Pharmacoeconomics Annual Symposium

Thursday 10th October 2024

Dublin Castle

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09.00am **Opening**

Stakeholder Perspectives on HTA	**9.00am to 10.30am**
National HTA Agency **Prof Michael Barry**	-
Healthcare Decision Maker **Mr Niall Redmond, Department of Health**	Page 1 - 6
Industry **Mr Shane Ryan, IPHA President**	Page 7 - 12
Patient Organisation Liaison **Ms Joan O'Callaghan, NCPE**	Page 13 - 19
Public/Patient **Mr Fergal Griffin, Neurofibromatosis Association of Ireland**	Page 20 - 26

Panel Discussion

Information about National Centre for Pharmacoeconomics, Ireland.

http://www.ncpe.ie

The NCPE has conducted the HTA of health technologies (including drugs) in Ireland since its establishment in 1998. HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The NCPE assesses evidence for comparative effectiveness, cost-effectiveness and expected budget impact of health technologies. This is done through assessment of evidence submitted by Health Technology Developers and also by independent systematic review. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

The NCPE plays a key role in international HTA organisations including the EU HTA Coordination Group (and associated Subgroups), the International Horizon Scanning Initiative, Beneluxa and ISPOR.

The NCPE is affiliated to the Department of Pharmacology and Therapeutics, Trinity College Dublin and has close collaborative links with International HTA agencies and academic centres.

The NCPE undertakes research to support evidence-based decision making and to inform national and international guidance. The NCPE also contributes to undergraduate and postgraduate teaching and research in Trinity College Dublin and beyond. The NCPE also provides national patient education programmes.

Information about the speakers – Morning session

Prof. Michael Barry is a Consultant Clinical Pharmacologist and Head of the Department of Pharmacology & Therapeutics at the University of Dublin, Trinity College. He is the clinical director of the National Centre for Pharmacoeconomics (NCPE) which conducts pharmacoeconomic evaluations on medicines prior to reimbursement under the Community Drugs schemes in Ireland. He is Past-President (2010-2011) of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). He was a board member of the Health Information and Quality Authority (HIQA) and is a member of a number of National Committees on pricing and reimbursement of medicines. Prof. Barry chairs the New Drugs Committee and the Medication Safety Committee at St. James's Hospital, Dublin. In 2013 he was appointed as Clinical Lead for the new HSE Medicines Management Programme. He is a fellow of the Royal College of Physicians in Ireland and is a specialty trainer for Pharmacology & Therapeutics. His research areas include the cost-effectiveness of high cost drugs including chemotherapeutic agents and biologic drugs, pricing and reimbursement and performance based risk sharing schemes. He has published widely on the cost-effectiveness of medicines in the Irish healthcare setting.

Mr. Niall Redmond

Niall Redmond is the Assistant Secretary General in the Department of Health with responsibility for Primary Care Oversight and Performance. He is responsible for overall leadership and management of policy development and implementation oversight in relation to primary care nationally. This includes policy development, oversight and reform of key primary care services including General Practice, Pharmacy, Oral Health and the Enhanced Community Care Programme. He oversees policy on the various community drugs schemes; the pricing and reimbursement of drugs including implementation of sectoral framework agreements and effective international collaboration on relevant issues. Niall has over 20 years of public policy experience across a number of Government Departments. He is currently a member of the Department of Health's Management Board and co-chairs the Medicines Sustainability Taskforce.

Mr. Shane Ryan

Shane is the General Manager at Takeda and was part of their startup team in Ireland. He has almost 25 years biopharmaceutical industry experience having worked with a number of companies in a variety of roles and locations. Shane currently serves on several industry boards. He holds third level qualifications in Chemistry and Business and is the recently appointed President of the Irish Pharmaceutical Healthcare Association (IPHA). He has served on their board and chaired numerous committees during over the past years in the Association. He is also a strong advocate and executive sponsor of efforts to advance diversity, equity and inclusion. Shane has a particular interest in patient empowerment, digital health, equitable access to medicine as well as industry reputation and its societal impact.

Ms. Joan O'Callaghan

Joan O'Callaghan is a Senior Health Technology Assessor and Lead on Patient and Public Involvement at the NCPE. She is a graduate of the School of Pharmacy, Trinity College Dublin. Upon completion of her degree she completed her pre-registration training at St. James's Hospital, Dublin. Joan subsequently worked as a pharmacist in the hospital and community settings. Prior to taking up her current position Joan worked at the Health Products Regulatory Authority (HPRA) as both a Pharmaceutical Assessor and a Research Scientist. Her research in the HPRA focused on the use of biosimilar medicines. Joan holds a Masters by Research from University College Cork and a MSc. in Biopharmaceutical Science from IT Sligo. Joan's current research interests include stakeholder involvement in health technology assessment.

Mr. Fergal Griffin

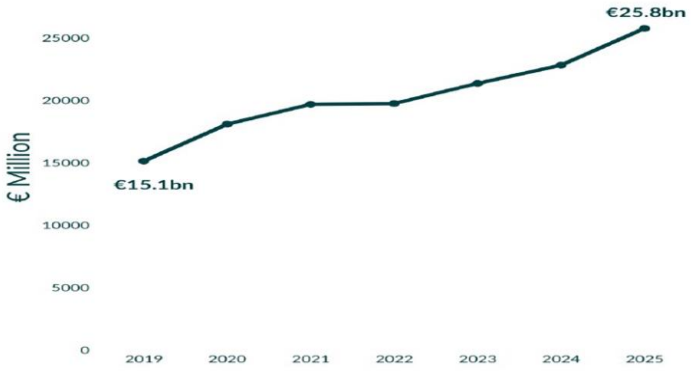
Fergal Griffin is the General Manager of the Neurofibromatosis Association of Ireland (NF Ireland), an organization dedicated to supporting over 3,000 individuals in Ireland affected by Neurofibromatosis, a genetic disorder that causes the development of tumors on nerves throughout the body. With a passion for advocacy and patient support, Fergal plays a key role in ensuring that individuals and families impacted by Neurofibromatosis have access to the latest information and resources. Under his leadership, NF Ireland has expanded its services, including a 24-hour Helpline, educational literature, and awareness campaigns to help those affected feel less isolated. Fergal is deeply committed to empowering the NF community and advocating for improved healthcare and resources for those living with this complex condition

An Roinn Sláinte
Department of Health

NCPE Annual Symposium - Stakeholder Perspectives

Niall Redmond
Assistant Secretary General
Head of Primary Care Oversight and Performance
Department of Health

Budgetary Context



Total Medicines Expenditure

2022	€3.00+ bn
2023	€3.2+ bn
2024	€3.3+ bn*

*Estimation based on projected increase

- €1 in every €8 of the health budget spent on medicines

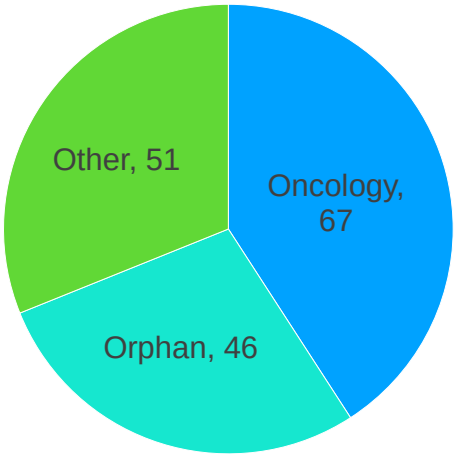
Framework Agreement on the Supply and Pricing of Medicines (FASPM) 2021-2025

State-Industry Partnership:

- pricing certainty
- continuity of supply
- market predictability

2021-2024:

- €128m funding available for new drugs
- 164 new drugs approved

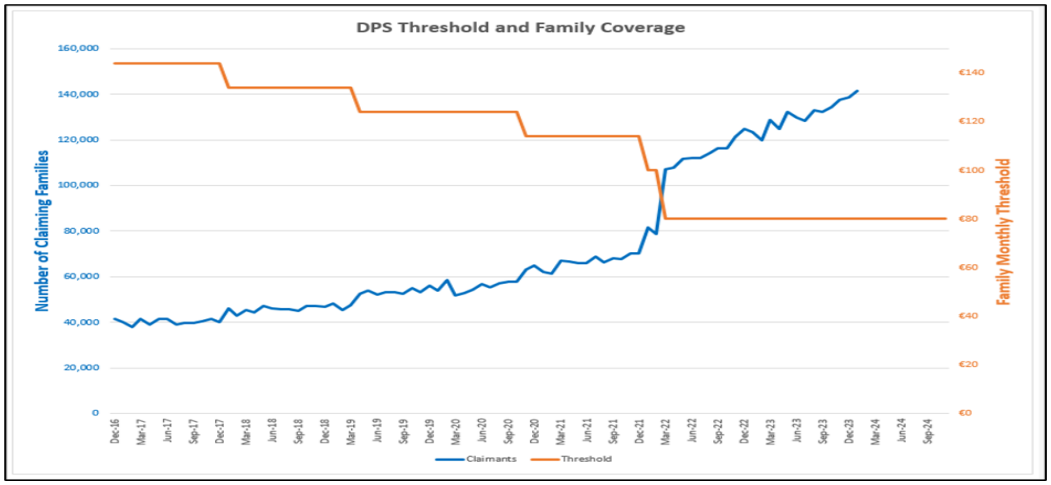


Reimbursement Approvals 2021 - 2024

Evolving Policy…Impacts

- Substantial progress towards the vision of Sláintecare
- Major affordability/eligibility measures adopted
  - *Free Contraception Scheme*
  - *Drug Payment Scheme: Twice as many claimants as in 2021*
- Expansion of Free GP Care to an additional 0.5m people
- Expansion of the Role of Pharmacy
- Digital Health Framework 2024

Evolving Policy…Impact Example



Medicines Sustainability Taskforce

- Part of Joint HSE-DoH Productivity and Savings Taskforce
- Finding efficiencies to deliver better treatment for more patients

- Best Value Biologics
- High-Tech Hub
- Hospital Medicines Management System
- Procurement
- Governance
- Interchangeable List

Minimum Savings Target 2024: €20m

Evidence for Policy Programme

- DoH-HRB collaboration
- Project grants: up to €300,000
- Timeline: up to 24 months
- 7 topics: issues shaping the future of health policy

- **EfP-4;** The development of data infrastructures to support on-going analyses of the impact of reimbursed medicines on healthcare service utilisation in Ireland

The Mazars Review – Enhanced Capacity

- Stakeholder submissions, including IPHA, MFI and IPPOSI were welcomed.

- Budget 2024 allocated funding for 34 WTE positions to improve capacity and be future-ready

- The HSE will launch an application tracker before year end to enhance transparency with real-time information

European Policy: Health Technology Assessment Regulation (HTAR)

- Takes effect in January 2025, Irish involvement facilitated by NCPE.
- Joint Clinical Assessments (JCAs) & Joint Scientific Consultations (JSCs) focused on clinical value
- P&R will continue to be assessed at the national level
- **HTA Coordination Group:** Ireland has a key role as a member of the sub-group for the identification of emerging health technologies.

Scope of HTAR	Effective Commencement
Oncology Drugs	12 January 2025
Oncology and Orphan Drugs	13 January 2028
All New Medicines	13 January 2030

International Horizon Scanning Initiative (IHSI)

Ireland, as a founding member, has access to

- a database of new pharmaceutical treatments
- High Impact Reports (HIRs)
- a comprehensive intelligence platform
- early insight on emerging technologies
- expertise of EEA partners and collaborators

Looking Forward

- Budget 2025 – Sustainability Programme – Commitment to **reinvest €30m** of new savings to support **new medicines**
- Biosimilars – Substitution?
- Eligibility Expansion – HRT
- Next FASPM
- HTAR Implementation
- National Clinical Trials Oversight Group established
- Ireland will chair the BeNeLuxA Steering Committee
- Collaboration and Partnership

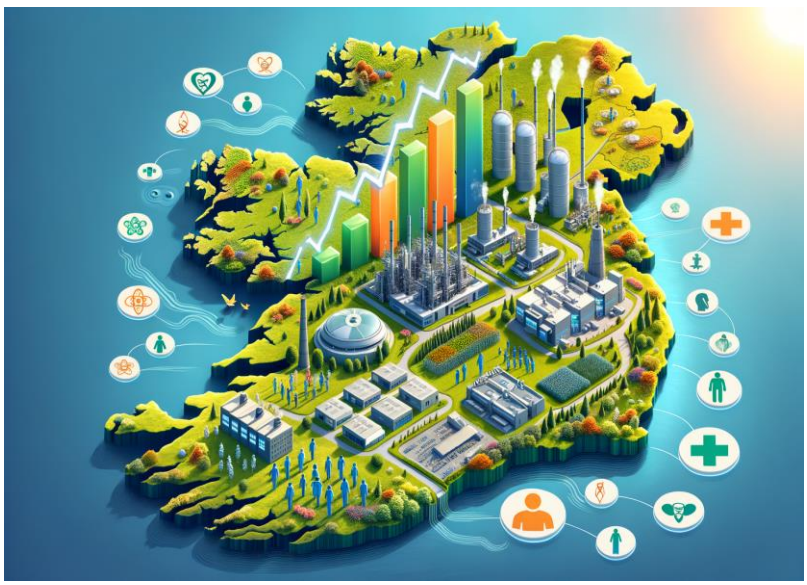
INNOVATE FOR LIFE

IPHA Outlook

Shane Ryan
IPHA President
October 10th 2024

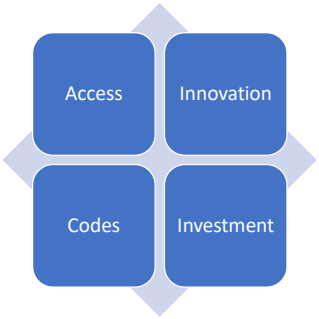
Irish Pharmaceutical Healthcare Association

medicines.ie



IPHA Focus

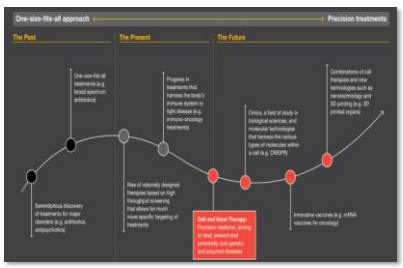
"To deliver a continuous flow of innovative medicines and vaccines for better health for patients".



Purposeful partnerships, trust and transparency to improve patient outcomes, **deliver healthcare advancement**, and **progress innovation** and **research**.

Reflections & excitement for the future

Innovation In Treatment



- Alzheimer's therapies
- Stem cells for CNS
- Psychoplastogens
- Gene therapy (e.g., haemophilia, IRD)
- CRISPR gene editing
- mRNA personalized vaccines
- BiTEs
- Remyelinating CNS therapies

Advances in Data, Digital & Technology

A huge opportunity for patients, citizens, healthcare ecosystem, industry and Ireland

EU Pharmaceutical Legislation

- We share the **common goals of providing equitable access** to medicines throughout EU Member States, reducing shortages and ensuring that Europe can be a world leader in medical innovation.
- While the legislation is wide-ranging, there is **ongoing uncertainty** regarding reducing baseline Regulatory Data Protection (RDP) by two years.
- This proposed cut could introduce unpredictable conditions and a further loss of competitiveness, **widening the innovation gap** between the EU and other global leaders such as the US and China.*
- It may also result in **fewer new medicines** being available to Irish patients and across Europe:

*The changes proposed by the Commission would decrease the amount of innovation expected in Europe by 22%, which equates to a 'loss' of 50 products between 2020 - 2035 compared to what would have been expected without a revision of the regulation.***

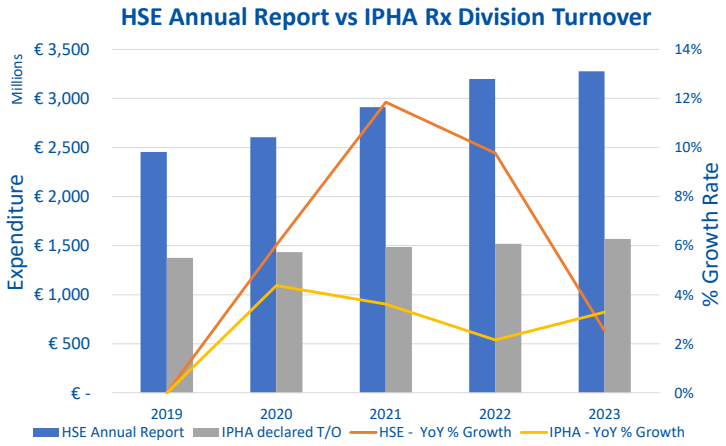
*Reference: Draghi Report here

**Reference: Dolon Report here

EU HTA – IPHA Perspective

- The benefits to patients can be realised, but only through an open and collective working dynamic.
- NCPE has been responsive to industry and IPHA meeting requests.
- Want to continue this positive engagement of working together.
- Our concern is that the benefits of earlier scoping will be lost if assessment has to recommence post JCA publication.

IPHA-State Agreement continues to deliver



- Estimate beyond €500m in efficiencies generated by end of this year
- HSE Meds Growth = 7.2% (Av. of 2021-2023)
- IPHA Growth = 2.9% on average (2021-2023)*
- IPHA companies account for 20% of HSE additional spending on medicines

*inclusive of rebates/confidential pricing

Ambition for the reimbursement process

1. To create space to work together in patients' interests.

2. Through partnerships, industry and State work collectively beyond transactional arrangements.

3. To achieve a system capable of decision-making within legislated time periods, which is comparable with peer European countries.

Irish Pharmaceutical Healthcare Association
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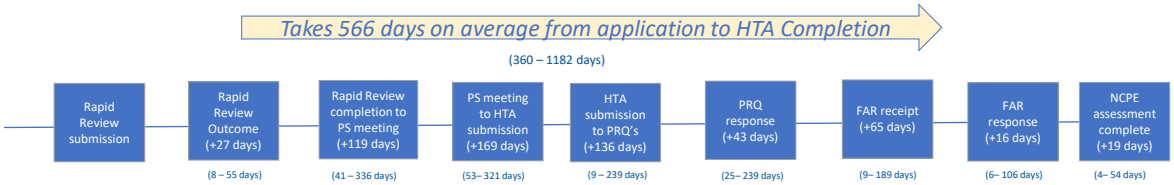
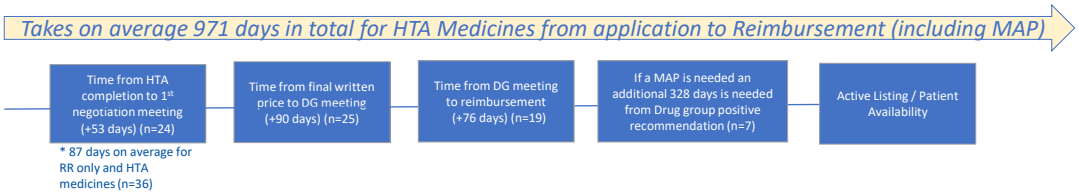
Shared ambition to improve decision timeline



- Based off medicines reimbursed following a full HTA between 1st Jan 2023 – 1st Oct 2024 (n=26), on average another **405 days** was required to achieve reimbursement post-NCPE decision



PS = Pre-submission, PRQ = Preliminary Review Questions, FAR = Factual Accuracy Report, DG = Drug group MAP = Managed Access Protocol

*Reference IPHA Data

What is our ask?

Through enhanced collaboration, between industry, NCPE, CPU and the Department of Health we can create a more transparent, efficient process for patients, healthcare professionals and the broader ecosystem.

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medicines information online

NCPE Annual Symposium
10th October 2024

Patient Organisation Submissions made to the NCPE

Joan O'Callaghan BSc Pharm MSc MRes MPSI
Senior Health Technology Assessor
NCPE Lead on Patient and Public Involvement

NCPE
National Centre for Pharmacoeconomics, Ireland

Importance of Patient Input

- Patients, carers and their families have specific knowledge and expertise to offer arising from their own lived experiences
- Patient Organisation input can highlight important aspects of a health condition or medicine that are:
  - Not well identified or well presented in the published literature, or
  - Not well captured in quality of life measures or other outcome measures used in clinical trials
  - Not well known and/or understood by experts in HTA and decision makers

NCPE Patient Organisation Submission Process

- NCPE has established a Patient Organisation submission process
- Applies to all medicines undergoing a full HTA
- Developed in consultation with Patient Organisations
- First introduced in 2016

NCPE
National Centre for Pharmacoeconomics, Ireland

NCPE Patient Organisation Submission Process

NCPE
National Centre for Pharmacoeconomics, Ireland

Identifying Patient Organisations

Patient Organisation Details

Question 1: Name of Organisation

Please give the full name of your organisation as it appears in your governing document.

Question 2: Alternative/Previous Names of Organisation

Please advise of any alternative names by which your organisation is known.

Question 3: Organisation's main or registered address

Please provide the full registered address of the organisation

Question 4: Type of Organisation *(please tick as appropriate)*

Type A – (see Note 1) ☐
Type B – (see Note 2) ☐
Type C – (see Note 3) ☐
Other ☐

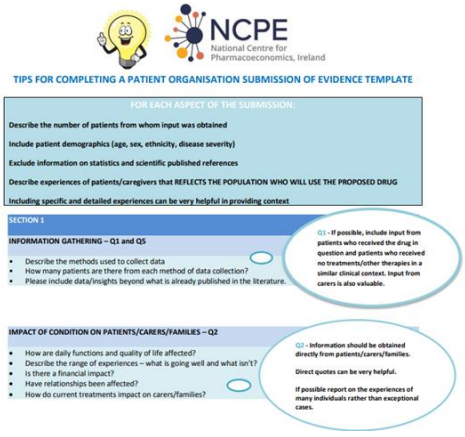
Further information on organisation type is available on www.governance.ie and additional information is provided at the end of this document.

Please submit a copy of your governing document e.g. Memorandum of Articles or Articles of Association. *Unincorporated organisations must still provide a written governing document to demonstrate that they operate under a set of rules.*

☐ **Enclosed**

Submission Template

- Details of how information was gathered
- Experience of patients, carers or their families
- Views on the difference the new medicine will make
- Views on how the medicine will address any unmet need
- Declaration of interests



Supports for Patient Organisations

- Open lines of communication
- Initial meeting
- Support person available
- Guidelines and tip sheet
- Examples of previous submissions
- Plain language summaries
- NCPE deliver a HTA module in an annual national Patient Education Programme

National Patient Education Programme

- 10-week module
- Principles and Practices of HTA
- Face-to-face and virtual meetings, workshops and online training materials

Feedback from National Patient Education Programme

Interesting - well laid out - well organised - relevant - genuine advice about how patients can get involved - clear and easy to understand

Extremely useful and interested to hear what all guest speakers had to say

Mix of workshops and content was well linked together

Very accessible information

NCPE
National Centre for Pharmacoeconomics, Ireland

Initiatives to increase awareness

NCPE
National Centre for Pharmacoeconomics, Ireland

New initiatives to increase awareness

- Oncology HTAs listed in monthly newsletter to Cancer Support Groups
- Publication of one page explainer article on ‘Making a Patient Organisation Submission to the NCPE’
- In April 2024 held first webinar with open invitation to all Patient Organisations


The Alliance of Community Cancer Support Centres and Services

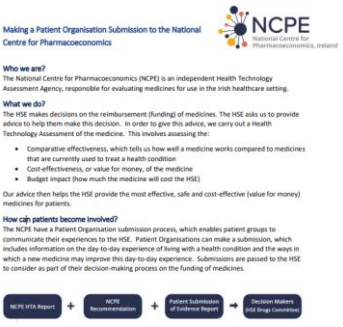
News

for the Cancer Support Community

May 2024

Inside this issue:

- News & Updates
- Upcoming Events
- Cancer Survivorship Programmes and Services
- Research Opportunities


Making a Patient Organisation Submission to the National Centre for Pharmacoeconomics

NCPE National Centre for Pharmacoeconomics, Ireland

Who we are?

The National Centre for Pharmacoeconomics (NCPE) is an independent Health Technology Assessment Agency, responsible for evaluating medicines for use in the Irish healthcare setting.

What we do?

The HSE makes decisions on the reimbursement (funding) of medicines. The HSE asks us to provide advice to help them make this decision. In order to give this advice, we carry out a Health Technology Assessment of the medicine. This involves assessing the:

- Comparative effectiveness, which tells us how well a medicine works compared to medicines that are currently used to treat a health condition
- Cost-effectiveness, or value for money, of the medicine
- Budget impact (how much the medicine will cost the HSE)

Our advice then helps the HSE provide the most effective, safe and cost-effective (value for money) medicines for patients.

How can patients become involved?

The NCPE have a Patient Organisation submission process, which enables patient groups to communicate their experiences to the HSE. Patient Organisations can make a submission, which includes information on the day-to-day experience of living with a health condition and the ways in which a new medicine may improve this day-to-day experience. Submissions are passed to the HSE to consider as part of their decision-making process on the funding of medicines.

NCPE HTA Report + NCPE Recommendation + Patient Submission of Evidence Report → Decision Makers (HSE Drugs Committee)

NCPE National Centre for Pharmacoeconomics, Ireland

Topics covered in online webinar

- Patient Organisation submission process
- Interpreting NCPE recommendations
- Who can contribute to the Patient Organisation submission?
- Gathering information: Tips and Tools
- Presenting your findings
- Resources

NCPE National Centre for Pharmacoeconomics, Ireland

Conclusion

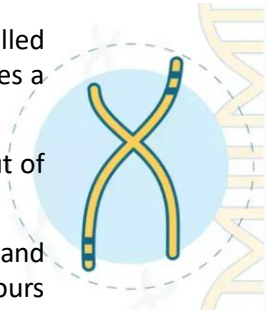
- NCPE proactively invite and support Patient Organisations to make submissions to the decision maker on on-going HTAs
- For the past 4 years just under half of completed HTAs had a Patient Organisation submission
- We continue to liaise with Patient Organisations and are launching new initiatives in order to increase awareness of and engagement with the submission process

THE NEUROFIBROMATOSIS ASSOCIATION OF IRELAND

WHO ARE NF IRELAND

- The neurofibromatosis association of Ireland, known as NF Ireland, serves as a support network for those diagnosed and their families.
- NF Ireland acts as a voice for neurofibromatosis patients, offering services such as a 24-hour helpline, literature on the condition and raising awareness to ensure those affected understand they are not alone in their journey with the disorder.
- Our main goal is to inform affected individuals and provide the latest information, aiming to help them lead healthy lives.

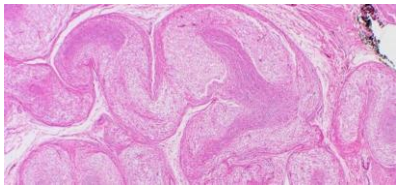
WHAT IS NEUROFIBROMATOSIS



- The nf1 gene is located on chromosome 17. This gene produces a protein called neurofibromin that helps regulate cell growth. When the gene is altered, it causes a loss of neurofibromin. This allows cells to grow without control.
- Nf-1 is usually diagnosed in early childhood and appears in an estimated one out of every 3,000 infants.
- It is characterized by changes in skin colouring (pigmentation), neurologic and skeletal impairments and risk for development of benign and malignant tumours throughout life.

WHAT ARE PLEXIFORM NEUROFIBROMAS

- A tumour that forms in the tissue that covers and protects the nerves.
- Plexiform neurofibromas can occur anywhere in the body, outside of the brain and spinal cord.
- They can occur on the face (including around the eye), neck, arms, legs, back, chest, abdomen, and internal organs.
- Approximately 20-50% of individuals with NF1 develop plexiform neurofibromas, many of which are inoperable due to their size, location, or involvement with critical structures like nerves and organs.



ALTERNATIVE TREATMENTS FOR PLEXIFORM NEUROFIBROMAS

When compiling the Patient Organisation Submission we discussed alternative treatments options with our patients and families:

- **Surgery**: Surgical removal or reduction of tumours may be necessary, particularly if they cause pain or functional impairment.
- **Pain Management**: Effective pain management strategies, including medications and nerve blocks, are essential for improving quality of life.
- **Physiotherapy**: Tailored physiotherapy can enhance mobility and strength, especially if the tumours affect physical function.
- **Psychological Support**: Accessing psychological support is important for managing the emotional impact of living with a chronic condition like plexiform neurofibromas.

SELUMETINIB OVERVIEW & MEDICAL USES

- Selumetinib is used for the treatment of neurofibromas in those with neurofibromatosis type I .
- Selumetinib, sold under the brand name Koselugo, is a medication for the treatment of children, two years of age and older.
- Selumetinib Medication is proven to shrink neurofibromatosis type 1 (NF1) plexiform neurofibromas (PN) when PN cannot be completely removed by surgery.

Koselugo (selumetinib)

CLINICAL STUDY FINDINGS

Although not fully necessary for the Patient Organisation Submission we felt it was good to have an understanding of some of the clinical findings for our submission:

- First FDA/EMA approved treatment for the NF community.
- 66% (33/50) of children treated with selumetinib saw their pn shrink by at least 20%.
- Almost all children taking koselugo saw their tumour shrink or stay about the same.
- Of the children who responded to treatment with selumetinib, 97% (32/33) saw results within one year.

KEY BENEFITS OF SELUMETINIB

When compiling the Patient Organisation Submission we compiled the benefits of the drug from patients and families feedback:

- **Improved Quality of Life**: Selumetinib significantly enhances daily living by reducing the size and severity of plexiform neurofibromas, leading to fewer symptoms and discomfort.
- **Minimized Invasive Surgery**: The medication decreases the need for surgical interventions, reducing associated risks and recovery time for patients.
- **Pain Reduction**: Selumetinib effectively alleviates pain rela improving overall comfort and well-being.
- **Enhanced Well-Being for Children**: For paediatric patients, better symptom management allows them to participate more fully in school and social activities, promoting emotional and social development.

PATIENT ORGANISATION SUBMISSION PROCESS

Reason NF Ireland engaged with the NCPE:

- **Advocate for NF Patient Needs:** Ensure the NF **patient voice** in Ireland is heard in the approval process, highlighting the impact of NF1 on quality of life.
- **Provide Real-World Evidence:** Share **real-world insights** on selumetinib's benefits, complementing clinical data.
- **Highlight Unmet Medical Need:** Emphasize the **urgent need** for new nf1 treatments, as alternative options are currently limited.
- **Support Long-Term Cost Savings:** Demonstrate how the drug can reduce costly interventions and **healthcare burdens** over time.
- **Contribute to Informed Decision-Making:** Provide a **holistic view** of selumetinib's benefits, including mental health and social impact.
- **Increase Access to Treatment:** Advocate for **timely approval** to ensure Irish patients access this **life-changing therapy** without delays.

PATIENT ORGANIZATION SUBMISSION PROCESS

Putting the Patient Organisation Submission together:

- **Patient Engagement:** Gathered information through email, MS Forms, phone calls, and face-to-face interactions to understand patient experiences and needs.
- **Research and Information Gathering:** Conducted comprehensive research on treatments and identified gaps.
- **Collaboration with Patients and families:** Worked closely with family members on a 1 to 1 bases to establish real world examples of the benefits of the drug v the alternatives.
- **Drafting the Submission:** Created a draft highlighting the need for treatments like Selumetinib and the importance of access.
- **Clinical Date:** Although not necessary for our patient org submission we felt it was important to be mindful of the clinical data findings.

PATIENT ORGANIZATION SUBMISSION PROCESS

Putting the Patient Organisation Submission together:

- **Review and Refinement:** Revised the draft based on feedback from patient representatives, families and also important adults that would have benefitted from taking the drug.
- **Final Submission:** Submitted the finalized document to NCPE for review and initial feedback.
- **Continuous Feedback Loop:** Established ongoing communication with patients and their families for future insights and advocacy.

NCPE SUPPORT FOR OUR PATIENT ORGANISATION

Throughout our engagement with the NCPE, we utilized various communication mediums, including the NCPE website, email, and online meetings.

- **Clear and Accessible Resources**: The NCPE website was not only clear and user-friendly but also provided valuable resources, including well-organized examples, templates, and detailed explainers. This transparency made the process straightforward and helped us navigate the submission requirements effectively.
- **Active Engagement from the NCPE**: The NCPE staff were highly engaged and supportive during the process. They facilitated communication through Zoom meetings and responsive email correspondence, ensuring we had the guidance needed at every step. Their willingness to assist made a significant difference in our preparation.
- **Overall Impact**: The support and resources provided by the NCPE greatly enhanced our understanding of the patient organization submission process. Their commitment to assisting us not only streamlined our efforts but also instilled confidence in our approach, ultimately benefiting the NF patients we represent.

GENERAL OBSERVATIONS

Observations on the Patient Organization Submission Process

- **Complexity of the Process:** The submission process requires multiple skills, including **data collection**, **research**, and **analysis**. It demands both clinical insight and real-world patient experiences for a comprehensive submission.
- **Clarity on Decision Weighting:** There is a **lack of transparency** regarding how much weight the patient submission carries in the final decision-making. More clarity here would help ensure patient input is valued appropriately.
- **Social Costs**: **Quantifying social costs** is difficult without prior surveys. It's also important to clarify what constitutes a social cost, such as **caregiver burden**.
- **Importance of the Patient Voice:** Despite challenges, the process ensures that the **patient voice** is included, offering real-world insights that clinical trials may not capture.
- **Challenges in Data Collection**: Gathering information, particularly on **social costs** or **long-term effects**, can be challenging without existing surveys, which can reduce the overall detail and depth of the submissions.

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THANK YOU