



Pharma
Summit **25**

Evolving through change



Dr Roisin Adams
Head of HTA Strategy
and External Engagement



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EU HTA: The Changing Face of HTA

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Chair, EU Member State HTA Coordination group,
Head of HTA Strategy, NCPE, Ireland

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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MDR and IVDR

New Biotech Act

EU Pharmaceutical Package Reform

Three main areas of contention:

- Data Exclusivity
- Compulsory licensing
- Unitary Supplementary Certificates

EU HTAR

Came into force 12th January 2025

Where is Europe at currently?

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Belgium first called for a law to tackle drug shortages in May 2023.

Where is Europe at currently?

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

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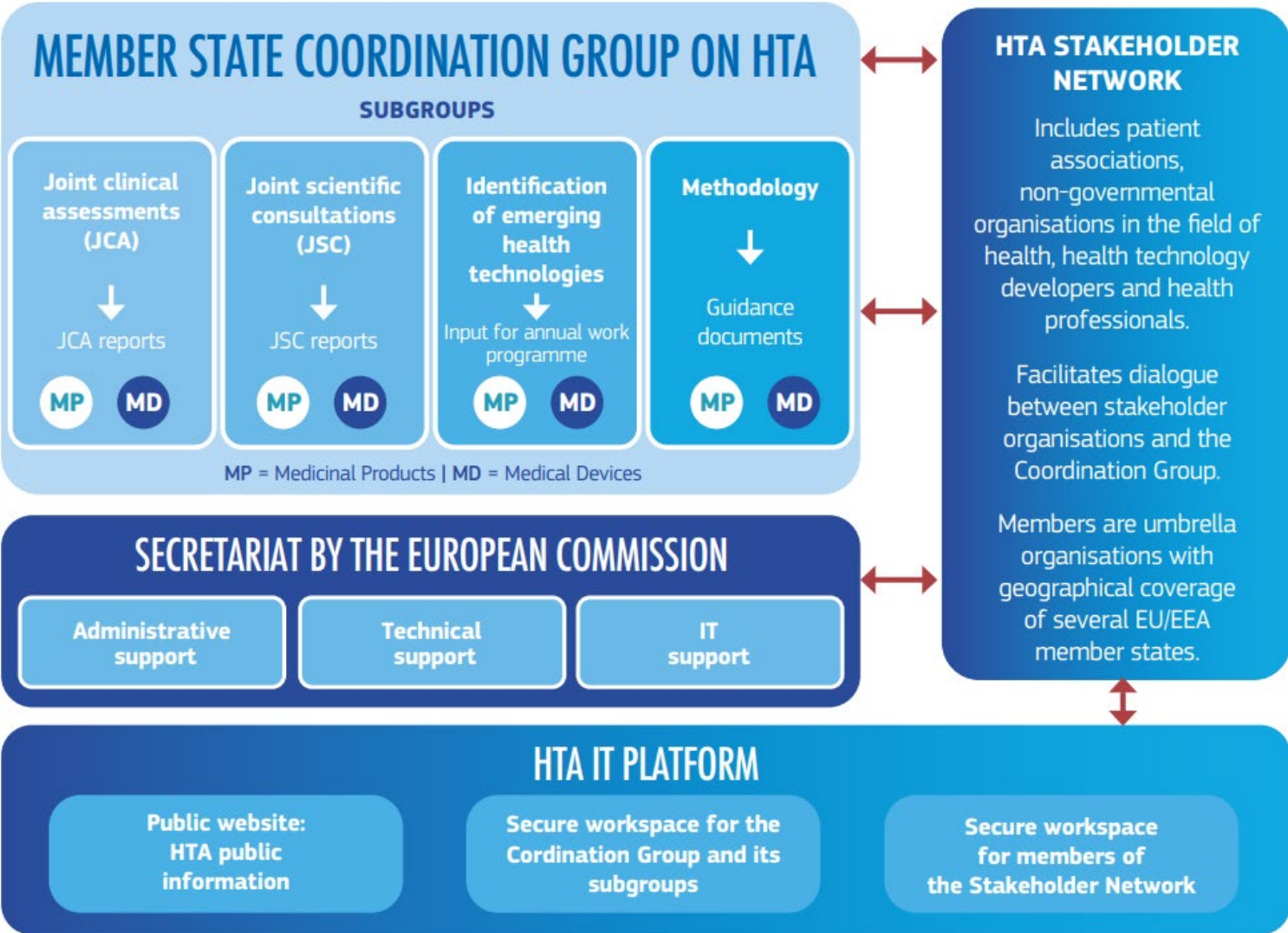
Proposal for a

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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

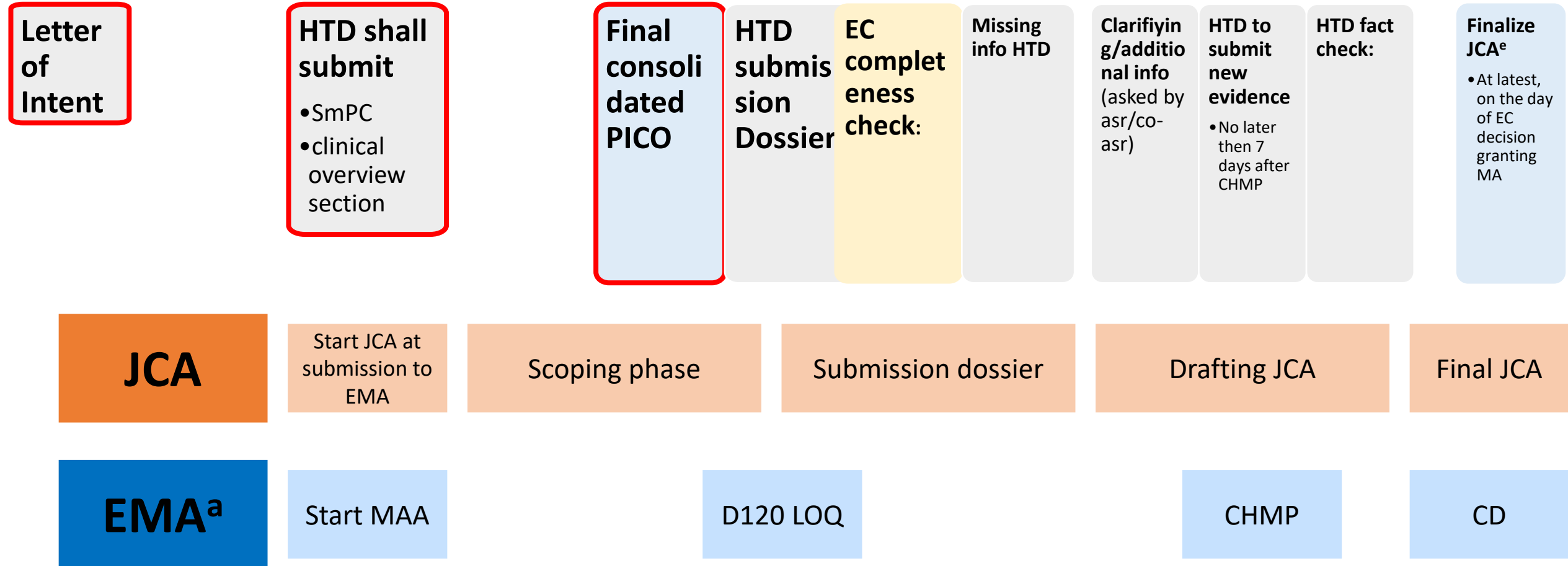
10 JCA guidances, endorsed by the HTACG are available here:

- [Key documents - European Commission](#)

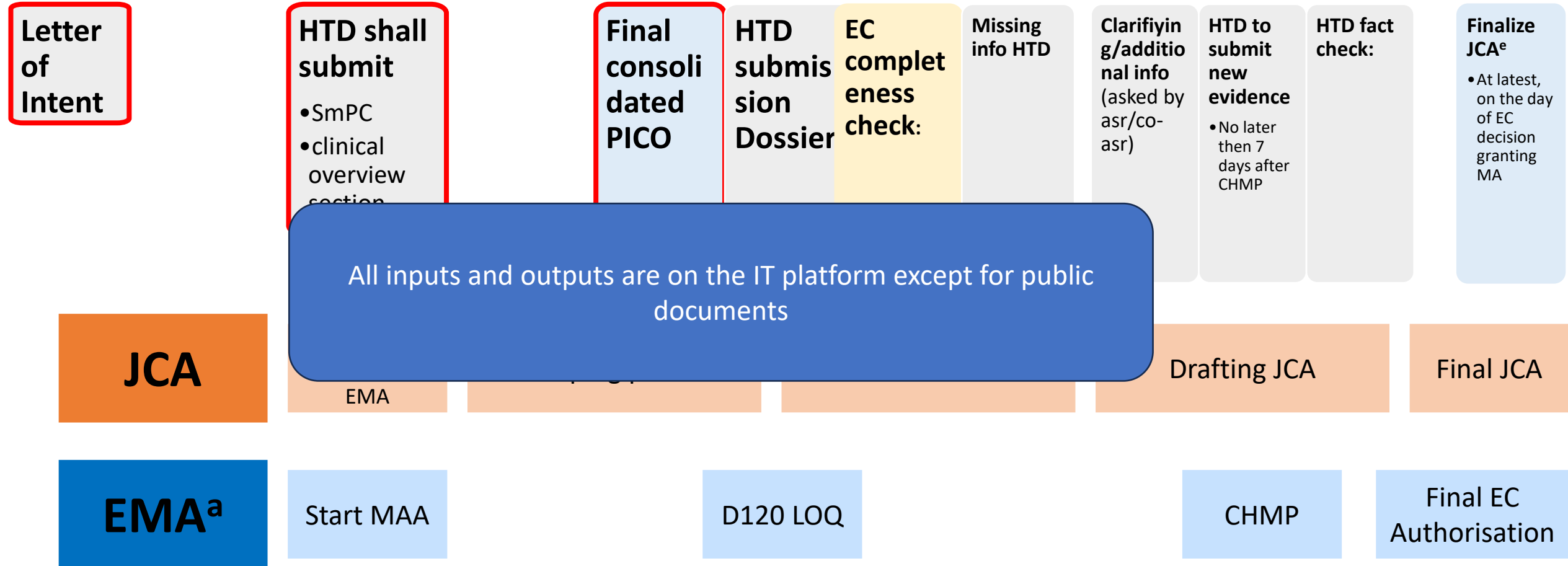
Work Programme 2025

- 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



JCA timeline in parallel to EMA



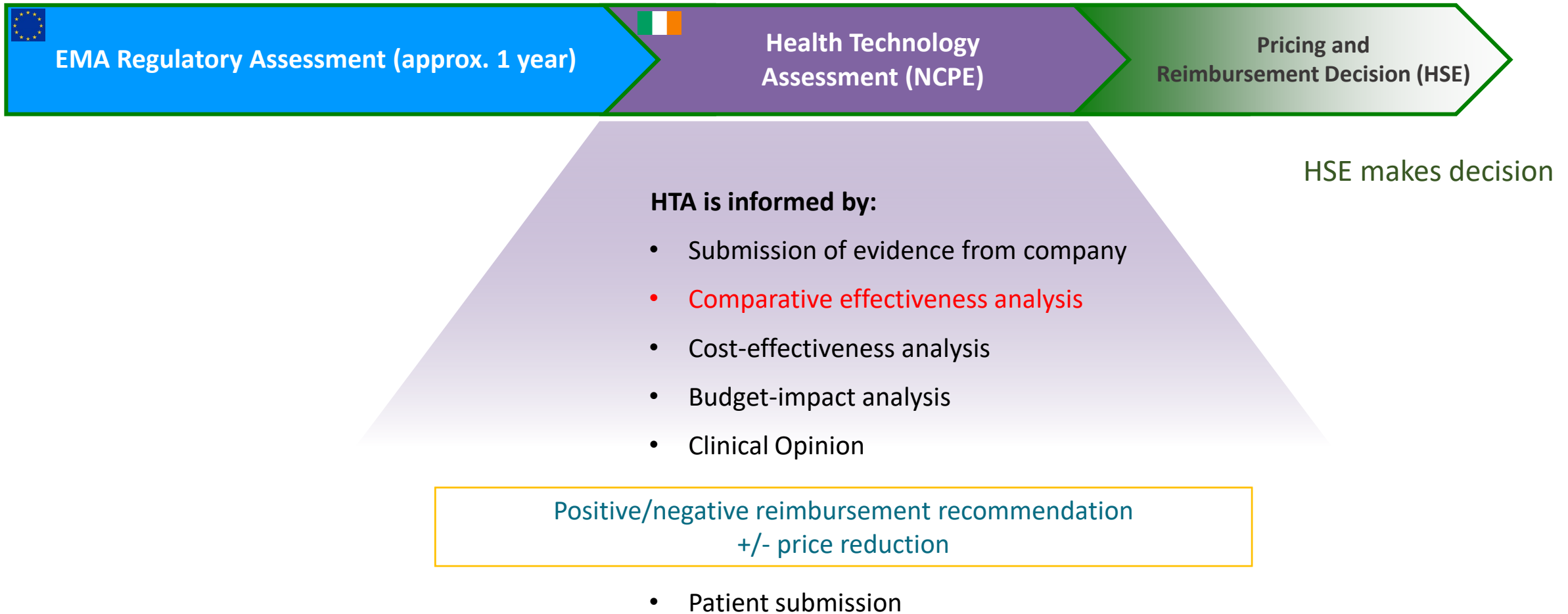
Joint Scientific Consultations (Early advice)

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



1. Company application for marketing authorisation of Drug X

4. Marketing authorisation granted by EU Commission

EMA Regulatory Assessment (approx. 1 year)

Joint Clinical Assessment (approx. 1 year +30 days)

Health Technology Assessment

Pricing and Reimbursement Decision

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

2. JCA of Drug X starts

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

- “Scientific analysis of the relative effects...and degree of uncertainty”

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

Collaboration with Regulatory Bodies



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

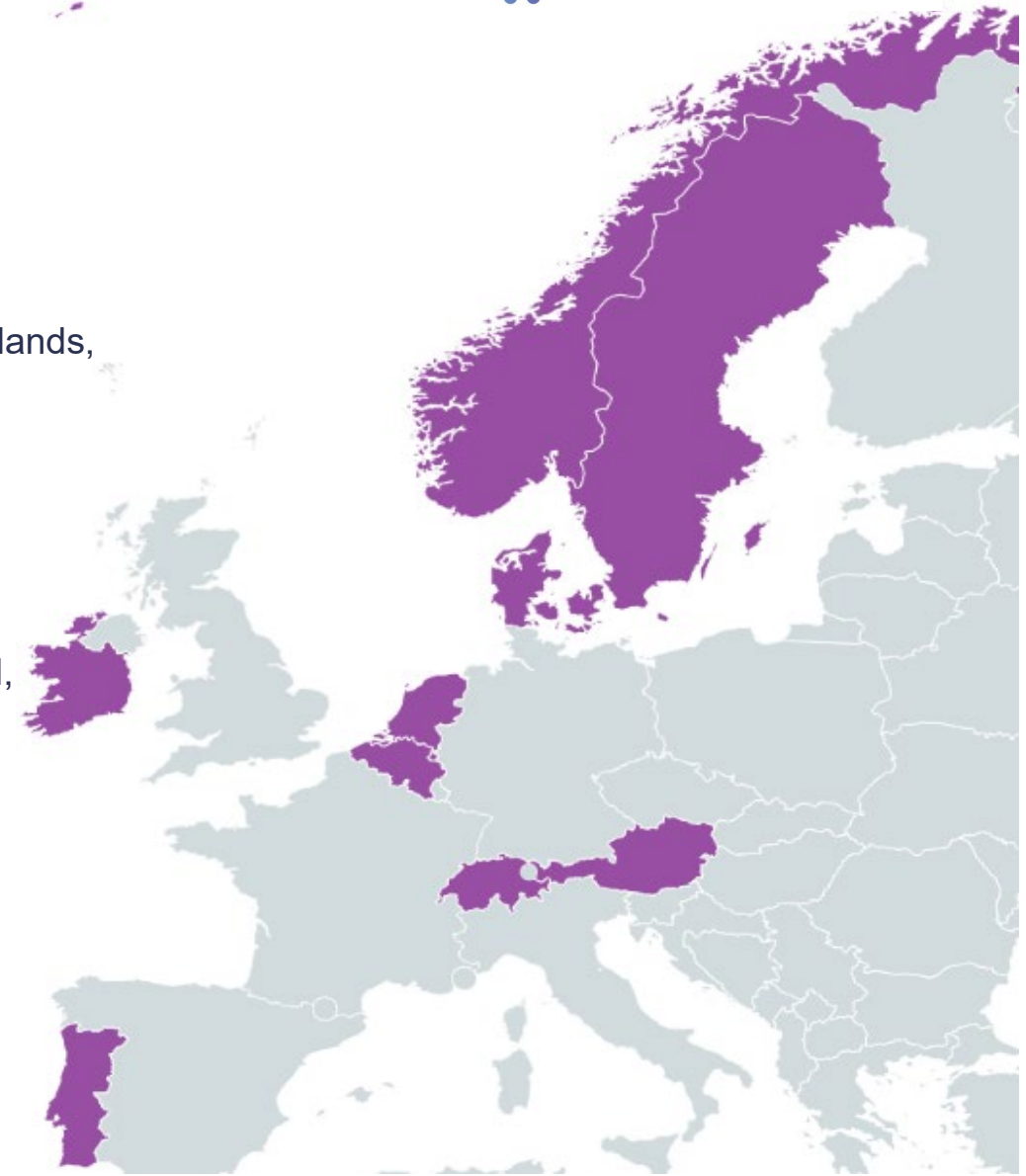
International Horizon Scanning Initiative

Why IHSI?



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

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



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



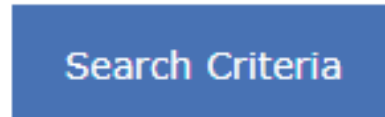
ClinicalTrials.gov



Clinical Trials



EUROPEAN MEDICINES AGENCY
SCIENCE. MEDICINES. HEALTH



8813 results found

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Search Results

Viewing 1-10 out of 530,051 studies

Showing results for: All

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

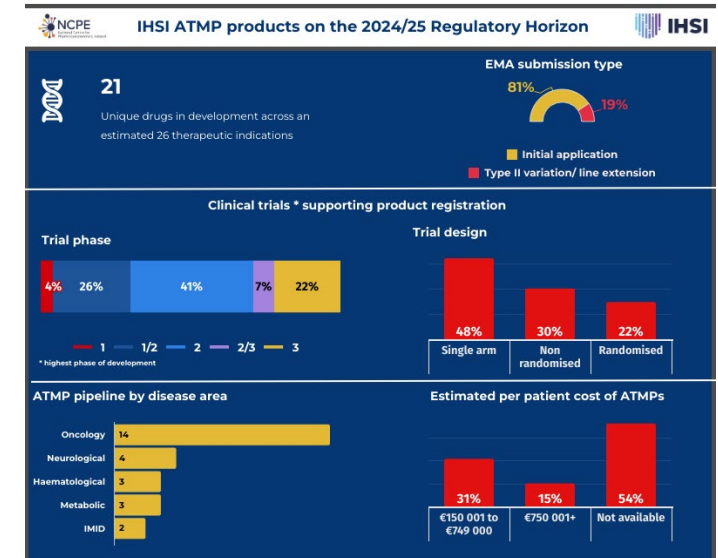
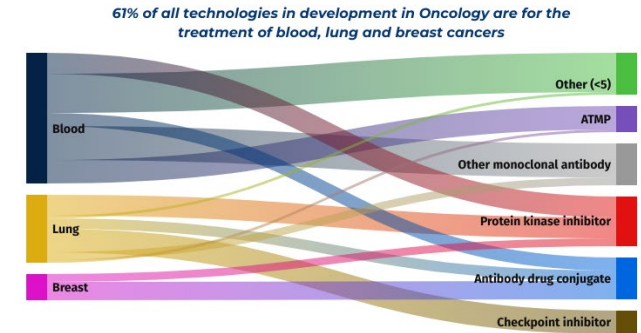
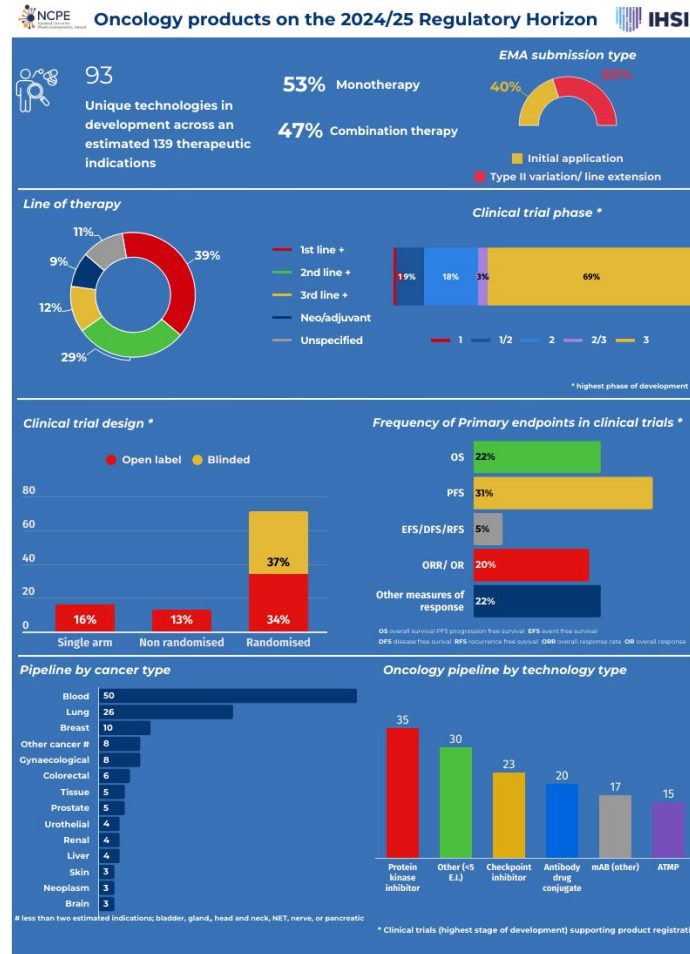
- ⦿ Effective planning for health technology assessment e.g. early PICOs, targeted disease area analysis
- ⦿ Early signal volume risk to the system (multiple type II variations) for expensive medicines
- ⦿ Savings opportunities – Biosimilars and generics on the horizon
- ⦿ Mitigate system risks - evergreening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



Drive efficiencies through effective planning for health technology assessment

Targeted analysis of evidence landscape underpinning oncology and ATMP products

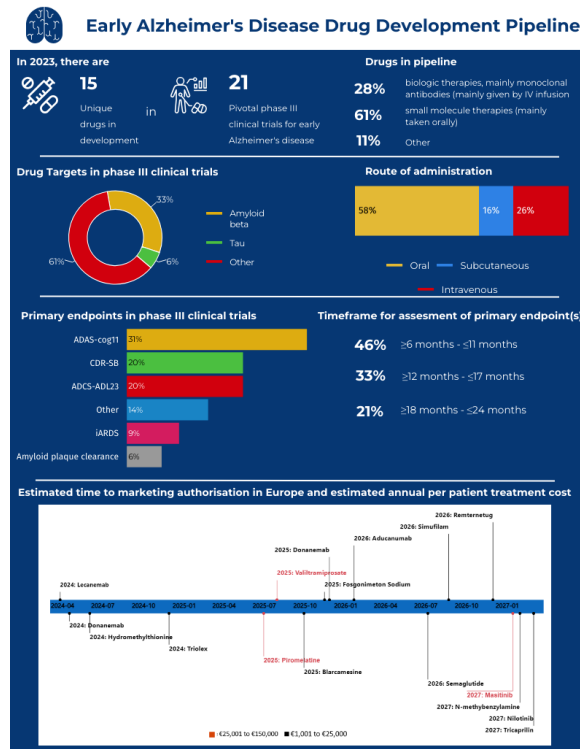
Early PICO – supporting JCA



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

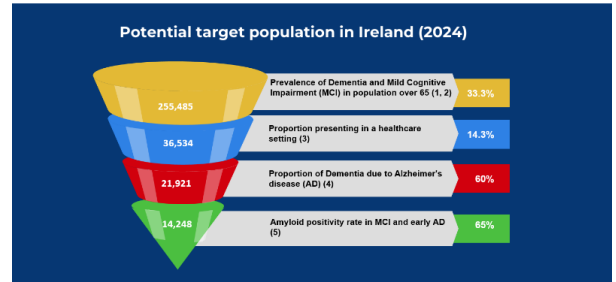
- Organisational
- Financial
- Efficacy



Clinical Dementia Rating Scale-Sum of Boxes (CDR-SB), Integrated Alzheimer's Disease Rating Scale (IADRS), Alzheimer's Disease Assessment Scale - Cognitive Subscale (ADAS-cog11), Alzheimer's Disease Cooperative Study - Activities of Daily Living (ADCS-ADL23)

Clinical Dementia Rating Scale-Sum of Boxes (CDR-SB), Integrated Alzheimer's Disease Rating Scale (IADRS), Alzheimer's Disease Assessment Scale - Cognitive Subscale (ADAS-cog11), Alzheimer's Disease Cooperative Study - Activities of Daily Living (ADCS-ADL23)

Health system challenges: monoclonal antibody disease modifying therapies



Clinical trials

- Lack of robust relationship between amyloid status and clinical outcomes

Efficacy

- Limited data on the natural history of Alzheimer's disease
- Limited certainty as to whether there is sufficient follow up to be confident of a sustained treatment effect
- Lack of data on long-term effectiveness

Safety

- Between 2 and 3 in 10 people who receive lecanemab or donanemab may develop amyloid-related imaging abnormalities (ARIA), which involves brain bleeding, brain swelling, or a combination of the two (6, 7)

Determining eligibility

- Amyloid positivity tests (PET scan, lumbar puncture) for diagnosis

Service change

- Monthly/biweekly intravenous infusions
- Significant monitoring requirements including MRI

Uncertainties

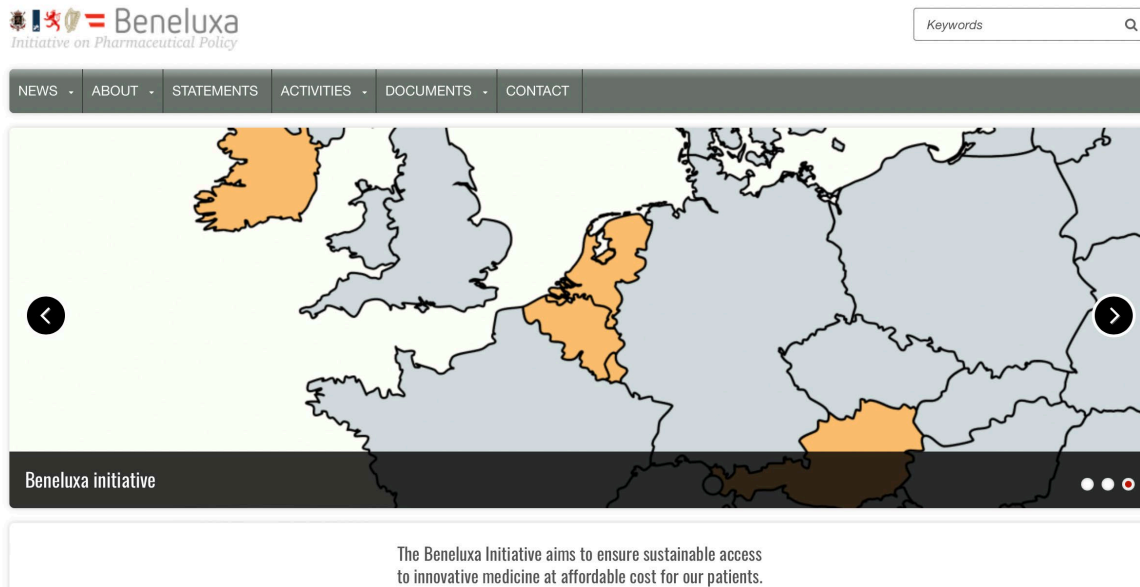
- Treatment duration
- Defining the minimum clinically important change in outcomes in clinical practice
- Uncertain prevalence estimates particularly for MCI

(1) <https://tinyurl.com/2h3vex3> (2) <https://tinyurl.com/c4akzu4> (3) <https://tinyurl.com/34xa3da> (4) <https://tinyurl.com/5n795mvu> (5) <https://tinyurl.com/2em69uf> (6) <https://tinyurl.com/bdhj9yb> (7) <https://tinyurl.com/yvxxj84>

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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.



The screenshot shows the Beneluxa Initiative website. At the top left is the logo with the text "Beneluxa Initiative on Pharmaceutical Policy". To the right is a search bar labeled "Keywords". Below the logo is a navigation menu with links: NEWS, ABOUT, STATEMENTS, ACTIVITIES, DOCUMENTS, and CONTACT. The main content area features a map of Europe where Ireland, the Benelux region (Belgium, Netherlands, Luxembourg), and Spain are highlighted in orange. The text "Beneluxa initiative" is visible in the bottom left corner of the map area. At the bottom of the page, a paragraph states: "The Beneluxa Initiative aims to ensure sustainable access to innovative medicine at affordable cost for our patients."

Thank you!