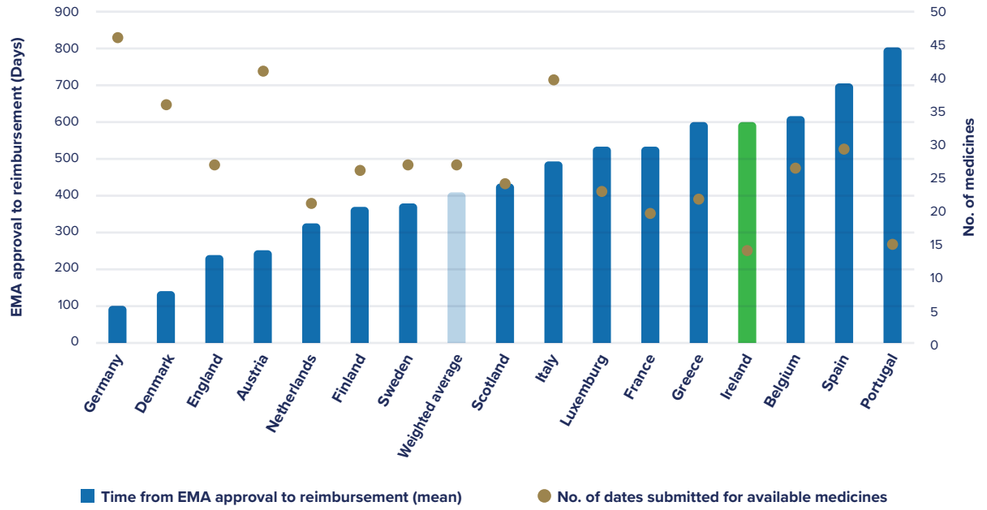


Figure 7. EFPIA Patient W.A.I.T. Indicator (2019 - 2022) for Time to availability for oncology medicines, looking at Ireland compared to basket countries



Ireland had 14 oncology medicines reimbursed at an average time of 589 days and by contrast Denmark had 36 medicines available with an average time of 134 days. The weighted average of surveyed countries was 27 medicines taking 383 days.

Figure 8. EFPIA Patient W.A.I.T. Indicator (2019 - 2022) for Time to availability for orphan medicines

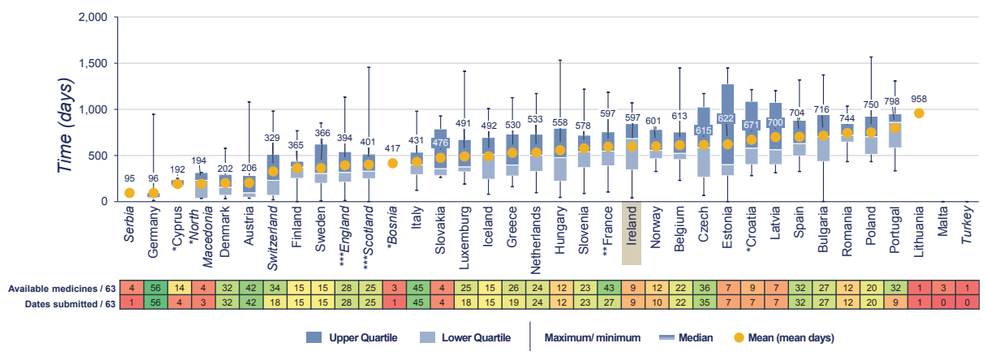
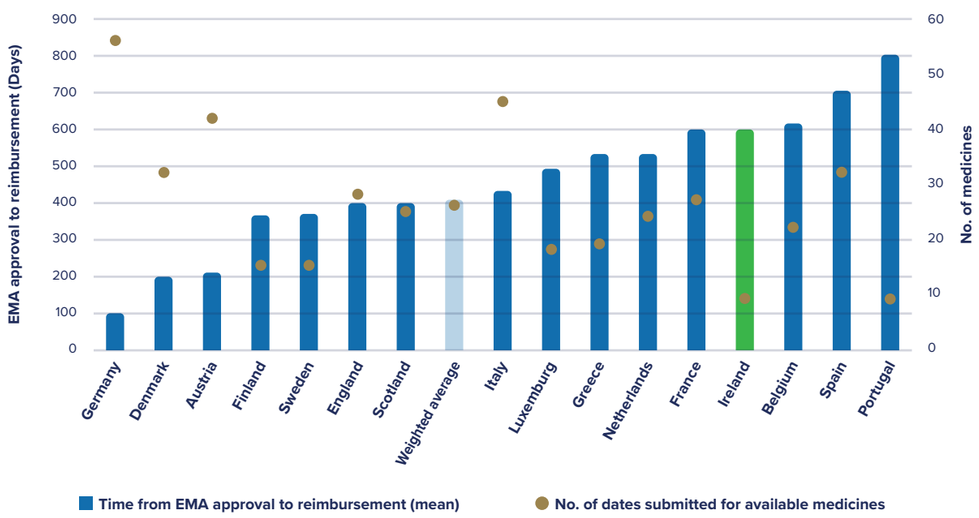


Figure 9. EFPIA Patient W.A.I.T. Indicator (2019-2022) for Time to availability for orphan medicines, looking at Ireland compared to basket countries



For Orphan treatments, nine were made available in Ireland at an average timeframe of 597 days from central European approval. The same numbers for Scotland were 25 medicines in 401 days. The weighted average across the surveyed countries was 26 medicines in 403 days. Weighted average is chosen so that the number of medicines is assessed against relative timelines.

The above information demonstrates that patients in Ireland do experience slower access to medicines than European peers. However, the survey is not rooted in either time to submission or from submission for reimbursement. The timelines are spread across both pharmaceutical applications and reimbursement processing without differentiation between State processes and industry actions.

Irish Pharmaceutical Healthcare Association

Acknowledging the limitations of the above survey, a recent OECD working paper[13] further explored reimbursement system delays, examining access timelines across 13 high clinical benefit medicines. Here the authors examined the time between central European approval for a medicine and application to the local health system across thirteen medicines in twenty-two countries.

It shows that Ireland ranks 7th for these medicines in terms of time to application but 20th on average in terms of time in the reimbursement system. A further analysis of this dataset demonstrates that Ireland ranks 20th even on a weighted average basis.

Figure 10. OECD working paper – Time from EMA approval to application

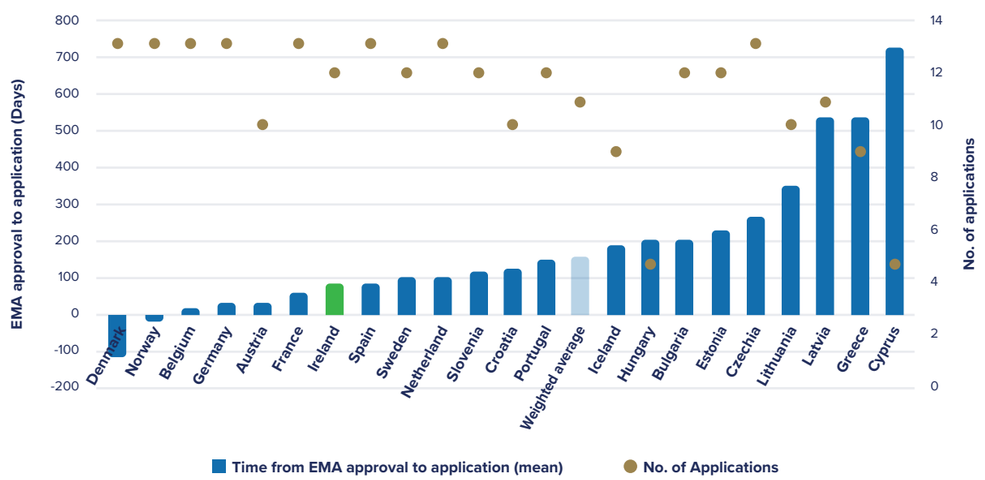
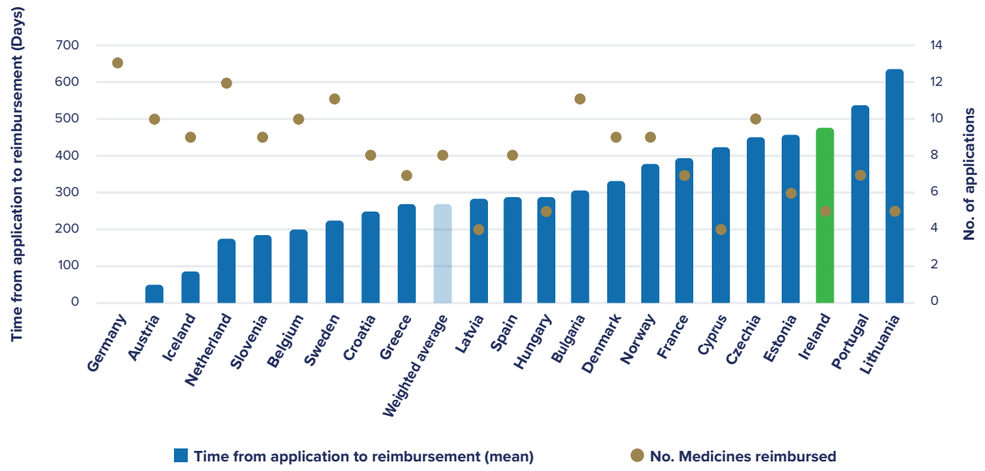


Figure 11. OECD working paper - Time from application to reimbursement



13 Hofmarcher, T., C. Berchet and G. Dedet (2024), "Access to oncology medicines in EU and OECD countries", OECD Health Working Papers, No. 170, OECD Publishing, Paris

Again, this study is limited in that it doesn't measure how companies and health systems interact with a view to advancing standards of care from pharmaceutical innovation. It does however further support the contention that Ireland suffers from a disparity in care standards between it and peer countries due to significantly longer access times.

2.6 Conclusion

It is imperative that the HSE only reimburse a medicine which meets the required assessment criteria, as set out in the Act. However, it is of equal importance that the processes for assessing and deciding on a medicine for reimbursement should be efficient, streamlined and within a predictable, acceptable timeframe to ensure that potential lost opportunities for better healthcare outcomes for patients does not occur.

Patrick's story:

At 48 Patrick was diagnosed with CLL. This came as quite a shock as he wasn't sick, rather he was planning to run a marathon and only went for a check-up to ensure all was ok. The prognosis at first was six or seven years of remission, after receiving chemotherapy, before the likelihood of leukaemia returning. However, due to genetics, the chemotherapy unfortunately did not work for Patrick. As a father of two young children this was a very scary time.

But thankfully, during a chance conversation between his consultant and one of her colleagues, Patrick was made aware of a clinical trial. This was for a targeted medicine which was specific to his disease type. Luckily, he was an eligible candidate and ten years later, because of this clinical trial, he is living a full and happy life.

Due to innovations in new medicines, Patrick now gets to enjoy those significant life moments with his family, which he feared he would not experience when he was first diagnosed.

Chapter 3

Medicines Expenditure: An analysis

3.0 Introduction

The State spends more than €3 billion per year on all medicines, including distribution costs, non-medicine items, pharmacy dispensing fees and VAT. From time to time, concern is expressed about growth in that spending. According to recent HSE Annual Reports, net expenditure of pharmaceuticals by the HSE has seen average annual growth rate (AAGR) of 6.3% from 2021 to 2023. While the most recent year for which data is available (2023) showed that growth was heavily attenuated and came to 2.5%, this contrasts with the overall HSE growth rate for the same year of 5.9% (see Table 26).

Table 12. HSE medicines spend 2021 – 2023

HSE Annual Report	2021	2022	2023	2021-2023 AAGR
Pharmaceutical Services (€)	2,700,027,000	2,899,290,000	3,115,039,000	7.7%
Drugs and Medicines (€)	516,086,000	644,394,000	586,596,000	6.8%
Less Rebate from Pharmaceutical Manufacturers (€)	230,675,000	270,814,000	343,087,000	24.4%
Less Prescription Levy Charges (€)	61,682,000	63,579,000	65,298,000	2.9%
Less Rebate from Pharmaceutical Manufacturers (€)	11,351,000	12,385,000	15,593,000	18.7%
Total Net Expenditure Medicines (€)	**2,912,405,000**	**3,196,906,000**	**3,277,657,000**	**6.3%**
YoY % Growth		9.8%	2.5%	

Source: HSE Annual reports 2021-2023
https://www.hse.ie/eng/services/publications/corporate/annualrpts.html

Similarly, the medicines spend has remained stable as a proportion of the overall health spend during the period of the Agreement ranging between 13.7% (2022) and 13.2% (2023). This has occurred against a backdrop of major demographic changes, combined with various expansions of eligibility criteria for public access to medicines in State schemes.

Demographics

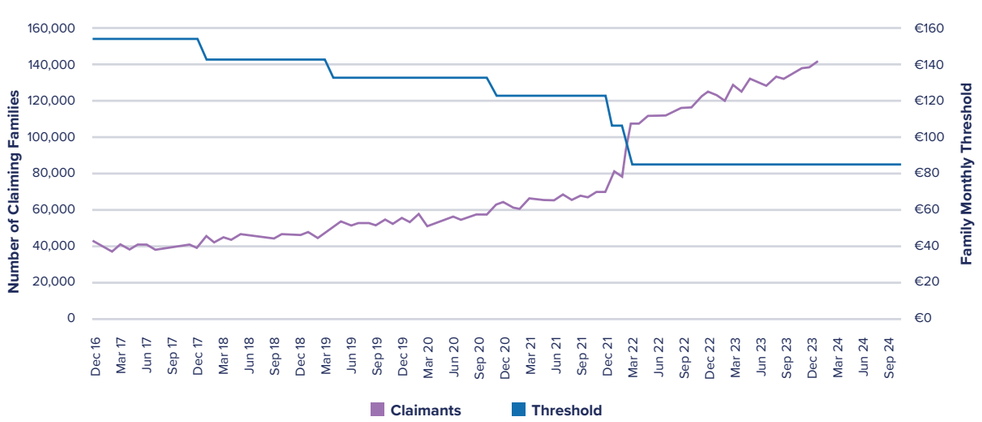
Ireland's population has increased over 10% since 2018 (See Appendix 4, Table 20). But of significance for the health service is that the population aged 65 and over has grown by 23.2% in that time. The latter cohort are recognised as requiring more extensive access to the health services and medicines.

Eligibility criteria and changes to policy GMS and DPS (2018-2023)

There has similarly been consistent growth both in terms of total payments and the number of claims made under the General Medical Scheme (GMS) and the Drugs Payment Scheme (DPS) (See Appendix 4, Tables 21 and 22). Worth noting is the total claims in the DPS growing by a significant 112% and the doubling of payments since 2018 (See Appendix 4, Table 22). Eligibility criteria and changes to policies have also been implemented through the analysed period. As mentioned, there are also non pharmaceutical costs, such as pharmacy dispensing fees, wholesale fees and VAT which are part of the HSE Medicines Budget. For example, pharmacy dispensing fees account for 13% growth from 2021 to 2023 and IPHA estimate that the retail VAT has also grown by 13% over the same period (See Appendix 4, Table 23 and 24).

It is also worth noting that between 1st January 2018 and 1st March 2022, the Drugs Payment Scheme (DPS) threshold has been reduced by Government by 44%, from €144 to €80, entailing an additional spend on medicines by the HSE.

Figure 12. Numbers of DPS family Claimants and Reduction in Thresholds (Dec 2016 -Sep 2024)



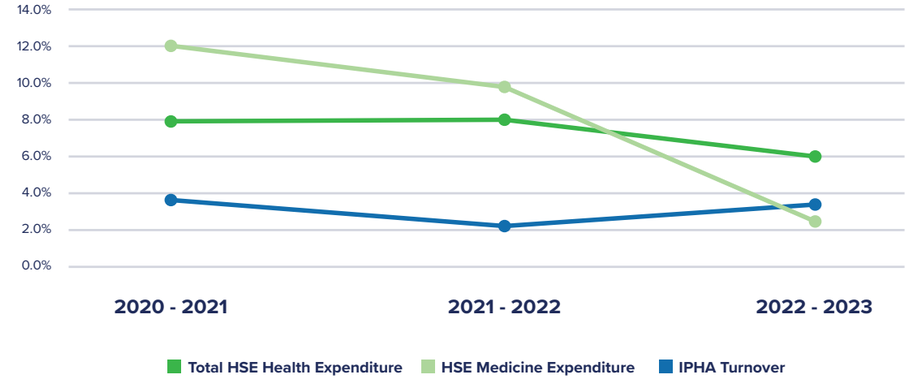
Source: Department of Health – Presentation at NCPE Seminar 2024

3.1 IPHA Members Sales and growth compared to HSE (2021-2023)

In order to measure the HSE's spend on the products of IPHA members, each company shares its prescription division turnover with IPHA allowing for net expenditure trends to be aggregated and captured.

It is important to note that the following figures represent expenditure on IPHA members' medicines only rather than all medicines, and that they represent net price expenditure inclusive of discounts and rebates rather than headline list prices. They demonstrate a clear trend of the growth in IPHA members' medicines being much lower than the general rate of growth in medicines spend over the period indicated.

Figure 13. Comparison on % growth Expenditure from 2021-2023

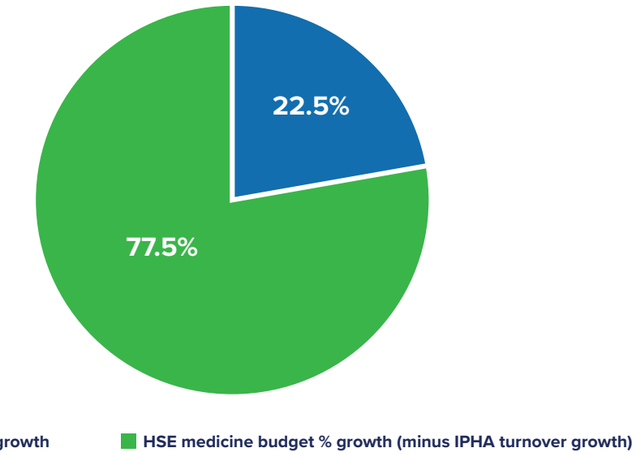


The overall pattern is clear that under the 2021 IPHA Agreement, the average annual growth rate in net sales of IPHA medicines from 2021 to 2023 was 2.8%. This contrasts with the 6.3% AAGR for all medicines (Appendix 4 Table 26 and 27).

The overall share of medicines expenditure growth from 2021-2023 that can be attributed to IPHA members is 22.5% (€82m) or just over or one euro in every five. This is significantly less in percentage terms than both the health service spend, as well as growth in the pharmaceutical medicine spend (€365m). The remainder of the growth (77.5%) can be attributed to non-IPHA members, pharmacy dispensing fees, distribution costs and non-medicine items.

This has enabled the Government in Budget 2025 to allocate €30m to funding new medicines within the HSE from efficiencies alone, without the need for new Exchequer funding. While that cannot be sustained indefinitely, it is illustrative of the value of Agreement-driven and other savings. Similarly, we note that in response to a parliamentary question, the HSE confirmed that there are savings/underspends when it comes to new medicines due to successful commercial negotiations with companies. (PQ: 39312/24 – response to Deputy Sean Sherlock)

Figure 14. IPHA Share of Growth of HSE Medicines spend



Source: IPHA turnover and HSE Annual Report

It is equally worth noting that pharmaceutical rebates have grown by an AAGR of 24.1% since 2021, according to the HSE annual reports. As outlined, overall medicine expenditure grew at an AAGR of 6.3%, therefore rebates are growing nearly 4 times more than overall medicine expenditure (See Table 12).

3.2 Ireland in context - OECD Position on Pharmaceutical Expenditure

According to the OECD's inter country analysis on pharmaceutical expenditure (albeit with caveats about comparable hospital and ambulatory spending patterns), Ireland has gone from a reported position of the 3rd most expensive country in the EU in 2012[14] to being just above the OECD33[15] average USD 614 spend on medicines and lower than the EU-27 average per capita.

It is also worth noting that, according to this report, the share of Ireland's health budget that is used by medical goods (primarily pharmaceuticals) has decreased from 14% in 2012 to 13% in 2022. The EU-27 average for the same period has remained stable at 19%. This six-percentage points difference represents €1.5bn.

3.3 Conclusion

It is clear that the IPHA Agreement is working effectively to attenuate growth in the medicines budget and that several other factors, such as demographics and policies to widen eligibility, are contributing to the growth levels. The learning from this is that focus on the next Agreement should be to address process challenges.

14 OECD (2014), "Pharmaceutical expenditure", in Health at a Glance: Europe 2014
15 OECD (2023), Health at a Glance 2023: OECD Indicators, OECD Publishing, Paris

Leona's story:

About nine years ago, Leona was diagnosed with chronic and abdominal migraines. At this time, she had two small children and while at the best of times motherhood can be challenging, it was exceptionally so for Leona who suffered almost daily from debilitating headaches. Because of the severity of these migraines, she often spent most of her day in bed which meant that she could not return to work after maternity leave or enjoy social activities and hobbies. She felt like she was not living her best life due to constantly feeling unwell, which led to stress and guilt. She particularly struggled with how it impacted her role as a mother to two young boys.

But for Leona relief finally came when she was prescribed a migraine specific medicine. Following a long arduous journey involving numerous tests, consultant visits and other unsuccessful treatments, because of a new medicine, she is now living the life she previously craved and can be the mother she wants to be.

While Leona understands that her current treatment might not be effective long term, she is no longer afraid of what this means for her health. She is very hopeful, because of ongoing innovation in medicines development, that other migraine specific treatments will come on board that will be as effective.

Chapter 4

Review of 2021 Agreement

4.0 Introduction

In December 2021 the current IPHA Framework Agreement on the Supply and Pricing of Medicines came into effect, the intention of which was:

"That patients and prescribers [would] have access to a range of originator and other medicines, used according to best practice, while also delivering better value for money for both the individual patient and the State. In entering this agreement, the State aim[ed] to ensure reduced prices and security of supply for originator medicines".

With the next Agreement due for negotiation in 2025, it is important to assess the current Agreement in detail - to ascertain what has worked well and what needs to be improved going forward.

IPHA acknowledges that most of the procedures and text outlined in the Agreement are invaluable from a market certainty perspective. The pricing measures have been implemented in full and significant savings have been achieved.

As outlined, while the Agreement did not contain a specific commitment by the State to provide new funding for new medicines, IPHA accepted that it was participating in the Agreement, in part, due to strong signals that a new State funding paradigm would be in place. This commitment has been mostly lived up to.

Conversely, regarding some specific Agreement commitments which were entered into in good faith, it is now clear that these have not yet been met by the State. These centre around i) sufficient administrative resources for the HSE to implement the reimbursement process in the efficient and timely way envisaged (ii) an increase in the number of expected 'slots' [individual medicines agenda items] at the HSE Drugs Group. And as already outlined in detail in previous chapters iii) the provisions of Schedule 1 and iv) adherence to the Health Act, 2013, in respect of the timing of HSE decisions on reimbursement within 180 days.

4.1 Achievements and Value of Current Agreement

The most important achievement of the Agreement is that 106 IPHA medicines have been reimbursed to date (December 2024) improving the standards of care for patients in Ireland who, as a result, could access various innovative new treatments for disease areas including cancers, cardiovascular, respiratory, Parkinson's and many others. See Appendix 3.

Table 13. Numbers of IPHA medicines reimbursed

Year	Reimbursed
2021*	12
2022	45
2023	23
2024	27

* October – December 2021

The Agreement creates operational certainty for industry and the HSE regarding various procedures. These were instrumental in allowing both parties navigate the combined challenges of Brexit, Covid-19, the Best Value Medicines procedures and continue to help to manage the impact of some medicines shortages.

- Therefore, the considered view is that much of the Agreement text concerning procedures does not require amendment and it currently contains many flexibilities to navigate such issues.

Since 2021, the savings consequent on Agreement pricing measures has contributed to an improved funding environment for new medicines with Budget allocations for new medicines of €50m, €30m, €18m, €30m (albeit originally zero which was eventually overturned by the Government) and a further €30m for 2025 to be achieved through savings. These allocations are to fund what is termed as 'new developments' within State budget processes (in this case, new medicines). The high and growing level of funding for 'Existing Level of Service' ('ELS') medicine provisions (in effect, paying for medicines after their initial first year of reimbursement) is also facilitated by the savings created by the Agreement. Currently the total ELS budget of the HSE is over €3bn.

- The pricing measures in the Agreement are also predictable and certain. IPHA members have fulfilled their commitments to generate efficiencies thus far in the region of **€500m**, which is projected to reach over **€600m** by the end of the term of the Agreement.

It is clear that participating in the Agreement is of major benefit to the HSE and to patients in many instances..

4.2 Agreement Commitments not met to date

While IPHA recognises that much of the current Agreement text is appropriate, we believe there are four key failures of the current Agreement that IPHA will seek to address in our discussions with State representatives on new Agreement including any pricing measures (Summarised in Table 14).

The Agreement contains specific commitments to 'timely' processing of pricing and the reimbursement of applications, both in the introduction and in Clause 14.1. It states that:

*"The State intends that **sufficient administrative resources** are in place to **ensure timely processing** of pricing and reimbursement applications for new products, subject to compliance with this pricing framework."*

IPHA's evidence and experience is that the system is not operating as intended with the 'timely processing' of applications, as set out above.

Table 14. Commitments / expectations not met in the Agreement

Unmet or Still in Process Commitments / Expectations	Evidence
Sufficient Administrative Resources to ensure timely processing of applications	Considered a good faith commitment, however, recruitment on an additional 34 personnel across the reimbursement system only commenced in the Summer of 2024 and processing of applications in a timely manner is not occurring.
Number of Drugs Group Slots	Number of Drugs Group slots has not reached 50 in any given year.
Provisions of Schedule 1	There is little published evidence that many commitments contained here are adhered to. The current HTA completion timeframe takes 265 days of State time. The schedule commits the HSE to endeavour to consider a medicine application 14 days after assessment. There is little evidence this occurs. The schedule commits the 180-day decision timeline and implementation within 45 days of this. There is also a commitment to endeavour to reach a decision within 45 days of recommendation at Drugs Group. To meet this commitment and the 180-day timeline, DG meetings should be arranged 135-180 days after application. Medicines that require a managed access protocol are implemented over a year after the Drugs Group meeting and not 90 days as is implied in Schedule 1.
Adherence to Health Act	Decisions are rarely made within the legislated timeframe of 180 days + 'Clock stops' where industry must respond to written request for information. The IPHA Agreement refers to the provisions of this Act Act repeatedly throughout the schedule.

4.2.1 Administrative resources

IPHA recognise that the above commitment on resources was made in good faith in 2021, however it lacked specifics on how it would be achieved and governed. This became particularly apparent when the specific number of staff which would be required to optimise processing of applications became apparent upon examination through the Mazars Working Group process. It was two years into the Agreement that an allocation of 34 staff was identified as necessary and the process to hire those staff only started in summer 2024. The additional staff allocation is a very positive development but is unlikely to have any impact before the end of the IPHA Agreement. Therefore, the system has been operating with insufficient resourcing which has resulted in the lengthy timelines as outlined above. It should not be allowed to happen again that the effect of insufficient resources to operate a continuous-flow, timely reimbursement system would have to be seen in clearly excessive timelines in the eyes of all stakeholders (clinicians, patients, companies, political leaders, HSE staff) to be addressed. A permanent, well-designed and appropriately resourced system is both better and available to be put in place.

4.2.2 HSE Drugs Group

A written commitment had also been made by the Department of Health (letter dated 9th December 2021 (see Appendix 6) to having at least 50 slots in 2022 for the HSE's Drugs Group. As indicated in the following table, this did not happen for 2022 and 2023, nor does it seem to have happened in 2024.

Table 15. Drug Group Table

	2022	2023	2024
Number of slots	46	44	47

4.2.3 Agreement Schedule 1

On the specifics of Schedule 1 of the Agreement, there have been some positive outcomes:

- Rapid Reviews are generally completed within the targeted timeframe.
- Reimbursements, except for medicines requiring a Managed Access Protocol (MAP), are generally made available to patients within 45 days of EMT decision.

However, as already outlined in the above timelines, IPHA believe that the provisions of Schedule 1 are not generally being met and that the Agreement does not make clear how Schedule 1 should be measured or governed to ensure adherence to commitments made therein. According to this research:

- IPHA has little evidence that applications post-assessment are 'considered' within 14 days.
- Decisions are not taken within 180 days and with the Clause 9 commitment to 'endeavour' to decide within 45 days of Drugs group, therefore drugs group should be taking place at day 135-179 of application. This is not currently the case.
- Decisions subject to the development of a Managed Access Protocol are rarely implemented within 45 days of decision as per Clause 11.
- Companies also are not typically notified of the specific date of the Drugs Group meetings where their application is due to be discussed.

4.2.4 Adherence to the Health Act 2023

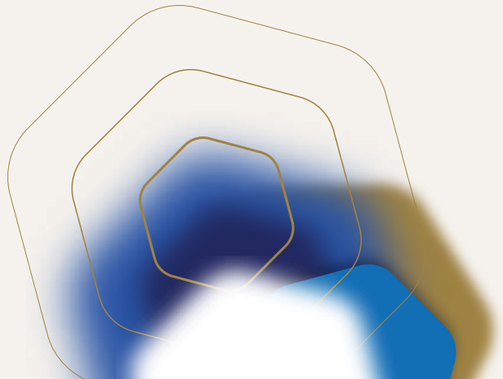
As detailed in this paper, the State's pricing and reimbursement process is a significant, but not the exclusive, source of delays in patient access to new medicines. However, the evidence demonstrates clearly that the 180-day timeframe as set out in the Health Act 2013 is not being adhered to.

In summary:

- The State's processes for Rapid-Review-only medicines exceeded the legislative timeframe by 36 days or by 16% during the 2022-2024 period.
- The State's processes for HTA medicines exceeded the legislative timeframe by 368 days or 164% during the surveyed period.

4.3 Conclusion

Therefore, given these changes and the above outlined inadequacies within the process, there are several compelling reasons to re-draft Schedule 1 to ensure the reimbursement system is fit-for-purpose and provides operational certainty to stakeholders.



Irish Pharmaceutical Healthcare Association

Chapter 5

The Way Forward

5

Key Principles for a new Agreement

IPHA members have unanimously endorsed the following key principles upon which the new Agreement should be based. These key principles and reasonable expectations by IPHA members have been informed by the above research on access timelines but also lived experiences of making medicines available for patients in Ireland.

1. Ensuring patients in Ireland have access to a steady stream of pharmaceutical therapeutic advances within clear policy-driven timing after market authorisation.

As has been outlined, fast and fair access to life-enhancing new medicines and vaccines is dependent upon applications for reimbursement and an efficient reimbursement process and timelines. In Ireland, the best possible patient care is not being delivered in all cases, due to delays within the current system. Reform is needed; however, without clear goals in mind, improvement is unlikely. IPHA contends that the following clear steps should be taken to implement the required process reform for the timely processing of applications:

1. The procedures of the reimbursement system should be based on a requirement, in all foreseeable normal circumstances, to achieve the 180-day timeline on HSE decisions, as stipulated in the Health Act (exclusive of clock stops) in a publicly-transparent way and to provide clarity for applicants as to when they can expect the next step in their application to take place.
2. Schedule 1 of the existing Framework Agreement should be replaced with a detailed description of the steps in an improved process, with accompanying timelines, aligned to the timepoints contained in the Medicine Application Tracker, discussed below.
3. The Programme for Government commitment to ‘early access’ pathways for certain medicines with a focus on rare diseases, can be addressed via the IPHA Agreement. The reimbursement system can be flexible to address patient needs in a manner consistent with the Act and clinical advice. A pilot should be initiated in 2025. These measures can be achieved by a HSE which is resourced to, and capable of, discharging its responsibilities effectively under Health Act 2013.

2. Predictability and stability in medicines expenditure

Prior to 2021, funding for the adoption of new, innovative medicines was inconsistent and unpredictable. For example, the zero funding of 2020 resulted in a requirement by the State to allocate €50m for 2021 to fund the backlog of applications that had built up through 2020. The 2021 Agreement was achieved in the context of strong investment signals from the State with amounts of €50m and €30m allocated in Budgets 2022 and 2023 respectively. The State continued to invest substantially in medicines during the period of the current agreement, except for the initial allocation for Budget 2024 of zero, which was later reversed. Any such uncertainty around funding should be avoided in future.

In this context, the Programme for Government’s commitment to developing a multi-annual funding approach for health services is very welcome. It will be a very positive development if IPHA members feel confident they can engage in a new Framework Agreement while the State puts in place a secure and adequate multi-annual funding method for health, including new and Existing Level Service (ELS) medicines expenditure growth.

The following steps will help in this:

1. Combination of new exchequer funding each year and reinvestment of Agreement savings. On-going and detailed annual horizon scanning between IPHA companies and HSE.
2. The State (HSE, DoH) further developing the ability to predict savings and plan medicines expenditure well, particularly on new therapies.
3. HSE reports on differentiated drivers of expenditure growth (and savings) across medicines expenditure, identifying new medicines expenditure specifically and including:
    a. Recognition of, and provision for, true demographic effects on medicines expenditure growth
    b. Recognition of, and provision for, drivers of expenditure growth from policy changes affecting eligibility and levels of support in State schemes.

3. Process transparency and communication

The Mazars Review highlighted the need for increased transparency in the reimbursement process. IPHA members universally have experienced protracted time periods, often lasting several months, where there is no communication from counterparts involved in the reimbursement process and where an approximate timeline to each step is not visible. Patients, clinicians and industry need clarity around the process and sight of when the next stage in the application for the reimbursement of a medicine will occur.

Noting a commitment in the Programme for Government to review the reimbursement system, reform needs to reflect the need for greater transparency. In achieving this reform the following steps should be followed, while noting the commitment to indicative timelines in the 2025 HSE Service Plan:

1. Indicative timelines should be provided for the duration between the following milestones:
    - Time from Rapid Review to scoping meeting
    - Time to receipt of preliminary review questions
    - Time to receipt of factual accuracy report following submission of preliminary review questions
    - Time from factual accuracy check report to HTA publication
    - Time to first HSE CPU meeting post HTA
    - Time from written commercial offer by applicant to response
    - Time from forwarding of application to HSE DG to consideration by HSE DG
    - Time to implementation of a Managed Access Protocol (MAP) where applicable

2. Identification of, and adherence to, individual steps and sub-timelines designed to enable the HSE to comply with the 180-day Health Act timeframe for decision, with transparent reporting of each.
3. Structured role in horizon scanning for leading clinicians across major clinical groups to prioritise newly authorised medicines of particular importance for clinical care in Ireland and communicate to industry and HSE their view on importance of early filing and efficient processing of applications for reimbursement.
4. Use of EFPIA/IPHA initiatives providing information on filings for reimbursement for new medicines.

4. Financial measures linked to process efficiencies and accelerated patient access

IPHA members made significant commitments to the State in the 2021 Agreement and have met these:

1. Automatic price reductions on medicines upon Loss of Exclusivity were increased;
2. Rebate levels grew by 64% over the previously agreed levels;
3. Annual downward-only realignment to European pricing averages were continued.

These were agreed partly on the basis that IPHA understood the Government was committed to investing in innovative medicines and that the provision of available funding would serve to enhance the reimbursement system through more efficient and speedier timelines. The latter has not occurred as evidenced by the timelines set out in this paper, many steps of which cannot be influenced by industry. IPHA members have a legitimate and reasonable expectation that applications should be processed in accordance with the Act, including the 180-day timeline, with transparency, and with the Programme for Government policy commitment to access 'as fast as possible' as the driver. For these reasons,

1. The status quo should include compliance with the Health Act 2013, in particular, section 18 where the 180-day timeframe for HSE decisions is set. Full compliance with the Act is not a matter for negotiation. All parties are bound by the Act.
2. To support a collective commitment by IPHA members to the value of the Agreement and to incentivise and reward process improvements by the HSE, there needs to be a link between Agreement pricing measures and implementation of improved Schedule 1 steps that deliver speedier and more predictable timing for patient access, visible to all stakeholders, including the steps after a formal HSE reimbursement decision (e.g. timeframes for Managed Access Protocols).

5. Regular dialogue scheduled between industry and the Agreement parties

The next Agreement is an opportunity to establish a new framework for regular discussion between IPHA and the State about the operation of the pricing and reimbursement system, and a means for all parties to work collaboratively to improve patient access to new medicines on an ongoing basis.

Through the Mazars Working Group process, both IPHA and patient groups valued the dialogue that took place with the State in 2023 about how the medicines reimbursement process is functioning and how all stakeholders can collaborate to enhance its performance. However, since the Mazars Implementation Working Group completed its consultation, progress on process reform has been minimal, effectively awaiting recruitment of new staff at the HSE and NCPE.

It is important that patient access timelines remain in focus, and it is vital to have an established outlet for these discussions with IPHA collectively, thereby outside the context of each company's negotiations over a specific medicine. We therefore propose:

1. The establishment of a platform for regular dialogue to monitor timelines based on the Medicines Tracker data, which will identify delays, and allow for discussions on ways that all parties can collaborate to enhance process efficiency.
2. A yearly implementation review with DoH and HSE as a platform for dialogue on adherence to Health Act (Supply of Medicinal Goods 2013) and mutual Agreement commitments. This will place some governance commitments on all parties to ensure the Agreement is being implemented as intended.
3. In addition, given significant political interest in the reimbursement timelines for particular medicines or groups such as medicines for rare diseases or cancer (as highlighted in the Programme for Government), it is appropriate for the parties to the Agreement to provide an annual report to the Oireachtas Health Committee on the operation of the Agreement, based on the review meeting above.
4. Establishing a structured forum for ongoing collaborative engagement, data sharing, troubleshooting and improved governance etc. with key departments and agencies.

The above represents a series of reforms that industry believe will improve patient care, allow for more productive partnership and improved health system functioning.

Conclusion:

Reasonable Expectations of IPHA Members

The Programme for Government commitment to ensure patients in Ireland have access to new medicines as quickly as possible offers an opportunity for reform of the current reimbursement system. As Schedule 1 of the IPHA Agreement constitutes the policies and procedures and cites some provisions of the Health Act 2013, IPHA sets out now what it views as reasonable expectations of its members when it comes to the implementation of the Agreement and further principles of good governance in relation to the management of applications for the reimbursement of medicines by the HSE.

1. IPHA members can reasonably expect the HSE to adhere to its legislative timelines. Any clock stops based on information requests should be made clearly in writing outlining the reason behind the request and how it is material to a potential reimbursement decision. These should directly relate to matters contained in either (i) the HIQA Guidelines on HTA or (ii) the criteria for HSE decisions set out in Schedule 3, Part One of the Act.
2. For the purposes of clarity, waiting for a preliminary scoping meeting, waiting to receive preliminary review questions, scheduling of meetings with the HSE following completion of the pharmacoeconomic assessment, awaiting consideration of the HSE Drugs Group and HSE Executive Management Team, time to receive feedback on an application do not constitute stop clocks under the legislation.
3. The clock commences on application submission and only stops when information requests are made in writing.
4. It must be clear that all actors in the process operate in a manner consistent with the HSE's Code of Governance and that normal standards of oversight and transparency are in place. The governance should be enabling adherence to the Health Act 2013.
5. The precise role and detailed description of the steps to be taken the by HSE or the NCPE on its behalf should be formally documented in the provisions of the Framework Agreement.
6. IPHA members are entitled to expect the HSE's full accountability for the reimbursement process end-to-end, so as to fulfil legal obligations.

Irish Pharmaceutical Healthcare Association

Appendices

Appendix 1

Reimbursement template survey distributed to IPHA members

Company	INN	Brand	Indication	Time from Application to Reimbursement	Time from assessment completion to Reimbursement

Time from assessment completion to 1st commercial negotiation meeting	Time from final written price offer to Drug Group meeting	Time from final written price offer to reimbursement	The number of price negotiation meetings per medicine	Time from Drugs group positive recommendation to implementation of reimbursement	The number of considerations of medicine at drugs group

Appendix 2

Studies that show that speed of access to healthcare is fundamental to health outcomes

DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics, 47, 20-33.

Chowdhury, S., Mukhopadhyay, S., & Lala, A. (2021). Advances in cancer therapeutics: Speed of access and impact on patient outcomes. Clinical Oncology, 33(3), 154-163.

Moon, S., Bermudez, J., & 't Hoen, E. (2017). Innovation and access to medicines for neglected populations: Ten years of the UNITAID model. Health Affairs, 36(6), 928-935.

Kubler P, (2018) Fast-tracking of new drugs: Getting the balance right, Australian Prescriber

Thomas, D. W., Burns, J., Audette, J., Carole, B., & Hay, M. (2016). Clinical development success rates 2006-2015. Biotechnology Innovation Organization.

Vanier et al, Rapid access to innovative medicinal products while ensuring relevant health technology assessment. Position of National Health Authority, France.

Lichtenberg, FR (2019). How many life-years have new drugs saved? A three-way fixed-effects analysis of 66 diseases in 27 countries, 2000–2013. Int Health, 11 (5), 403-416.

Goulart, B. H., Ramsey, S. D (2013). Life expectancy gains from cancer prevention and treatment: A population-based analysis. Journal of Clinical Oncology, 31(47), 327-332.

Simpson, A., Mowry, E., Newsome, S (2021). Early Aggressive Treatment Approaches for Multiple Sclerosis. Curr Treat Options Neurol, 23, 19. [

European Federation of Pharmaceutical Industries and Associations (EFPIA) (2021). Healthcare Innovation and Economic Growth: The Role of Pharmaceuticals.

Claxton, K., Martin, S., Soares, M., Rice, N., Spackman, E., Hinde, S., & Sculpher, M. (2015). Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. Health Technology Assessment, 19(14), 1-503

Lichtenberg, FR (2019). How many life-years have new drugs saved? A three-way fixed-effects analysis of 66 diseases in 27 countries, 2000–2013. Int Health, 11 (5), 403-416. [CrossRef]

Goulart, B. H., Ramsey, S. D (2013). Life expectancy gains from cancer prevention and treatment: A population-based analysis. Journal of Clinical Oncology, 31(47), 327-332.

Simpson, A., Mowry, E., Newsome, S (2021). Early Aggressive Treatment Approaches for Multiple Sclerosis. Curr Treat Options Neurol, 23, 19. [CrossRef]

European Federation of Pharmaceutical Industries and Associations (EFPIA) (2021). Healthcare Innovation and Economic Growth: The Role of Pharmaceuticals.

Claxton, K., Martin, S., Soares, M., Rice, N., Spackman, E., Hinde, S., & Sculpher, M. (2015). Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. Health Technology Assessment, 19(14), 1-503

Appendix 3

IPHA Members' New Medicines Reimbursements from October 2021 - December 2024

Table 16. Reimbursed medicines 2021 (October to December)

2021	Medicine	RR/HTA	Indication
1	Entyvio	RR	For subcutaneous administration is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or an anti-TNFα.
2	Entyvio	RR	For subcutaneous administration is indicated for the treatment of adult patients with moderately to severely active **Crohn's disease** who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or an anti-TNFα.
3	Kadcyla	HTA	As a single agent, for the adjuvant treatment of adults with HER2-positive, early **breast cancer** who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy.
4	Keytruda	HTA	Is indicated as monotherapy or in combination with platinum and 5-fluorouracil, for the first-line treatment of metastatic or unresectable recurrent **head and neck squamous cell carcinoma (HNSCC)** in adults whose tumours express PD-L1 with a combined positive score.
5	Mayzent	HTA	Treatment for adult patients with s**econdary progressive multiple sclerosis (SPMS)** with active disease evidenced by relapses or imaging features of inflammatory activity.
6	Nucala	RR	Mepolizumab 100mg solution in pre-filled pen and mepolizumab 100mg solution in pre-filled syringe are indicated for severe refractory **eosinophilic asthma** in adults and adolescents aged 12 years and over.
7	Polivy	HTA	In combination with bendamustine and rituximab is indicated for the treatment of adult patients with relapsed or refractory **diffuse large B-cell lymphoma (DLBCL)** who are not candidates for haematopoietic stem cell transplant (HSCT).
8	Quofenix	RR	For the treatment of **acute bacterial skin and skin structure infections (ABSSSI)** in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of these infections.
9	Rydapt	HTA	In combination with standard daunorubicin and cytarabine induction and high dose cytarabine consolidation chemotherapy, and for patients in complete response followed by midostaurin single agent maintenance therapy, for adult patients with newly diagnosed **acute myeloid leukaemia (AML)** who are FLT3 mutation positive.
10	Tafinlar plus	HTA	In combination with trametinib, is indicated for the adjuvant treatment of adult patients with **stage III melanoma** with a BRAF V600 mutation, following complete resection

11	Tecentriq	RR	Monotherapy for the first-line treatment of adult patients with metastatic **non-small cell lung cancer (NSCLC)** whose tumours have a PD-L1 expression ≥50% tumour cells (TC) or ≥10% tumour-infiltrating immune cells (IC) and who do not have EGFR mutant or ALK-positive NSCLC
12	Tremfya	RR	Treatment for **active psoriatic arthritis** in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy

Table 17. Reimbursed medicines 2022

2022	Medicine	RR/HTA	Indication
1	Adcetris	RR	In combination with cyclophosphamide [C], doxorubicin [H] and prednisone [P] (CHP) in combination for use in adult patients with previously untreated systemic **anaplastic large cell lymphoma (sALCL)**
2	Adcetris	HTA	Treatment of adult patients with **CD30+ Hodgkin's lymphoma** at increased risk of relapse or progression following autologous stem cell transplant
3	Adcetris	RR	Treatment of adult patients with **CD30+ cutaneous T-cell lymphoma (CTCL)** after at least 1 prior systemic therapy (license extension)
4	Adtralza	RR	For the treatment of moderate to severe **atopic dermatitis** in adults who are candidates for systemic therapy
5	Bavencio	HTA	Monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic **urothelial carcinoma** whose disease has not progressed with first line platinum-based induction chemotherapy
6	Blincyto	RR	Treatment of paediatric patients (aged 1 year plus) with high-risk first-relapsed Ph- CD19+ B-precursor **acute lymphoblastic leukaemia** as part of consolidation therapy
7	Cibinqo	RR	For the treatment of moderate-to-severe atopic dermatitis in adults aged 18 years and older who are candidates for systemic therapy
8	Darzalex	HTA	In combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed **multiple myeloma** who are eligible for autologous stem cell transplant
9	Dupixent	RR	For severe **atopic dermatitis** in children 6 to 11 years old who are candidates for systemic therapy
10	Emgality	RR	For the prophylaxis of **migraine** in adults who have at least four migraine days per month
11	Epidyolex	HTA	As adjunctive therapy of seizures associated with **Dravet Syndrome** in conjunction with clobazam, for patients two years of age and older

12	Epidyolex	HTA	As adjunctive therapy of seizures associated with **Lennox-Gastaut Syndrome** in conjunction with clobazam, for patients two years of age and older
13	Epidyolex	RR	As adjunctive therapy of seizures associated with **tuberous sclerosis complex (TSC)** for patients 2 years of age and older
14	Evrenzo	RR	For the treatment of adult patients with s**ymptomatic anaemia** associated with chronic kidney disease
15	Ilumetri	HTA	For the treatment of moderate to severe **plaque psoriasis** in adults who are candidates for systemic therapy
16	Iluvien	RR	For the prevention of relapse in recurrent **non-infectious uveitis** affecting the posterior segment of the eye
17	Imnovid	RR	In combination with bortezomib and dexamethasone is indicated for the treatment of adult patients with **multiple myeloma** who have received at least one prior treatment regimen including lenalidomide.
18	Jardiance	HTA	For the treatment of **symptomatic chronic heart failure** with reduced ejection fraction
19	Kesimpta	RR	For the treatment of adult patients with **relapsing forms of multiple sclerosis (RMS)** with active disease defined by clinical or imaging features
20	Keytruda	RR	For the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory **classical Hodgkin lymphoma** who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option
21	Lorviqua	RR	As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced **non-small cell lung cancer (NSCLC)** previously not treated with an ALK inhibitor
22	Ngenla	RR	For the treatment of children and adolescents from three years of age with growth disturbance due to **insufficient secretion of growth hormone**
23	Nubeqa	HTA	For the treatment of adult men with **non-metastatic castration resistant prostate cancer (nmCRPC)** who are at high risk of developing metastatic disease
24	Opdivo plus Yervoy	RR	For the first-line treatment of metastatic **non-small cell lung cancer (NSCLC)** in adult patients whose tumours have no sensitising EGFR mutation or ALK translocation
25	Phesgo	RR	In combination with chemotherapy in the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or **early-stage breast cancer** at high risk of recurrence and in combination with Docetaxel in adult patients with HER2-positive **metastatic or locally recurrent unresectable breast cancer,** who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease

26	Ponvory	RR	Treatment for adult patients with **relapsing forms of multiple sclerosis (RMS)** with active disease defined by clinical or imaging features
27	Rinvoq	RR	For adults with **active psoriatic arthritis** who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs
28	Rinvoq	RR	For the treatment of moderate to severe **atopic dermatitis** in adults and adolescents 12 years and older, who are candidates for systemic therapy
29	Rinvoq	RR	For active **ankylosing spondylitis (AS)** in adult patients who have responded inadequately to conventional therapy
30	Rinvoq	RR	For the treatment of adult patients with moderately to severely active **ulcerative colitis** who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent
31	Rozlytrek	RR	Monotherapy for the treatment of patients with ROS1-positive advanced **non-small cell lung cancer (NSCLC)** not previously treated with ROS1 inhibitors
32	Skyrizi	HTA	Alone or in combination with methotrexate, is indicated for the treatment of **active psoriatic arthritis** in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs)
33	Skyrizi	RR	Is indicated for the treatment of moderate to severe **plaque psoriasis** in adults who are candidates for systemic therapy
34	Spravato	HTA	In combination with a SSRI or SNRI is indicated for adults with treatment-resistant **Major Depressive Disorder**, who have not responded to at least two different treatments with antidepressants in the current depressive episode
35	Tecentriq	HTA	In combination with carboplatin and etoposide is indicated for first-line treatment of adult patients with **extensive-stage small cell lung cancer (ES-SCLC)**
36	Tecentriq	HTA	In combination with nab-paclitaxel is indicated for the treatment of adult patients with unresectable locally advanced or metastatic **triple-negative breast cancer** whose tumours have PD-L1 expression ≥ 1% and who have not received prior chemotherapy for metastatic disease
37	Tenkasi	RR	For the treatment of **acute bacterial skin and skin structure infections (ABSSSI)** in adults
38	Venclyxto plus Gazyvaro	HTA	For the treatment of adult patients with previously untreated **chronic lymphocytic leukaemia (CLL)**
39	Vocabria plus Rekambys	RR	**HIV-1 infection** in adults who are virologically suppressed on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class
40	Vumerity	RR	For the treatment of adult patients with **relapsing-remitting multiple sclerosis (RRMS)**

41	Vyndaqel	HTA	For the treatment of wild-type or hereditary transthyretin **amyloidosis** in adult patients with cardiomyopathy
42	Xarelto	HTA	For the **prevention of atherothrombotic** events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events
43	Xeljanz	RR	Treatment for active polyarticular **juvenile idiopathic arthritis** (rheumatoid factor positive or negative polyarthritis and extended oligoarthritis), and **juvenile psoriatic arthritis** in patients 2 years of age and older, who have responded inadequately to previous therapy with DMARDs
44	Yescarta	HTA	Treatment of adult patients with relapsed or refractory **diffuse large B-cell lymphoma (DLBCL)** and **primary mediastinal large B-cell lymphoma (PMBCL)**, after two or more lines of systemic therapy
45	Zeposia	RR	Treatment of adult patients with **relapsing remitting multiple sclerosis (RRMS)** with active disease as defined by clinical or imaging features

Table 18. Newly reimbursed medicines 2023

2023	Medicine	RR/HTA	Indication
1	Akeega	RR	Niraparib in combination with abiraterone acetate and prednisone/prednisolone is indicated for the treatment of adults with **metastatic castration resistant prostate cancer (mCRPC)** and BRCA1/2 mutations (germline and/or somatic) in whom chemotherapy is not clinically indicated
2	Bimzelx	RR	Treatment of moderate to severe **plaque psoriasis** in adults who are candidates for systemic therapy
3	Dupixent	RR	For adults and adolescents 12 years and older as add-on maintenance treatment for **severe asthma** with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance
4	Erleada	HTA	For the treatment of metastatic hormone-sensitive **prostate cancer** in combination with androgen deprivation therapy
5	Evrysdi	HTA	For the treatment of **5q spinal muscular atrophy (SMA)** in patients 2 months of age and older, with a clinical diagnosis of SMA Type 1, Type 2 or Type 3 or with one to four SMN2 copies
6	Inrebic	RR	For the treatment of disease-related splenomegaly or symptoms in adults with **primary myelofibrosi**s, post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis who are JAK inhibitor–naive or have been treated with ruxolitinib

7	Jardiance	RR	For the treatment of **symptomatic chronic heart failure** with left ventricular ejection fraction >40%
8	Keytruda	HTA	Is indicated as monotherapy for the first-line treatment of adult patients with metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) **colorectal cancer** in adults
9	Keytruda	HTA	In combination with platinum and fluoropyrimidine-based chemotherapy, for the first line treatment of patients with locally advanced unresectable or metastatic carcinoma of the o**esophagus or HER-2 negative gastro-oesophageal junction adenocarcinoma** in adults whose tumours express PD-L1 with CPS≥10
10	Luxturna	HTA	For the treatment of adult and paediatric patients with vision loss due to inherited retinal **dystrophy** caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells
11	Onureg	RR	For maintenance treatment in adult patients with **acute myeloid leukaemia** who achieved complete remission or complete remission with incomplete blood count recovery following induction therapy with or without consolidation treatment and who are not candidates for, including those who choose not to proceed to, haematopoietic stem cell transplantation
12	Opdivo	RR	Nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic **oesophageal squamous cell carcinoma (OSCC)** with tumour cell PD-L1 (programmed death ligand 1) expression ≥1%
13	Opdivo	HTA	Nivolumab as monotherapy is indicated for the adjuvant treatment of adult patients with **oesophageal or gastro-oesophageal junction cancer** who have residual pathologic disease following prior neoadjuvant chemoradiotherapy
14	Opdivo plus Yervoy	HTA	First-line treatment of adult patients with unresectable malignant **pleural mesothelioma**
15	Opdivo plus Yervoy	HTA	Treatment of adult patients with mismatch repair deficient or microsatellite instability-high metastatic **colorectal cancer** after prior fluoropyrimidine-based combination chemotherapy
16	Padcev	HTA	Monotherapy for the treatment of adult patients with locally advanced or metastatic **urothelial cancer** (la/mUC) who have previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand 1 inhibitor
17	Rinvoq	RR	Treatment of adult patients with moderately to severely active **Crohn's Disease** who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent

18	Sativex	HTA	Treatment for symptom improvement in adult patients with moderate to **severe spasticity due to multiple sclerosis (MS)** who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy
19	Saxenda	HTA	Adult patients with an initial body mass index (BMI) of ≥30kg/m2 (obese), or ≥27kg/m2 to <30kg/m2 (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. The Applicant is seeking reimbursement in a subgroup of the licensed population, that is, as an adjunct to a reduced calorie diet and increased physical activity for **weight management** in adult patients with an initial body mass index of ≥35kg/m2 with pre-diabetes and high risk of cardiovascular disease.
20	Scemblix	RR	For the treatment of adult patients with Philadelphia chromosome positive chronic **myeloid leukaemia** in the chronic phase, who have previously been treated with two or more tyrosine kinase inhibitors
21	Vitrakvi	HTA	For patients with **solid tumours that display a Neurotrophic Tyrosine Receptor Kinase (NTRK)** gene fusion
22	Vyepti	RR	For the prophylaxis of **migraine** in adults who have at least four migraine days per month
23	Zejula	HTA	Monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III and IV) **high grade ovarian, fallopian tube** or **primary peritoneal cancer** who are in response (complete or partial) following completion of first-line platinum-based chemotherapy

Table 19. Newly reimbursed medicines 2024

2024	Medicine	RR/HTA	Indication
1	Bimzelx	RR	Indicated alone or in combination with methotrexate, for the treatment of **active psoriatic arthritis** in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs
2	Bylvay	HTA	For the treatment of **progressive familial intrahepatic cholestasis (PFIC)** in patients aged 6 months or olde
3	Darzalex	HTA	In combination with lenalidomide (Revlimid®) and dexamethasone for the treatment of adult patients with newly diagnosed **multiple myeloma** who are ineligible for autologous stem cell transplant
4	Darzalex	HTA	For the treatment of adult patients with newly diagnosed systemic **light chain amyloidosis**
5	Enhertu	HTA	As monotherapy for the treatment of adult patients with unresectable or metastatic **HER2-positive breast cancer** who have received one or more prior anti-HER2-based regimens

6	Evenity	HTA	For the treatment of **severe osteoporosis** in postmenopausal women at high risk of fracture
7	Keytruda	HTA	Is indicated in combination with chemotherapy as n**eoadjuvant** treatment, and then continued as monotherapy as **adjuvant** treatment after surgery for the treatment of adults with locally advanced, or early-stage **triple negative breast cancer** at high risk of recurrence
8	Keytruda	HTA	Is indicated for the adjuvant treatment of adults and adolescent (≥12 years) with **stage IIB or IIC melanoma** following complete resection
9	Keytruda	HTA	Is indicated as monotherapy for the adjuvant treatment of adults with **renal cell carcinoma** at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions
10	Livtencity	RR	For the treatment of **cytomegalovirus (CMV)** infection and/or disease that are refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adult patients who have undergone a haematopoietic stem cell transplant or solid organ transplant
11	Nilemdo	HTA	In adults with **primary hypercholesterolaemia** (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet: In combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated
12	Nustendi	HTA	In adults with **primary hypercholesterolaemia** (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet (a) in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe (b) alone in patients who are either statin – intolerant or for whom a statin is contraindicated and are unable to reach LDL-C goals with ezetimibe alone and (c) in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without a statin
13	Omjjara	RR	**Treatment of disease-related splenomegaly** or symptoms in adult patients with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.
14	Opdivo	RR	In combination with platinum-based chemotherapy for the **neoadjuvant** treatment of resectable **non-small cell lung cancer** at high risk of recurrence in adult patients whose tumours have PD-L1 expression ≥ 1%
15	Opdivo	HTA	Is indicated for the adjuvant treatment of adults with **muscle invasive urothelial carcinoma (MIUC)** with tumour cell PD-L1 expression ≥1%, who are at high risk of recurrence after undergoing radical resection of MIUC

16	Polivy	HTA	In combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (pola-R-CHP) is indicated for the treatment of adult patients with previously untreated **diffuse large B-cell lymphoma (DLBCL)**
17	Produodopa	RR	Treatment of advanced levodopa-responsive **Parkinson's disease** with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results
18	Rozlytrek	RR	As monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age and older with **solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK)** gene fusion, who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and who have not received a prior NTRK inhibitor and who have no satisfactory treatment options
19	Rukobia	RR	In combination with other antiretrovirals, is indicated for the treatment of adults with multidrug resistant **HIV-1 infection** for whom it is otherwise not possible to construct a suppressive anti-viral regimen
20	Skyrizi	RR	Treatment of adult patients with moderately to severely active **Crohn's disease** who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent. The Applicant is seeking reimbursement in a subgroup of the licensed population, as second-line treatment after failure of the first biologic therapy
21	Sotyktu	RR	Treatment of moderate to s**evere plaque psoriasis** in adults who are candidates for systemic therapy
22	Tecentriq	HTA	For the treatment of adult patients with advanced or unresectable **hepatocellular carcinoma** who have not received prior systemic therapy
23	Tecentriq	HTA	As an adjuvant treatment following complete resection and platinum-based chemotherapy for adult patients with **NSCLC** with a high risk of recurrence whose tumours have PD-L1 expression on ≥ 50% of tumour cells and who do not have EGFR mutant or ALK-positive NSCLC
24	Tepmetko	HTA	For the treatment of adult patients with advanced **non-small cell lung cancer (NSCLC)** harbouring alterations leading to mesenchymal-epithelial transition factor gene exon 14 (METex14) skipping, who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy
25	Trodelvy	HTA	Is indicated as monotherapy for the treatment of adult patients with unresectable or metastatic **triple-negative breast cancer** who have received two or more prior systemic therapies, including at least one of them for advanced disease
26	Venclyxto	HTA	In combination with a hypomethylating agent is indicated for the treatment of adult patients with newly diagnosed **acute myeloid leukaemia (AML)** who are ineligible for intensive chemotherapy
27	Verzenios	HTA	In combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, node positive early **breast cancer** at high risk of recurrence.

Appendix 4

Table 20. Irelands total population & population aged 65 and over (2018-2024)

	2018	2019	2020	2021	2022	2023	2024	2018 - 2024
Total population	4,884,900	4,958,500	5,029,900	5,074,700	5,184,000	5,281,600	5,380,300	10.1%
YoY % Growth		1.5%	1.4%	0.9%	2.2%	1.9%	1.9%	
Population aged 65 & over	676,400	701,400	726,100	747,400	781,300	806,300	833,200	23.2%
YoY % Growth		3.7%	3.5%	2.9%	4.5%	3.2%	3.3%	

Source: CSO

Table 21. GMS total payments & total claims (2018-2023)

GMS	2018	2019	2020	2021	2022	2023	2018 - 2023
Total Payments (€)	966,349,869	969,787,344	975,255,894	991,772,194	1,015,607,700	1,045,236,911	8.2%
YoY % Growth		0.4%	0.6%	1.7%	2.4%	2.9%	
Total Claims	59,326,912	60,176,425	61,062,484	62,754,498	65,327,676	68,347,247	15.2%
YoY % Growth		1.4%	1.5%	2.8%	4.1%	4.6%	

Source: PCRS Annual Report

Table 22. DPS total payments & total claims (2018-2023)

DPS	2018	2019	2020	2021	2022	2023	2018 - 2023
Total Payments (€)	67,362,845	75,471,256	82,666,086	96,139,505	143,502,112	167,926,174	149.3%
YoY % Growth		12.0%	9.5%	16.3%	49.3%	17.0%	
Total Claims	7,633,295	7,901,647	8,554,971	9,585,130	13,570,809	16,155,882	111.7%
YoY % Growth		3.5%	8.3%	12.0%	41.6%	19.0%	

Source: PCRS Annual Report

Table 23. Pharmacy Dispensing fees

Dispensing fees	2021	2022	2023	2021 - 2023
(€) Million	434.8	468.3	491.9	
YoY % Growth		7.7%	5.0%	13%

Source: PCRS Monthly Pharmacy Fees – www.sspcrs.ie/

Table 24. VAT

VAT Retail estimate	2021	2022	2023	2021 - 2023
(€) Million	144.8	156.9	163.2	
YoY % Growth		8.4%	4.0%	13%

Source: Calculation using PCRS Annual Report

Table 25. Non-Drug items included in HSE medicines expenditure

	2021	2022	2023	2021 - 2023
(€) Million	143.7	155.5	179.1	
YoY % Growth		8.2%	15.1%	25%

Source: Calculation using PCRS Annual Report

Table 26. Overall HSE health expenditure compared to HSE medicine expenditure

	2021	2022	2023	2021 - 2023 AAGR
Total HSE Health expenditure (€)	21,642,513,000	23,363,470,000	24,749,003,000	7.2%
YoY % Growth		8.0%	5.9%	
Total HSE Medicine expenditure (€)	2,912,405,000	3,196,906,000	3,277,657,000	6.3%
YoY % Growth		9.8%	2.5%	
% Medicine spend/Total HSE spend	**13.5%**	**13.7%**	**13.2%**	

Source: HSE Annual report

Table 27. IPHA reported sales 2021 to 2023 net of Agreement rebates

IPHA	2021	2022	2023	2021 - 2023 AAGR
Turnover (€)	1,487,102,231	1,519,183,139	1,569,188,536	2.8%
YoY % Growth		2.16%	3.29%	5.5%

Figure 15. IPHA Turnover Trend Vs HSE pharmaceutical spend

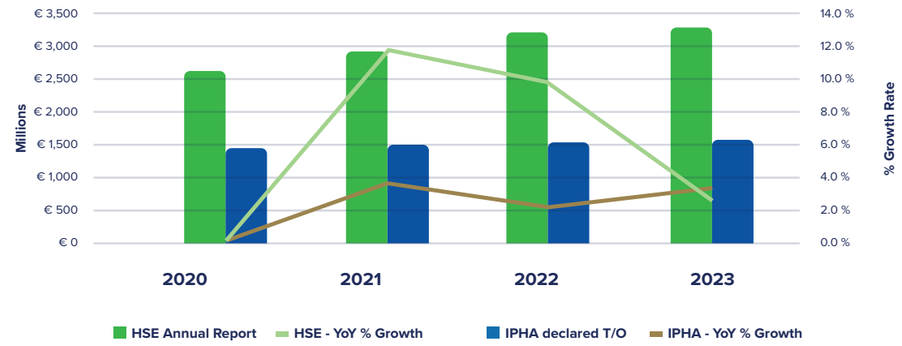


Figure 16. Expenditure on retail pharmaceuticals per capita in 2012[1]

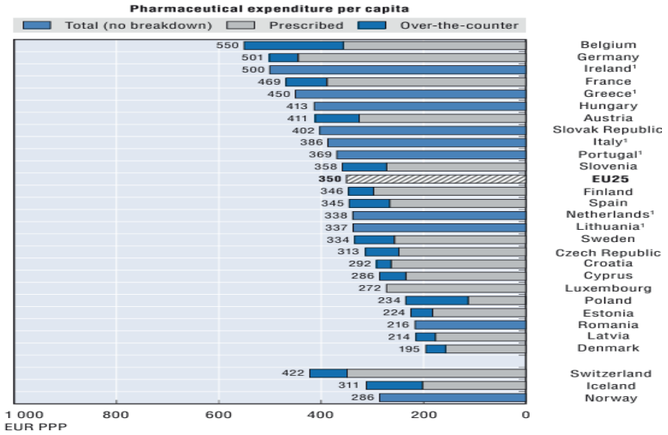
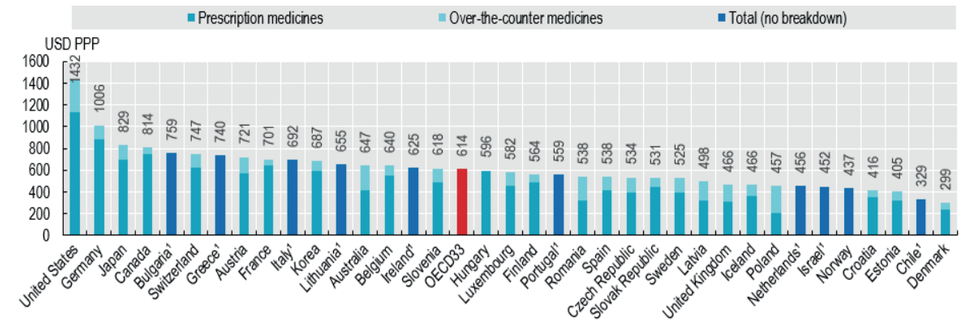


Figure 17. Expenditure on retail pharmaceuticals per capita in 2021[1]



Appendix 5

External studies showing similar time for application to reimbursement in Ireland

1. https://axishealthcareconsulting.com/wp-content/uploads/2024/11/ISPOREurope24_Gribbon_PT27_POSTER.pdf
2. https://www.ispor.org/docs/default-source/euro2024/isporeuropeoflathartahpr84poster143561-pdf.pdf?sfvrsn=e0f26c6_0
3. https://mappatientaccess.com/wp-content/uploads/2023/09/HTA-and-reimbursement-timelines-in-the-Republic-of-Ireland-v1-04Oct2022-1.pdf

Appendix 6

DoH correspondence to IPHA regarding Drug Group slots for 2022

Mr. Paul V. Reid
President
Irish Pharmaceutical Healthcare Association
7 Clanwilliam Terrace
Dublin 2
D02 CC64

9 December 2021

RE: Framework Agreement on the Pricing and Supply of Medicines 2021-2025

Dear Paul,

The State team is pleased that our formal engagements over the past several months have brought about a negotiated agreement that will assist in addressing the continuing sustainability challenge in relation to the pricing and reimbursement of medicines in Ireland.

This multi-annual, medium-term agreement covering IPHA branded drugs reimbursed under PCRS schemes and in hospitals should bring greater certainty regarding pricing and access to patients, the HSE, and industry through an agreed pricing framework.

Given IPHA members' willingness, under the terms of this agreement, to contribute further to addressing the cost and affordability challenge over the next four years, the State will be enabled to continue to put in place sufficient administrative resources to support the timely processing of pricing and reimbursement applications for new products, subject to compliance with this pricing framework. To this end, the following measures have already been implemented:

- The HSE has increased the number of planned Drugs Group meetings for 2022 (from 10 to 11). The HSE will examine required capacity for 2023 as part of the National Service Plan 2023 Horizon scanning process.
- The HSE has revised the terms of reference of the Drugs Group to increase the opportunity for alternates to be nominated to ensure that a quorum can be reached more easily.
- The HSE is confident that these changes will deliver at least 50 slots for medicines deliberations at Drugs Group during 2022.