THE PHARMACEUTICAL MANAGERS' INSTITUTE

Pharma Summit 25

Evolving through change

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EU HTA: The Changing Face of HTA

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NCPE
National Centre for
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Where is Europe at currently?

- *2025 Polish presidency
- 2025 Denmark
- 2026 Cyprus
- 2026 Ireland

Olivér Várhelyi

COMMISSIONER (2024-2029) | Health and Animal Welfare

Where is Europe at currently?

Critical Medicines Act

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795

EU Pharmaceutical Package Reform

Where is Europe at currently?

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EU Pharmaceutical Package Reform

Three main areas of contention:

- Data Exclusivity
- Compulsory licensing
- Unitary Supplementary Certificates

MDR and IVDR

EU HTAR

New Biotech Act

Came into force 12th January 2025

Where is Europe at currently?

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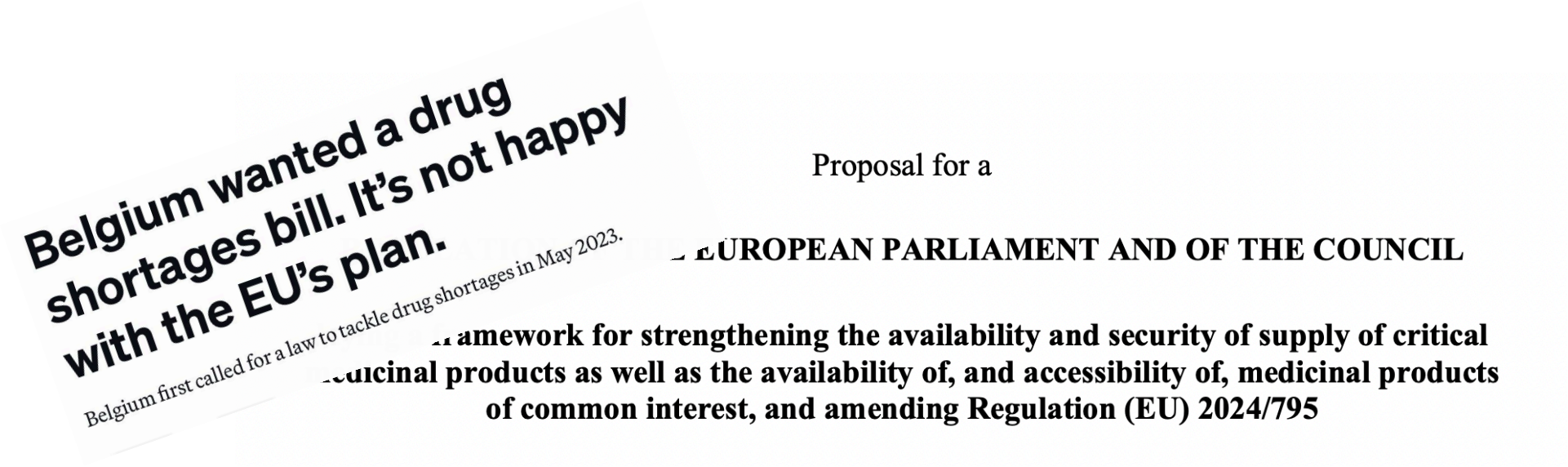
Where is Europe at currently?



Belgium wanted a drug shortages bill. It's not happy with the EU's plan.

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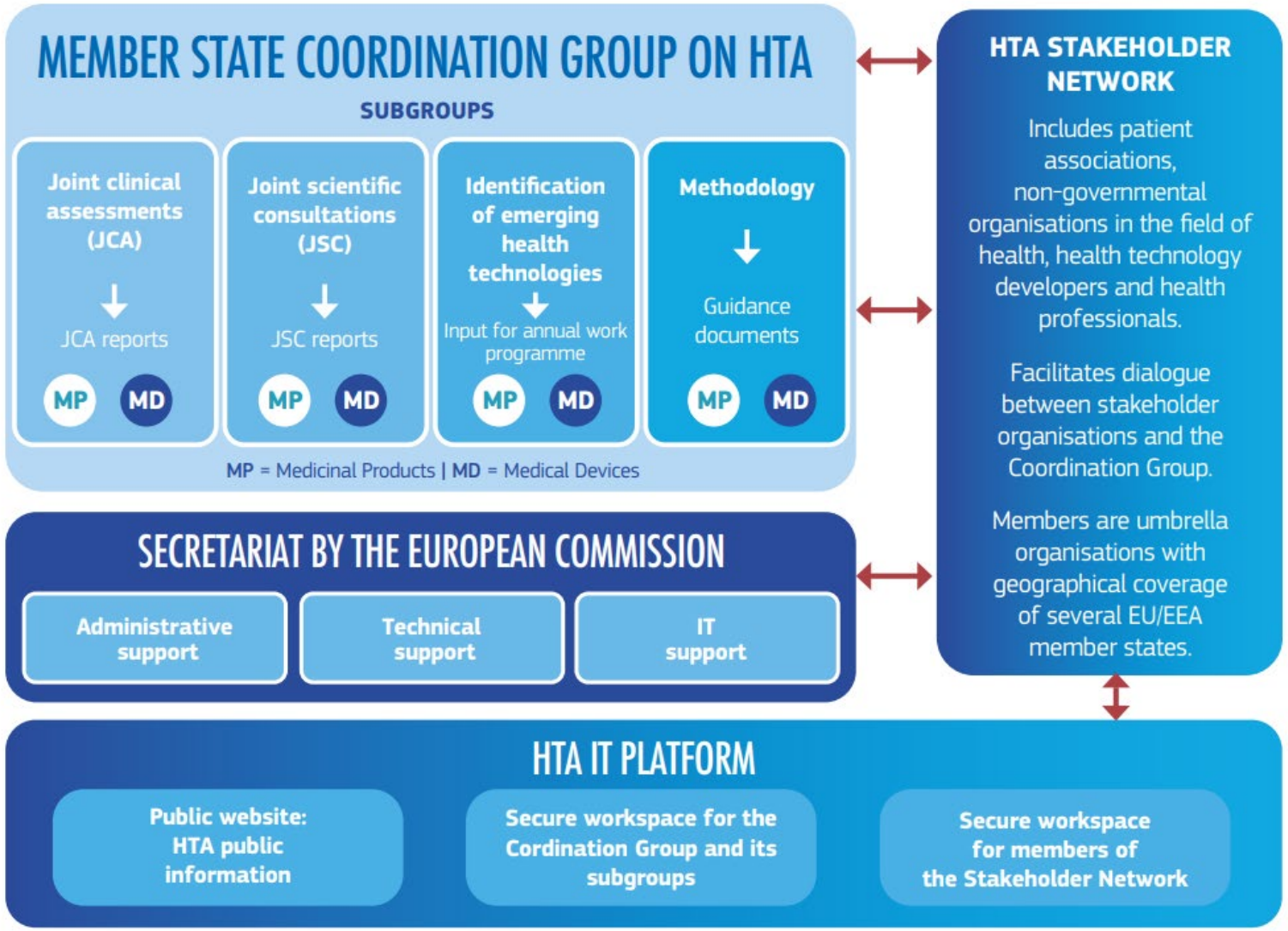
Governance



HTA CG

Joint Clinical Assessments – where are we at?

- Predict to assess approx. 25 products in 2025
- Submissions monthly in line with Market Authorisation Application
- First reports in early 2026
- Summary report and dossier will be published after the joint work is completed.
- EC will not develop a public side of the IT platform and will use the Europa website to publish.

HTAR became available on 12 January 2025

- New active substance in oncology and ATMP are in scope for JCA
- 2 JCA have started

10 JCA guidances, endorsed by the HTACG are available here:

- Key documents - European Commission

Work Programme 2025

- 5 MD/IVD guidances (with MPG SG)
- Guidance on how to fill the JCA report template – MP (with MPG SG)
- Interim versions are available of the patient/clinical expert input template, for situations in which the JCA SG wants to seek their input
- Production of JCAs

JCA timeline in parallel to EMA

Letter of Intent

HTD shall submit
- SmPC
- clinical overview section

Final consolidated PICO

HTD submission Dossier

EC completeness check:

Missing info HTD

Clarifiying/additional info (asked by asr/co-asr)

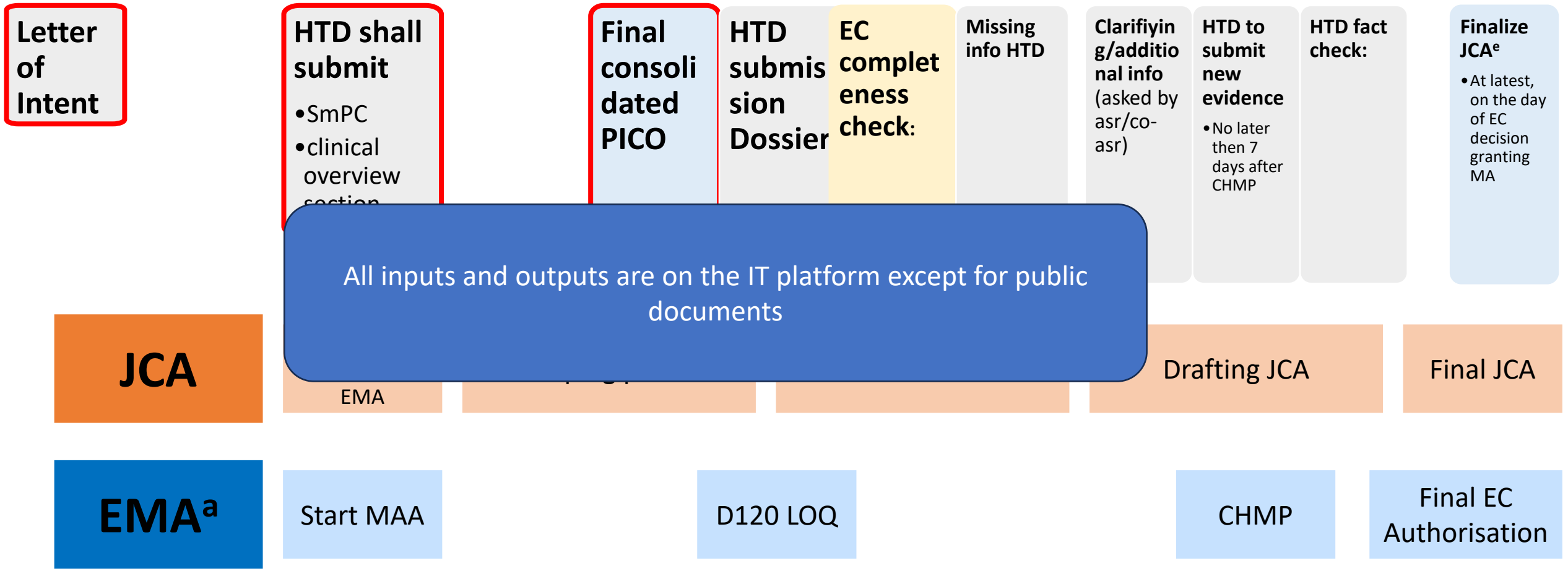
HTD to submit new evidence
- No later then 7 days after CHMP

HTD fact check:

Finalize JCA[e]
- At latest, on the day of EC decision granting MA

JCA	Start JCA at submission to EMA	Scoping phase	Submission dossier		Drafting JCA	Final JCA
EMA[a]	Start MAA		D120 LOQ		CHMP	CD

JCA timeline in parallel to EMA



Joint Scientific Consultations (Early advice)

Number of JSC defined in 2025 work programme of the HTACG

- **2025: 10 JSC planned with the aim to continuously increase capacities in the coming years**
  - **2nd request period: 2-30 June 2025**
  - **HTD can request to have with HTA and EMA or with HTA alone.**
- **Outcome of the JSC procedure:**
  - JSC Outcome document with **common position + individual positions by Member states (MS) in an annex (further specifications)**
  - **Not in the public domain**

What does this mean for Ireland?

Current process for drug licensing/assessment/reimbursement

HSE makes decision

HTA is informed by:

- Submission of evidence from company
- Comparative effectiveness analysis
- Cost-effectiveness analysis
- Budget-impact analysis
- Clinical Opinion

Positive/negative reimbursement recommendation
+/- price reduction

- Patient submission

Slide Acknowledgement Emer Fogarty

1. Company application for marketing authorisation of Drug X

4. Marketing authorisation granted by EU Commission

5. JCA Report published **jointly by Member States**, *& EEA countries*

- *"Scientific analysis of the relative effects….and degree of uncertainty"*

3. PICO survey sent to all Member States - determines the EU Assessment Scope

2. JCA of Drug X starts

- JCA must be *"**given due consideration**"* in national HTA
- Member states draw their **own conclusions** on overall clinical added value within their national context

Slide Acknowledgement Emer Fogarty

Collaboration with Regulatory Bodies

HEADS OF HTA AGENCIES GROUP

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 April 2025
EMA/115125/2025

Joint HTAb-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions

Outcome of a workshop series between HTA bodies and regulators

- Combined needs of regulatory and HTA had common themes
- Randomised evidence preferred and acknowledgement that Making trials easier to do in practice (and cheaper)
- Multiple estimands could be helpful for market access decisions
- Improved data sharing from trials and registries would allow easier interpretability

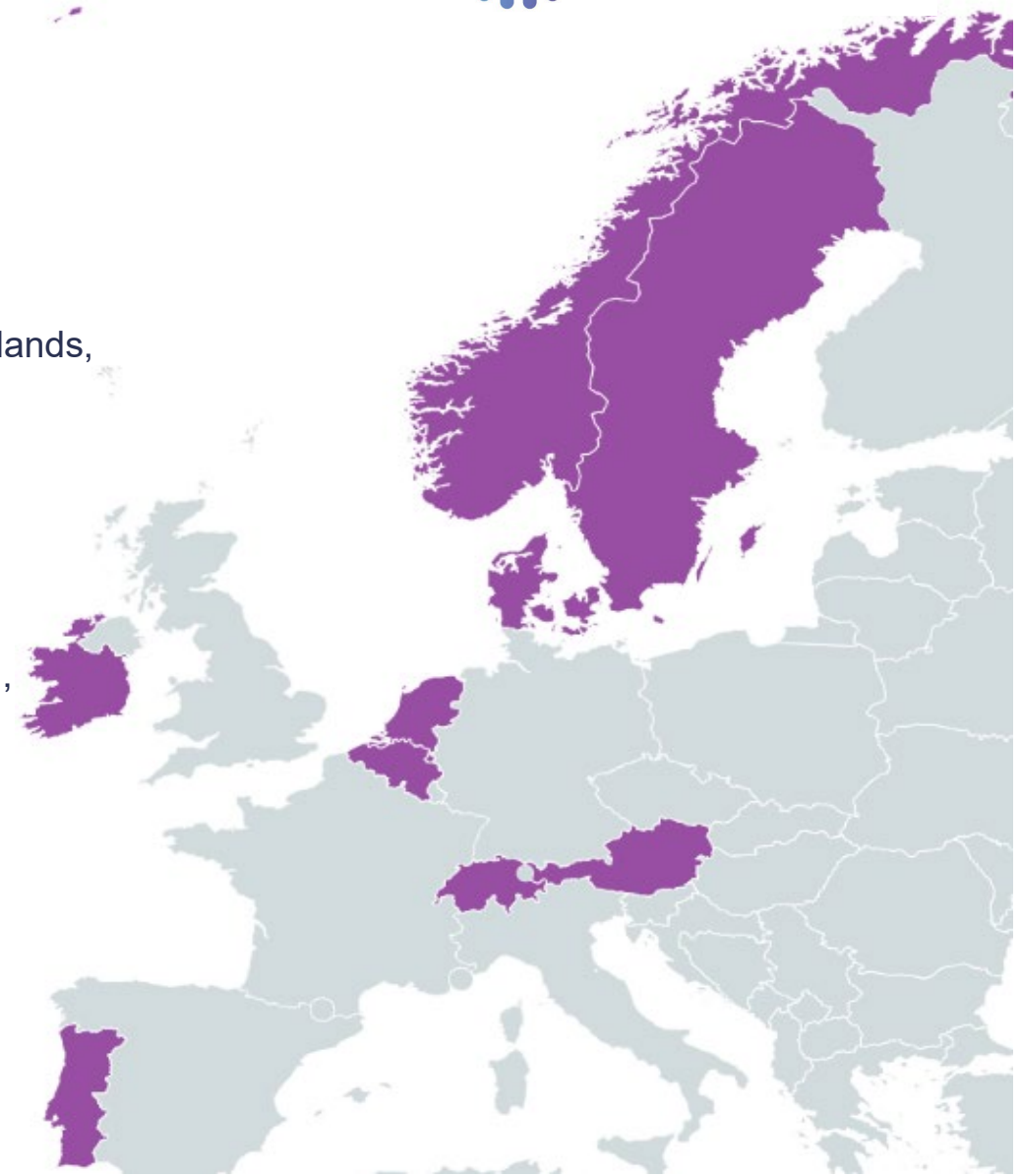
Thanks to Dr. David McConnell, NCPE

International Horizon Scanning Initiative

Why IHSI?

- Collaboration between Member States
- Consolidation of Horizon Scanning experts
- Publicly funded

- Belgium,
- The Netherlands,
- Ireland,
- Denmark,
- Sweden,
- Norway,
- Switzerland,
- Portugal,
- Austria.



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National Centre for Pharmacoeconomics, Ireland

Challenges facing National Horizon Scanning Systems

Manual burden is so high – challenging to scan all clinical trial registries, company materials (pipeline, press releases), regulatory agencies to define the complete horizon for medicinal products

NIH National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov

Clinical Trials

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Search Criteria

8813 results found

Search Results

Viewing 1-10 out of 530,051 studies

Showing results for: **All**

Table of contents

Horizon Scanning data are commercially sensitive.

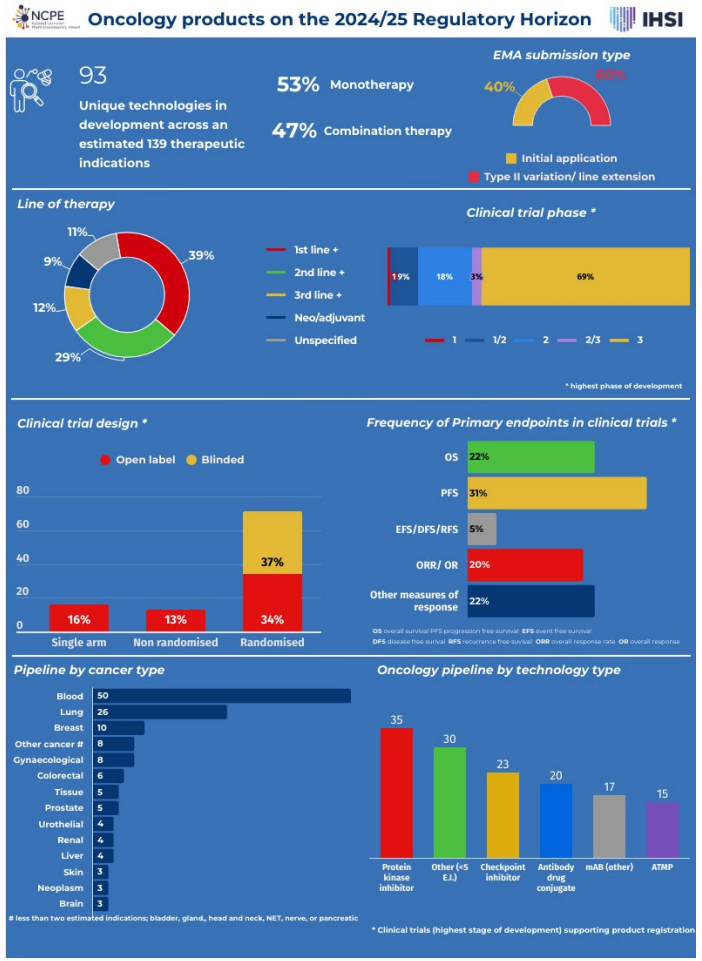
Terms of use and data availability are decided by pharmaceutical companies

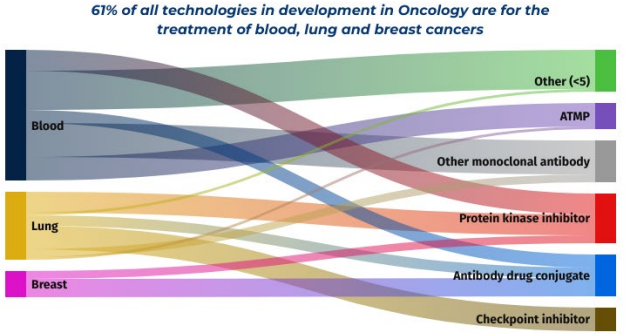
How can IHSI support health system preparedness in Ireland via Health Technology Management

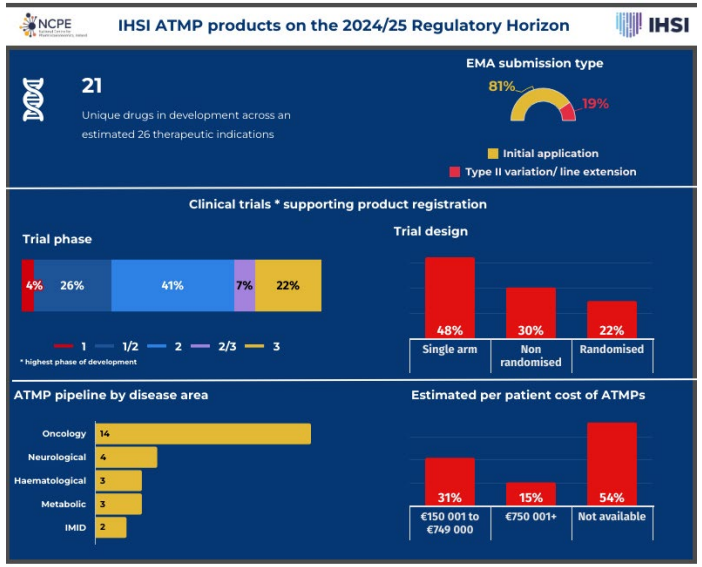
- Effective planning for health technology assessment e.g. early PICOs, targeted disease area analysis
- Early signal volume risk to the system (multiple type II variations) for expensive medicines
- Savings opportunities – Biosimilars and generics on the horizon
- Mitigate system risks - evergreening
- Identify emerging classes of technologies

Drive efficiencies through effective planning for health technology assessment

- Targeted analysis of evidence landscape underpinning oncology and ATMP products
- Early PICOs – supporting JCA

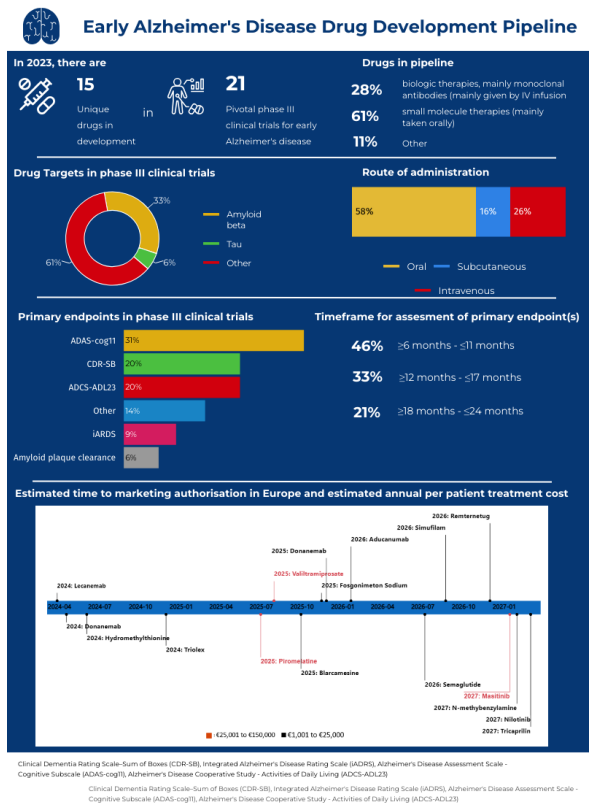


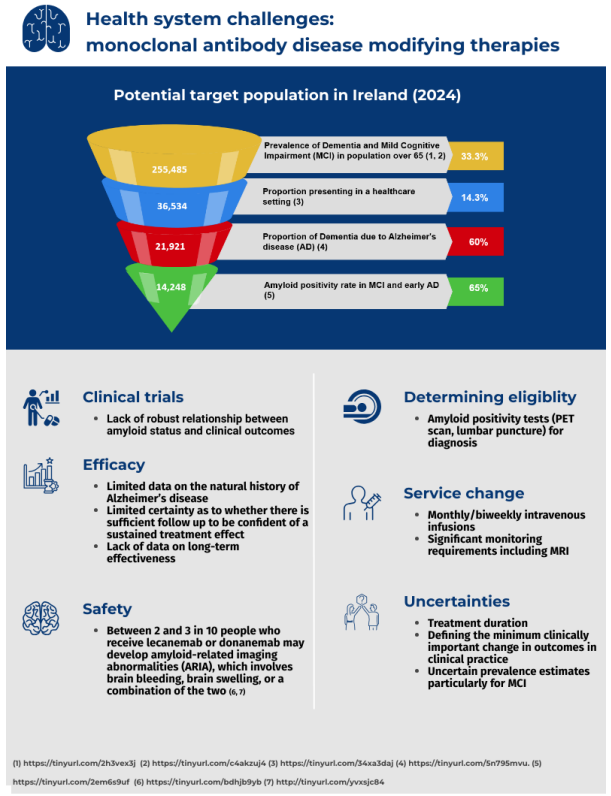




Identify ‘high cost’ and ‘high volume’ emerging classes of technologies

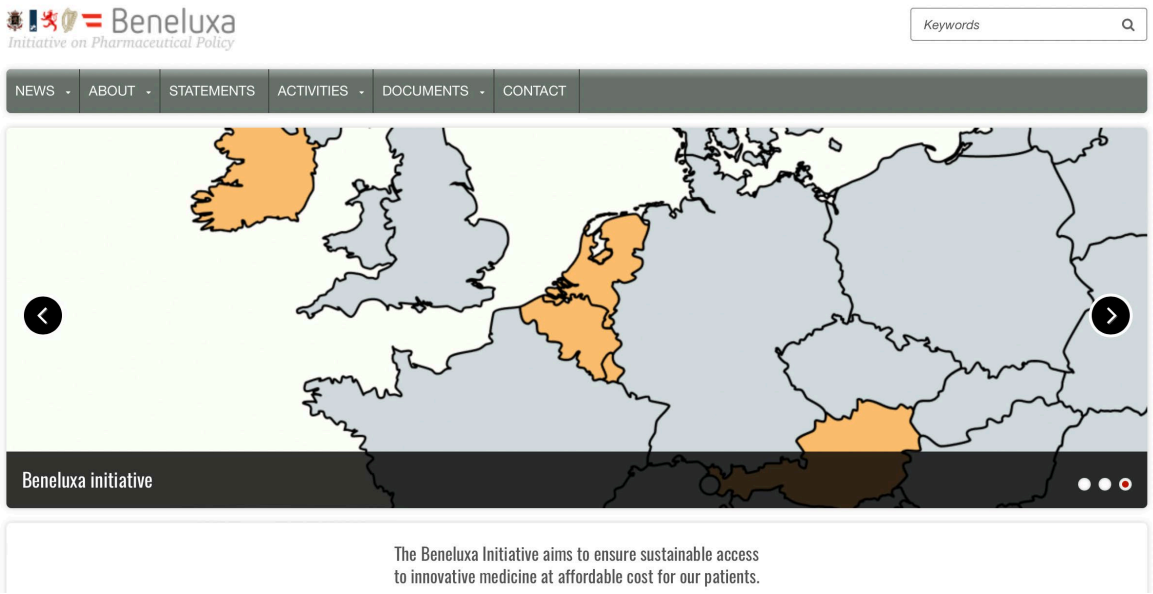
- Early reporting and deep dives into therapeutic areas which will have considerable impact across health system domains
  - Organisational
  - Financial
  - Efficacy





Beneluxa

- 2025 Ireland will chair Beneluxa, Luxembourg as co-chair
- How horizon scanning can help planning of joint work
- Role of EU HTA Regulation and its outputs for Beneluxa
- Continue to develop this model for cross country collaboration.



Thank you!

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