

Collaboration  
Initiative on the  
Reimbursement of  
Medicines



Beneluxa

*Initiative on Pharmaceutical Policy*



## *The Beneluxa Initiative...*

*... proof of concept for the 'coalition of the willing'*

Voluntary collaboration between BE, NL, LUX, AU & IE

**Main goal:** to ensure access to innovative drugs at affordable cost

Focus on P & R issues

**Main advantage:** well-established team, willingness to connect

*The Beneluxa Initiative...*

*... as a Sandbox*

new approaches/models can be developed, discussed (think tank), tested and modified

*... as an Initiator and Incubator*

for new (structured) initiatives (International Horizon Scanning Initiative)

*.... as an Initiator and Influencer*

opinion maker, triggers and spurs debates

## *'coalition of the willing' on 4 domains*

Horizon Scanning

Health Technology Assessment

Pricing and reimbursement, including joint negotiation

Information Sharing

## *DTF Horizon Scanning*

DTF Lead: NL

Incubator for International Horizon Scanning Initiative (IHSI)

Reorientation after successful implementation of IHSI

# *International Horizon Scanning Initiative*

*finalist for the European Innovation Procurement (EUIPA) Awards 2021*

Launched in 2019

8 participating countries

October 2021: signing off on 4 year contract with supplier for  
Development of the IHSI Joint Horizon Scanning Database  
Creation of High Impact Reports

Aim: level the playing field for stakeholders involved in the decision-making process  
for the pricing and reimbursement of pharmaceuticals

IHSI membership

# *DTF Health Technology Assessment*

DTF Lead: BE

DTF Co-lead: IR and NL

Sharing expertise and knowledge on HTA in daily work of the agencies - with outreach to agencies outside of Beneluxa

Joint HTA experiences:

- Orkambi → joint P&R
- Ocaliva
- Myalepta
- Zolgensma → joint P&R
- Zyntegla
- Spinraza (re-use of a report) → joint P&R
- Ongoing ...

# *DTF Pricing and Reimbursement*

DTF lead: NL

Ongoing pilots

Regular information exchange

Interaction with companies

Recently: Successful joint negotiation: Zolgensma

- Based on joint HTA (BE/IR/NL & AU as external reviewer)
- First BE/IR/NL negotiation
- First joint negotiation mandate

Next steps: learn from the experience

- different Willingness to Pay
- different timelines

→ How to improve the process ? What is needed ?



## *DTF Information Sharing*

DTF lead: AT

Joint Statements (next slide)

Successful webinars on policy issues and best practice

Main Chanel: Website, twitter

Mobilization through communication → Joint positioning

Under construction: up to date databank of all ongoing projects

DTF in development → goal is a well structured internal an external communication

## *Joint Statements*

- Statement assessment of COVID-19 monoclonal antibodies (2021)
- Short statement on Alzheimers's HTA (2021)
- Joint statement of the Beneluxa Initiative and the Nordic Pharmaceutical Forum (2021)
- Beneluxa Statement on high cost SMA treatments (2021)
- Beneluxa Position Statement on CAR-T (2020)
- No “lottery for life” - Statement by Beneluxa Health Ministers addressing the global managed access program designed by Novartis and Avexis (2020)
- Statement on Transparency of prices (2019)

- + Joint HTA assessment of ZYNTGLO
- + Outcome of joint negotiations for Zolgensma
- + Assessment of COVID-19 monoclonal antibodies is needed
- + [Archive](#)

## Archive

### 30 June 2021 - Beneluxa statement: award of contract to supply the International Horizon Scanning Database

We are delighted to share that today the International Horizon Scanning Initiative - IHSI - has made a major step forward in securing development of the international horizon scanning database which is open to all interested countries.

We share the enthusiasm of the IHSI for the future, believing that a big step has been taken allowing the authorities to better prepare themselves for future therapeutic innovations in order to offer patients rapid access to the most appropriate therapies.

Given the fast progress of the initiative, the importance for the public to access medicines within appropriate timelines and the amount of available data, collaboration with a well experienced, dedicated and highly motivated organization, which can provide the necessary tools, was the logical way forward.

After an international competitive tender process and several selection rounds, we are happy to announce that a promising candidate was found. We are especially proud as we consider IHSI to be the large scale spin-off of our own Beneluxa Horizon Scanning activities. To see our ideas and initiatives come to fruition is a huge accomplishment and pride. Taking this step, key activities will be further divided. While IHSI will concentrate on providing extensive and ready-to-use data, the Horizon Scanning activities of the Beneluxa initiative will focus on how to benefit from this data to the greatest extent.

Link to the news on the IHSI (International Horizon Scanning Initiative) website: <https://ihsi-health.org/2021/ihsi-awards-contract-to-supply-the-international-horizon-scanning-database/>

### 29 June 2021 - Short Statement on Alzheimer's HTA

The Beneluxa group is following with attention the therapies relative to Alzheimer's disease coming to the market. Recently the FDA in the US approved an anti-amyloid antibody amid some controversy; a decision from EMA is not yet available.

Beneluxa wishes to emphasize that clinical endpoints such as changes in cognitive scores or dementia scales are considered as the endpoints relevant for HTA agencies in Alzheimer's clinical trials. Biomarker data are not considered sufficient for demonstration of benefit for HTA agencies.

### 04 June 2021 - Joint statement of the Beneluxa Initiative and the Nordic Pharmaceutical Forum

In recent years, efforts to enhance international payer collaboration and the willingness to exchange expertise and knowledge have

# *A Business Plan for the Beneluxa Initiative*

Belgium : investment in further development of the Beneluxa Initiative

- Permanent secretariat
- Business plan, based on evaluation of operations and dynamics
  - Aim: Strengthening the robustness of the organisation
  - Strategic Goal: Being prepared for the presidency of the European Council of BE in 2024, IR in 2026, LUX and NL in 2029
  - BE Sponsorship, but deliverable is a business plan adoptable (or serve as a model for further development) by the other countries



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Back-up slides

## *Cooperation is part of the policy-mix*

- Information gathering on global markets benefits from joint approach
- National context determines course of action
- Joint negotiations only in selected cases

## *What works ?*

- Setting clear, common goals
- Mutual benefit needs to be clear
- Pragmatic approach
  - Focus on desired outcomes
  - Lean organisational structure

## *DTF Horizon Scanning*

- Early dialogue – strengthens collaboration
- Level playing field – potential for savings
- Prioritisation – potential to improve access
- Budget planning – potential for savings
- Efficiency gains – potential to improve access





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**Governments  
change the  
conversation with  
real data.**

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## Mission

IHSI provides data that empowers political decision-makers and payer organisation negotiators to drive for better pricing in medicinal products. IHSI data enables healthcare systems to prepare for disruptive technologies through data insights that deliver the leverage required to confidently assess new products coming to market.

[READ MORE](#)



## *DTF Pricing and Reimbursement*

- By structural exchange of information and testing through pilots of procedures or scenarios for joint negotiations that lead to financial arrangements and contracts
- That are compatible with and respect national legislation and competence and responsibility of the different stakeholders in the decision making process
- That respect confidentiality of the commonly negotiated financial details (..nothing changes compared with today..)
- THIS IS NOT JOINT PROCUREMENT

## *DTF Pricing and Reimbursement*

Key success factors:

- Mutual and common understanding on value and appraisal assessments – early dialogues on ‘willingness to pay’.
- Benefits must be clear for all partners (economies of scale and knowledge building; timely access;...)
- Pragmatic approach, trust and mutual commitment
- Political support (responsibility and accountability)
- Solid founded and well documented framework