IPHA's Mission:

The Government should aim to achieve an efficient, transparent, and responsive system with shorter timelines for patients to access new treatments.

Universal access to the latest medicines via the public system is a major health enabler allowing people to live longer, enabling healthy aging and preventing chronic illnesses. Accessing medicines allows people to be cared for in their homes and communities, thus freeing up acute care setting. They have improved the survival rate of three of the largest causes of death – cancer, cardiovascular and respiratory diseases – and are used to combat depression, prevent obesity and diabetes and assist with infertility. Crucially, people suffering from a rare disease, of which there are approximately 300,000 in Ireland, are often highly if not wholly dependent on medicines.

Yet currently there is an apparent lack of strategic medicines policy emphasis at government level. There is under-resourcing of the relevant official bodies, and reimbursement processes are not sufficiently streamlined and organised for different circumstances. This can have a direct effect on patient care, with potential quality of life improvements, progression-free disease survival and overall survival lost to Irish patients because of lengthy process times.

Accepting the premise that healthcare systems only reimburse medicines that are believed to improve the standards of care, patient safety or experience, or an improvement in efficiency, it stands to reason that extending the timeline for availability of new medicines delays such potential improvements. Given the various inputs required to achieve a health outcome, for example, a person's lifestyle, diet, economic and housing circumstances, as well as access to necessary healthcare interventions, quantifying the importance of a specific medicine can be difficult. Nonetheless, there are disease and treatment areas where the health outcome is significantly influenced by the pharmaceutical intervention available and/or is totally dependent on it.

In oncology, for example, a systematic review by Hanna et al. demonstrated that delays in treatment of just four weeks have been associated with a 6-16 percent increase in the risk of death[1]. Gotfit et al. noted in 2020 that in Canada the *'number of potential life-years lost during the drug regulatory and funding process in Canada is substantial'* when pricing and reimbursements were occurring typically between twelve and eighteen months[2]. An examination of eleven oncological medicine reimbursement times in Ireland estimated the number of life years lost due to the time gap between EMA authorisation and patient availability in Ireland to have been 2,600 years.[3]

Commentary on Access Timelines in Ireland

O'Reilly et al. conducted an assessment of the availability and reimbursement of systemic anti-cancer treatments (SACTs) and found that the impact of delays in Ireland and the UK *'may be clinically significant' compared to the USA*[4]. The findings from this study have been underlined as an issue, by the National Cancer Control Programme (NCCP). In a briefing note prepared for the HSE dated 20th April 2020, the NCCP stated in relation to the lack of availability of certain oncology medicines:

> *"While up to mid-2019 Ireland had lagged somewhat behind in terms of availability of drugs we are now at a point where several drugs of critical benefit to patients, that improve survival,*

[1] Hanna TP, King WD, Thibodeau S, Jalink M, Paulin GA, Harvey-Jones E, et al. Mortality due to cancer treatment delay: systematic review and meta-analysis. BMJ. 2020;371:m4087.

[2] Gotfrit J, Shin JJW, Mallick R, Stewart DJ, Wheatley-Price P. Potential Life-Years Lost: The Impact of the Cancer Drug Regulatory and Funding Process in Canada. Oncologist. 2020;25(1):e130-e7.

[3] Hofmarcher, T; 2022; Comparator Report on Cancer in Ireland – Disease Burden, Costs and Access to Medicines. Available from: https://ihe.se/wp-content/uploads/2022/07/IHE-Report-2022_4_.pdf.

[4] O'Reilly D, McLaughlin R, Ronayne C, De Frein AM, Macanovic B, Chu RW, et al. Cost and public reimbursement of cancer medicines in the UK and the Republic of Ireland. Ir J Med Sci. 2022.

are approved in most European jurisdictions, and are not approved in Ireland. This means that Ireland currently has a standard of care which is below the current international standard"[5].

As noted by Professor Alan Irvine, President of the Irish Hospital Consultants Association, and consultant in dermatology, in March 2021:

"Our pathway to approval for new therapies once the EMA (European Medicines Agency) have given Market Access approval is incredibly slow, laborious, bureaucratic, and inefficient, and we need to do better than that for our patients because innovations are no good unless they actually meet the patients who are likely to benefit from them." [6]

Similarly, Dr Austin Duffy, consultant oncologist at the Mater Hospital stated on publication of the IHE cancer comparator report on Ireland:

"Clearly, we have made important strides in the treatment of cancer in Ireland. Survival is improving, but more cases are diagnosed due to our ageing and increasing population. What is concerning is that Irish patients clearly have much slower access to new drugs, some of which can have a very dramatic impact on their condition and prognosis." [7]

These statements by clinicians are affirmed by former administrators in Ireland.

As written by former Director General of the Health Service Executive in Ireland, Tony O'Brien,

"*Too many patients and doctors have cause to see it (the pricing and reimbursement system) as the system that denies them vital treatment that they would be able to have and prescribe if they lived elsewhere...This is the hidden waiting list that is shortening many lives and destroying the quality of life of others."*[8]

Similar statements have been expressed by patient advocacy groups such as IPPOSI (Irish Platform for Patients Organisations, Science, and Industry) in 2017 and 2018. Their comprehensive report expressed a fear of what they termed the 'drug iceberg', i.e. a hidden lack of availability of vital medicines that would either be delayed in the Irish system or not launched within Ireland. Their report, based on multi-stakeholder input suggested that:

"Denied or delayed access to medicines represents a failure by Ireland to promote, protect and fulfil its human rights responsibilities."[9]

It is perhaps for this reason that health ministers and former health ministers have described the pricing and reimbursement system as 'broken' and something that needs to be improved.

Delayed Timelines

The timeliness of access to the most recently developed medicines is recognised as a contributor both to health outcomes and to the maintenance of care standards relative to other EU countries. Many chronic, rare, or life-threatening diseases can and will progress while a patient is awaiting access for a medicine.

[5] O'Reilly D, McLaughlin R, Ronayne C, De Frein AM, Macanovic B, Chu RW, et al. Cost and public reimbursement of cancer medicines in the UK and the Republic of Ireland. Ir J Med Sci. 2022.
[6] HSE Ireland; Launch of Dermatology Model of Care Video available at: https://youtu.be/GypDcXRzaHw.
[7] Irish Pharmaceutical Healthcare Association 2022; "Hundreds of cancer deaths could be avoided each year if survival rates matched western European standards, says new study for IPHA".
[8] Tony O'Brien, Business Post, December 2022 https://www.businesspost.ie/analysis-opinion/tony-obrien-our-medicines-system-would-be-better-off-without-the-hse-and-the-hse-without-it/.
[9] Ipposi, 'Steering a course to avoid the drug iceberg' https://www.ipposi.ie/2018/02/21/annual-theme-2018-access-medicines-2/

IPHA monitors reimbursement timelines for its member companies, which comprise the majority of companies that seek reimbursement for newly authorised advanced therapeutics and next generation medicines. The data estimates the timeline from a reimbursement application being made by the company to reimbursement of the medication. This data shows that, while there have been improvements since 2021 versus prior years, the length of time to reimbursement is still far in excess of that of peer countries and of the 180-day statutory benchmark.

Table 1 Average Time to Availability of IPHA Medicines in 2020-2023

Rapid Review medicines			
	n =	Start of NCPE assessment to reimbursement (days)	Completion of NCPE assessment to reimbursement (days)
2020	4	429	384
2021	17	511	467
2022	29	355	311
2023	9	400	361

Health Technology Assessment medicines			
	n =	Start of NCPE assessment to reimbursement (days)	Completion of NCPE assessment to reimbursement (days)
2020	8	1049	623
2021	25	989	470
2022	16	861	397
2023	12	1026	427

Oncology medicines			
	n =	Start of NCPE assessment to reimbursement (days)	Completion of NCPE assessment to reimbursement (days)
2020	9	896	542
2021	24	820	485
2022	17	686	452
2023	13	656	278

Orphan medicines			
	n =	Start of NCPE assessment to reimbursement (days)	Completion of NCPE assessment to reimbursement (days)
2020	4	799	463
2021	11	955	521
2022	11	757	498
2023	4	758	508

Source: IPHA analysis based on reimbursement applications data from NCPE website

Table 2 Summary of Average Time to Reimbursement from rapid review submission for RR and HTA Medicines in calendar days

Author	Time Period	Medicines that were Rapid Review only	Medicines requiring full HTA
IPHA (members only)	2022	348	825
McLoughlin et al. [10]	2021	324	948
Liu [11]	2017-2021 (Average)	300	858

Public/ Private divide

A lack of investment in new medicines, will contribute to the increasing inequalities in the private/ public divide.

In the absence of state investment, new medicines, which should be reimbursed on the public system may only be available through private hospitals. There has already been a growing tendency for this to occur, which is widening the inequalities within the public/ private divide of our health system, particularly for cancer care.

Relative to our peers, there is no specific policy in Ireland to support and guide healthcare providers, patients, or suppliers in the circumstance where a new medicine is not available to a patient as, in some cases, it is delayed within the reimbursement process. Patients currently rely on the efforts of

[10] McLoughlin D., Copeland C., Dooley B., 'Exploring Timelines for New Medicines Reimbursed in Ireland in 2021' (2022-11, ISPOR Europe 2022, Vienna, Austria), Value in Health, Volume 25, Issue 12S (December 2022). Accessible here: https://www.ispor.org/heor-resources/presentations-database/presentation/euro2022-3567/122446

[11] Liu, Xingyao (2022), HTA and reimbursement timelines: How long does it take to get reimbursement in Ireland? https://mappatientaccess.com/hta-and-reimbursement-timelines-how-long-does-it-take-to-get-reimbursement-in-ireland/

requesting physicians and private suppliers to address the gap – which can cause inequity within the treatment pathway. Some private entities (hospitals and private insurers) can come to supply agreements during this period, but the public system does not have a system for this. This cannot be allowed to continue.

To achieve our mission, IPHA proposes the following actions to ensure all patients have faster and equal access to new medicines.

1. ***Resourcing***

Relative to other European countries, the Irish pricing and reimbursement system appears to be significantly under-resourced.

The HSE CPU and the NCPE, acting as an advisory agency for the HSE, are the key bodies relevant to the assessment of medicines for reimbursement in Ireland. The NCPE has 20.5 whole time equivalent staff while the HSE CPU has 12 whole time equivalent staff.[12] While not directly comparable due to its broader remit than the Irish equivalent, it is notable that NICE in the UK has 723 staff, of whom 717 are direct employees.

The closest comparator to the NCPE in Ireland is the Scottish Medicines Consortium which has 35 whole time equivalent staff, or 75% more than NCPE. The number of people processing applications for reimbursement in Ireland remains notably low by European standards. Resource constraints are likely a significant factor which impacts upon the speed of the process, levels of communication, and commitment to timelines, and this must be fairly considered in any assessment of how Irish bodies perform.

Table 3 Staff Numbers in HTAs and Medicines Agencies in Europe.

Country	Agency	Employees
Ireland	NCPE 20.5 & HSE CPU 12	32
Denmark	Danish Medicines Agency	643
England & Wales	NICE	721
Germany	IQWIG	246
Germany	G-BA	220
Spain	AEMPS	524
Portugal	INFARMED	330
France	HAS	350 + 3000 experts
Finland	Fimea	250
Sweden	SBU	85 + 250 ad hoc
Belgium	KCE	63
Netherlands	ZIN	50 + 100 experts

Sources: Agency websites and/or annual reports

Increase personnel and resourcing of the NCPE and HSE.

As set out, in personnel terms, the Irish pricing and reimbursement system is significantly under-resourced relative to peer countries. Furthermore, pharmaceutical reimbursement applications are growing in number and complexity, with both higher opportunity and higher uncertainty likely in

[12] Dáil Éireann Debate, Tuesday 5th July 2022, Written answers (Question to Health) [35337/22], https://www.oireachtas.ie/en/debates/question/2022-07-05/616/?highlight%5B0%5D=35337

future. Based on current resources, IPHA would view the current system as insufficient in the context of many future pending medical innovations designed to deliver more personalised medicine.

2. ***Early Access / Conditional Access***
   There is a presumption that demand for innovative, new medicines is zero until they are reimbursed but that is not the case, hence the need for an Early Access Scheme to bring Ireland in line with European counterparts.

One of the most notable anomalies in Ireland's current reimbursement system is the absence of any means to provide patients with early access schemes to clinically innovative new medicines. Interim and early access models have reportedly been examined by Irish officials but are not supported by the Department of Health on the basis of HSE and NCPE advice that such pathways 'rest on the assumption that the collected data would support a positive reimbursement recommendation, which is often not the case'. [13]

Decision-making on new medicines can take up to 24-36 months following the submission of a reimbursement application; in some cases, longer. During this review and approval process, patients in Ireland will generally not have access to the licensed medicines regardless of healthcare need or potential benefit.

In response to these time periods, most healthcare systems in Europe have now implemented some interim agreements or frameworks to facilitate patient access in areas of high unmet need. Examples include the Early Access to Medicines Scheme, Innovative Licensing and Access Pathway, Innovative Drugs Fund, (EAMS, ILAP and IDF) in England, the ATU in France, the 648 list in Italy, and Royal Decree 1015/2009 for special access to medicines in Spain. These arrangements are generally publicly funded and focus on patients with high unmet need without suitable therapeutic alternatives and medicines that have received accelerated approvals based on early phase trial data. Ireland is an outlier in this area.

Currently, in some instances, a supplier may grant access on a named patient/compassionate basis ahead of EMA regulatory approval, but such arrangements tend to be *ad hoc* and infrequent. After EMA regulatory approval, arrangements to provide access free of charge have been sponsored by some companies, however these are not widespread and previously have been subject to criticism by agents involved in medicine assessments. The arbitrary nature of such supply represents a vulnerability to patients, clinicians, suppliers, and the State.

There are many instances where patients' need to access treatments will be highly time sensitive. Policy development, leadership and industry collaboration in this area could facilitate access ahead of the completion of the full assessment process. Indeed, such an approach would prioritise patient need, as envisioned under the Health Act (Pricing and Supply of Goods) 2013.

IPHA encourages examination of best practice in this area. To support this review, a potential pilot scheme is outlined below for consideration and further consultation; additional criteria could be applied to limit or expand the scope of any such scheme.

Terms of a Pilot Scheme

IPHA understands that the concerns around such schemes are based principally on two issues:

- If reimbursement was unsuccessful, then the supplier could withdraw treatment from a patient.
- That it would alter the price negotiation dynamic between the HSE and the supplier.

[13] Minister Stephen Donnelly, Dáil Éireann Debate, Vol. 1025 No. 4, Written Answer No. 493 of Wednesday 13 July 2022, [38275/22], https://debatesarchive.oireachtas.ie/debates%20authoring/debateswebpack.nsf/takes/dail2022071300110#WRW04300.

To address both concerns, IPHA proposes the introduction of a pilot scheme, selecting medicines where the financial impacts are relatively predictable for both sides e.g., orphan or end of life treatments. The scheme could be subject to strict criteria to mitigate against the above issues of concern.

Across all health spending new medicines expenditure is probably the most robustly assessed and budget impact medicines go through a strict evaluation process to determine if they will improve efficiency and standards of care before being made directly available to Irish patients. Acknowledging the importance of imposing a strict funding assessment, the process does however require between 20 and 30 steps before a medicine is approved, taking on average, over 1,000 days from the start of the NCPE assessment to reimbursement. As a consequence, Irish patients are suffering particularly in comparison to our European counterparts. The proposals for reform of the reimbursement system outlined above, IPHA believes, would address some of the delays encountered enabling a more streamlined and faster system of reimbursement.