IPPOSI

ACCESS TO MEDICINES IN IRELAND

SUMMARY REPORT

A summary of the discussion, recommendations, contributions and social media comments from the IPPOSI Access to Medicines, Digital Discussion

FIRST PANEL DISCUSSION:

THE PATIENT EXPERIENCE OF INVOLVEMENT IN ASSESSING AND REIMBURSING NEW MEDICINES IN IRELAND

CONTRIBUTORS: Professor Aine Carroll, UCD & HSE Drugs Group Chair; Aoife Kirwan, MS Ireland & HSE Drugs Group Patient Representative; Caitriona Ní Choitir, NCPE; and David McMahon, Irish Skin Foundation

Despite important leaps forward in public and patient involvement across the medicines assessment and reimbursement process in Ireland, it appears (to those actively engaging with the process) that some degree of mystery still surrounds the patient submission process. While acknowledging recent improvements in the clarity of information provided about the process and in the availability of a dedicated patient engagement lead within the NCPE, many patient organisations still have questions around the content of submissions. There is some confusion around what information should be include in the submission and what background information and research is expected of them. Some of this confusion arises from the fact that little is known about how patient submissions are reviewed and weighted into either the NCPE assessment or the HSE Drugs Group recommendation. Patient organisations highlight the need for greater feedback on how submissions are considered, alongside clinical and cost effectiveness data.

The drain on time and resources a submission requires of an already under-resourced patient organisation was also highlighted during the discussion. **David McMahon (CEO, Irish Skin Foundation)** admits absorbing up to 200 hours, interviewing over 450 patients with dermatitis, over a period of 18 months in order to respond to a first-in-class medicine for eczema – an undertaking which he acknowledges is not necessarily possible for every new medicine, or practical for smaller, more informal patient groups. David describes filing his submission in August 2019, but as yet, receiving no further information around its use or utility since. He queries whether different types of patient submissions – those which are more subjective or qualitative compared with those that are more scientific or quantifiable – are equally appreciated.

92

Participants

"Behind the process, there are real people who are desperate for access…" .

David Mc Mahon
CEO
Irish Skin Foundation

"When I joined the HSE Drugs Group, I thought 'I'm that patient representative, so I'm just going to say yes to everything', but the reality of the situation is very, very different. I'm there as a patient representative, but I'm there in the public interest, and it has to be fair".

Aoife Kirwan
Patient Representative
HSE Drugs Group

"Great to see @complexmarkets speaking at today's @IPPOSI event talking about #accesstomedicines and all its complexities. #moralmarkets"

@techspaces

"The preparation and contribution (of patient representatives) has been extremely valuable……and it's really nice to see, with the efforts of many, how appropriate patient and citizen representation on so many different committees are really changing things…"

Professor Áine Carroll
Independent Chair
HSE Drugs Group

"A cynical perspective could ask…

'Is this just a process, is this a way of siphoning off the frustration, desperation and need to include the communications of patients into an operational process?'

…now I don't believe that it is, but in an environment where there is no more feedback, then you wonder where the value lies"

David McMahon, Irish Skin Foundation

In addition to the logistics of preparing a patient submission, ethical considerations around preserving the anonymity of patients from smaller, more informal patient groups is a challenge according to **Caitriona Ni Choitir, Senior Health Technology Assessor and interim Patient Engagement Lead with the NCPE,** who reports that continuous improvements are being made to address how smaller, more informal patient groups can be engaged. She refers to the provision of one-to-one support for completing patient submissions, including tip sheets and checklists, but mentions that a number of proposed new medicines' applications are not accompanied by a patient submissions and questions where the patient voice can be identified in these instances?

Aoife Kirwan, patient representative on the HSE Drugs Group, encourages patient communities not to underestimate the value of using the patient submission to share stories about the 'lived experience' of patients with a particular condition. **Patient submissions (in full) are included with the papers given to the HSE Drugs Group members prior to a meeting** and reference is made to the content during deliberations. She supported the call for greater guidance to be given to both small and large patient organisations in identifying what information to include in submissions and what quality of information is required or suitable. Speaking about her own involvement journey as a patient representative on the HSE Drugs Group, she described her experience as 'positive' and a 'steep learning curve'.

Professor Áine Carroll, Independent Chair of the HSE Drugs Group, agrees that we are on an upward trajectory, pointing to a marked contrast in the situation before and after patient involvement.

SECOND PANEL DISCUSSION:

THE MEDICINES ASSESSMENT AND REIMBURSEMENT PROCESS: NEW AND EXISTING CHALLENGES

CONTRIBUTORS: Philip Watt, Cystic Fibrosis Ireland; Professor Susi Geiger,UCD; and Jim McGrath, IPHA

There seems to be increasing consensus around access to medicines challenges, coupled with *some* consensus around the potential solutions. While underscoring timely access as a long-standing patient priority, affordability is recognised as the primary concern of government – with the collective acknowledgement that many new medicines often come with eye-wateringly high price tags.

New medicines are increasingly complex, treating the cause of the condition rather than just the symptoms – but these advances come at a cost. Therefore there is a societal challenge to keep pharmaco-economics and politics apace with innovation – as patient expectations around access are unlikely to diminish. Efforts at the European level to promote cooperation around price negotiations, such as Beneluxa, are to be commended and supported. But across the board, greater patient involvement is key - patients have insights which can help unpack some of the complexity and suggest the outcome measures which can help improve the medicines assessment and reimbursement process.

Indeed, the number of European cooperation initiatives working to increase transparency seems to fly in the face of the argument that confidentiality is in the interests of society and of patients. There appears to be growing acceptance that there are often legal and economic incentives for industry, but too frequently sufficient emphasis is not placed on the corresponding obligations. States – both individually and collectively at the European level – need to be more strategic. The current work around the European Commission's Pharmaceutical Strategy may take a positive step in this direction. The European Clinical Trials Registry offers an example of new avenues for the traceability for public funds – which may go some way towards dissipating the notion that the public is paying twice – both as investors in research and as payers for medicines.

"There is a sense of shared frustration between patients and industry when scenarios occur where a new medicine receives a positive reimbursement decision but remains unavailable to the Irish patient due to insufficient funds in the medicines budget."
Jim McGrath, Irish Pharmaceutical Healthcare Association (IPHA)

According to the Irish Pharmaceutical Healthcare Association (IPHA), in April 2020, approximately 17 medicines were "stuck in the system", approved for reimbursement but with no funding available to facilitate access. This situation arose as a result of the Department of Public Expenditure decision in July 2019 to cease funding for all positive budget impact medicines. The situation is unsustainable in the longer-term.

"Challenges, but progress!"

Philip Watt
CEO
Cystic Fibrosis Ireland

"Confidentiality has never really guaranteed cheap prices! "

Susi Geiger
Professor of Marketing & Market Studies
UCD

"So important that the #PatientVoice is heard particularly when it comes to #access to new oncology medicines"

@yeates_liz

"The real access issues occur after…(the reimbursement approval process)"

Jim McGrath
Director of Commercial Policy
Irish Pharmaceutical Healthcare Association (IPHA)

"Really excellent webinar today @IPPOSI chaired @DerickOMisteal covering pertinent aspects to patient access in Ireland and featuring lots of great contributors including @INFO_NCPE and @AinemCarroll"

@AXISConsultLTD

"Very interesting discussions and thank you for having me on the panel to discuss the patient experience of involvement in assessing and reimbursing new medicines in Ireland".

Caitriona Ní Choitir
Senior Health Technology Assessor
National Centre for Pharmacoeconomics (NCPE).

"I really enjoyed this discussion today and learned a lot"

@BSugrTrampoline

"The queue of medicines is getting longer and longer, and the work of patient advocacy groups is growing and growing…"
Jim McGrath, IPHA

All agree, the process must be honoured, and patients must have access to medicines deemed both clinically and cost effective by the State's assessors. A call was made for the State to set forward its ambitions for medicines access, which would give all stakeholders some clarity around the future.

IPHA is completing a horizon scanning process with the HSE to share the pipeline of medicines coming down the track and to make the case for funding to be secured well in advance. Both patients and industry believe that greater data capture holds the key to access.

Within patient organisations, registries allow information on how patients are responding to new medicines to be collected. State support for registries is needed.

IPHA believes that real world evidence allows the value of new medicines to be assessed. Plans are currently underway with the National Cancer Control Programme to see how a pay-for-performance model might work in the future.

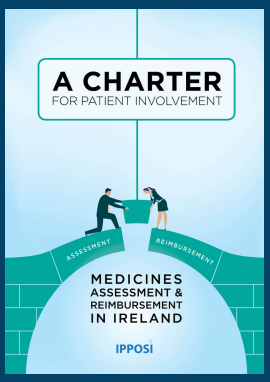
This and much much more will be at the heart of negotiations due to get underway between the Department of Health (DoH), the Health Service Executive (HSE) and Irish Pharmaceutical Healthcare Association (IPHA) in 2021 to arrive at a **new medicines pricing and supply agreement. The current, four-year agreement expired in July 2020, but it was extended until 2021 due to health sector concentration on the ongoing COVID-19 pandemic**.

Multi-stakeholder perspectives, including the patient perspective, must inform the development of the next DoH-HSE-IPHA agreement. IPPOSI has prepared a number of patient-centered recommendations which ask the DoH, HSE, and IPHA to consider in making preparations for these renegotiations. You can access these recommendations by clicking the link below.

IPPOSI perspective_IPHA-HSE Agreement 2020+

Background Information

A SUMMARY OF IPPOSI'S WORK AROUND THE TOPIC OF ACCESS TO MEDICINES



IPPOSI has long called for timely access to medicines for all Irish patients and for greater patient involvement across the assessment and reimbursement process. In 2017 and 2018, together with HRCI, we published the **IPPOSI-HRCI Drug Iceberg Reports** and in 2019 we launched the **IPPOSI Charter for Patient Involvement** – providing a detailed road map for how to increase patient involvement across the medicines assessment and reimbursement process in Ireland.

Find out more about our work here

A RECAP OF PUBLIC AND PATIENT INVOLVEMENT (PPI) ACROSS THE MEDICINES ASSESSMENT AND REIMBURSEMENT PROCESS IN IRELAND

National Centre for Pharmacoeconomics (NCPE)

Patient organisations make submissions as part of the NCPE Health Technology Assessment (HTA) process. The NCPE publicly consulted on the template for submissions in 2018, and a number of patient organisations have since availed of this opportunity to share the "lived experience" of their members around a particular condition and the perceived impact of a proposed new medicine on patient outcomes. The patient submissions are appended in full to the NCPE's HTA report to the HSE Drugs Group. A dedicated focal point for patient queries and support is identified within the NCPE (currently, Senior Health Technology Assessor and interim Patient Engagement Lead, Caitriona Ni Choitir,CNiChoitir@stjames.ie).The NCPE invites all patient organisations to get in contact to join their patient organisation database in order to receive notifications about upcoming HTAs of interest to their condition/community.

More about the NCPE submission process can be found here

HSE Drugs Group

Two patient representatives sit on the HSE Drugs Group, after expressions of interest were sought in 2018. Patient representatives sit in a generic capacity (i.e on behalf of all patients, rather than as representatives for their specific condition). There are also several clinicians represented on the Group. Training was provided to patient representatives around technical language and procedure in advance of joining the Group. Support is offered on an ongoing basis. Documents associated with the proposed new medicine are sent to all members, including the patient representatives, about one week before the Group meeting. The documents include the patient submission as part of the NCPE assessment stage of the process. A briefing is provided during the Drugs Group meeting and members weight up the burden of the condition on an individual's health, the clinical evidence for the efficacy of the proposed new medicine, and the budget impact of the proposed new medicine. Members then vote on whether to recommend or reject the proposed new medicine for reimbursement. The patient representatives vote as equal members and voting is randomised to avoid members feeling unduly swayed by how others before him/her have voted.

More about the HSE Drugs Group, including membership & minutes can be found here