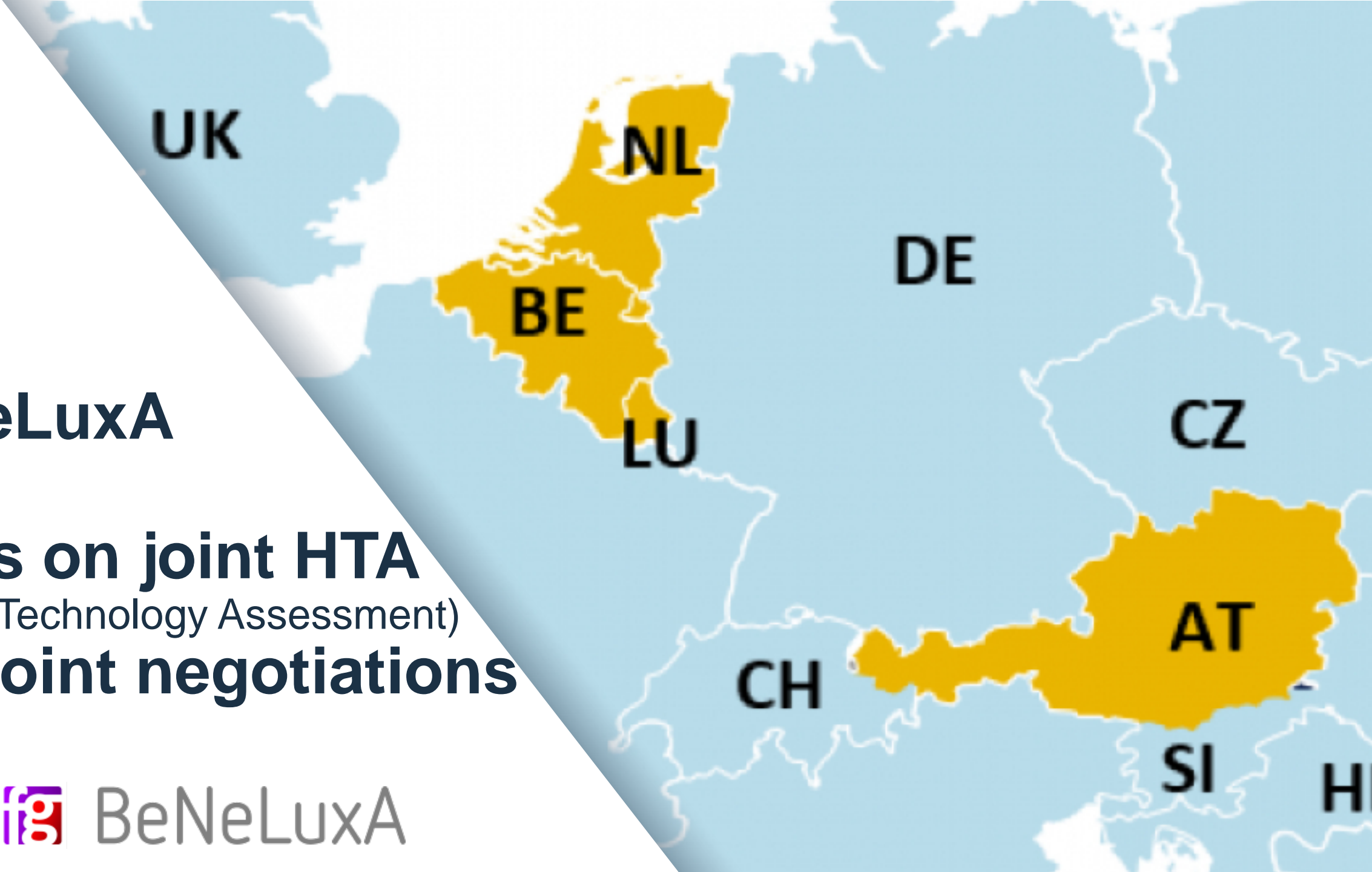


**BeNeLuxA**

**Pilots on joint HTA**  
(Health Technology Assessment)  
**and joint negotiations**



BeNeLuxA



# 1

## Pilot requirements



*Bread house, Brussels*

# Pilot requirements – HTA and negotiations

- A joint pilot is entered on a voluntary basis by all parties;
- A joint pilot can include two or more BeNeLuxA partners;
  - In general, Luxembourg does not actively participate in any joint HTA & negotiations pilot. Luxembourg can act as an observer and will receive the joint HTA report.
- A pilot will start with a joint HTA and if applicable, a joint negotiation can follow;
  - Joint price negotiation without a joint HTA will not be possible, as the joint negotiation will be based on a joint view on the (added) value of the pharmaceutical.
- In a joint procedure all the steps will be handled as one by the participating countries;
  - At this moment, no formal joint 'BeNeLuxA' reimbursement regulation is put in place;
  - All formal separate national reimbursement procedures according to national legislation will run in parallel;
  - One of the participating countries will be designated as the primary contact for the company in the pilot.
- Separate formal reimbursement decisions will be made in each participating country.

# 2

## Selection and eligibility of products



# Eligibility for a joint procedure

- Selection of pilots case-by-case.
- Focus on pharmaceuticals with (high) unmet medical need, expected added value and satisfactory degree of evidence.
- A candidate for a pilot must comply with national legislations, for example:
  - in the Netherlands only hospital pharmaceuticals that enter the “lock procedure”
  - in Belgium only pharmaceuticals submitted as Class 1 or orphan application
  - in Austria only pharmaceuticals that are classified as outpatient products in the Austrian health system
- A pilot candidate is only eligible if a reimbursement procedure has not yet started in any of the participating countries.
  - A candidate is preferably selected at least three months before a CHMP (Committee for Medicinal Products for Human Use) opinion is published.
- Manufacturer must be planning to commercialize the pharmaceutical in all BeNeLuxA countries.

# Pilot entry possibilities

## Company - driven

- Company contacts one of the BeNeLuxA country coordinators
- Company expresses willingness to collaborate on:
  - a partial pilot with only a joint assessment
  - a full pilot with joint HTA and joint negotiations procedure
- Company provides information on the product, including registration timelines, in a first orientation meeting with BeNeLuxA

## BeNeLuxA - driven

- Identification of product by the BeNeLuxA countries as a possible full or partial pilot candidate based on Horizon Scan
- One of the countries will initiate contact with the company for an orientation meeting on possibility and willingness to participate in a pilot

Orientation  
meeting

# 3

## Timing & Procedure



# Milestones in first stage of pilot procedure

- **Approximately 6 months before planned reimbursement application: orientation meeting**

Participants: Company and one of the participating BeNeLuxA countries

Objective: Informal exchange of information to explore the possibilities for a joint pilot procedure

Points of discussion: Eligibility of product for a full or partial joint pilot

- **Approximately 3 months before planned reimbursement application: kick-off meeting**

Participants: Company and all participating countries

Objective: An official Go/No Go for a joint procedure and a procedural framework

Points of discussion: Procedure for pilot, including timelines, choice of HTA process (<http://www.beneluxa.org/hta>), requirements for provisional file, language, confidentiality, commitment, communication, any points of concern.

- **At CHMP positive opinion: submission of provisional joint HTA file by company**



# Milestones in 2<sup>nd</sup> stage of pilot procedure

- **Upon completion of joint HTA (approximately 3 months after reimbursement application): (technical) Negotiation start-up meeting**

Participants: Company and all participating countries

Objective: An official Go/No Go for a joint negotiation

Points of discussion: Eligibility for joint negotiation, negotiation process and timelines, communication, reaffirming commitment

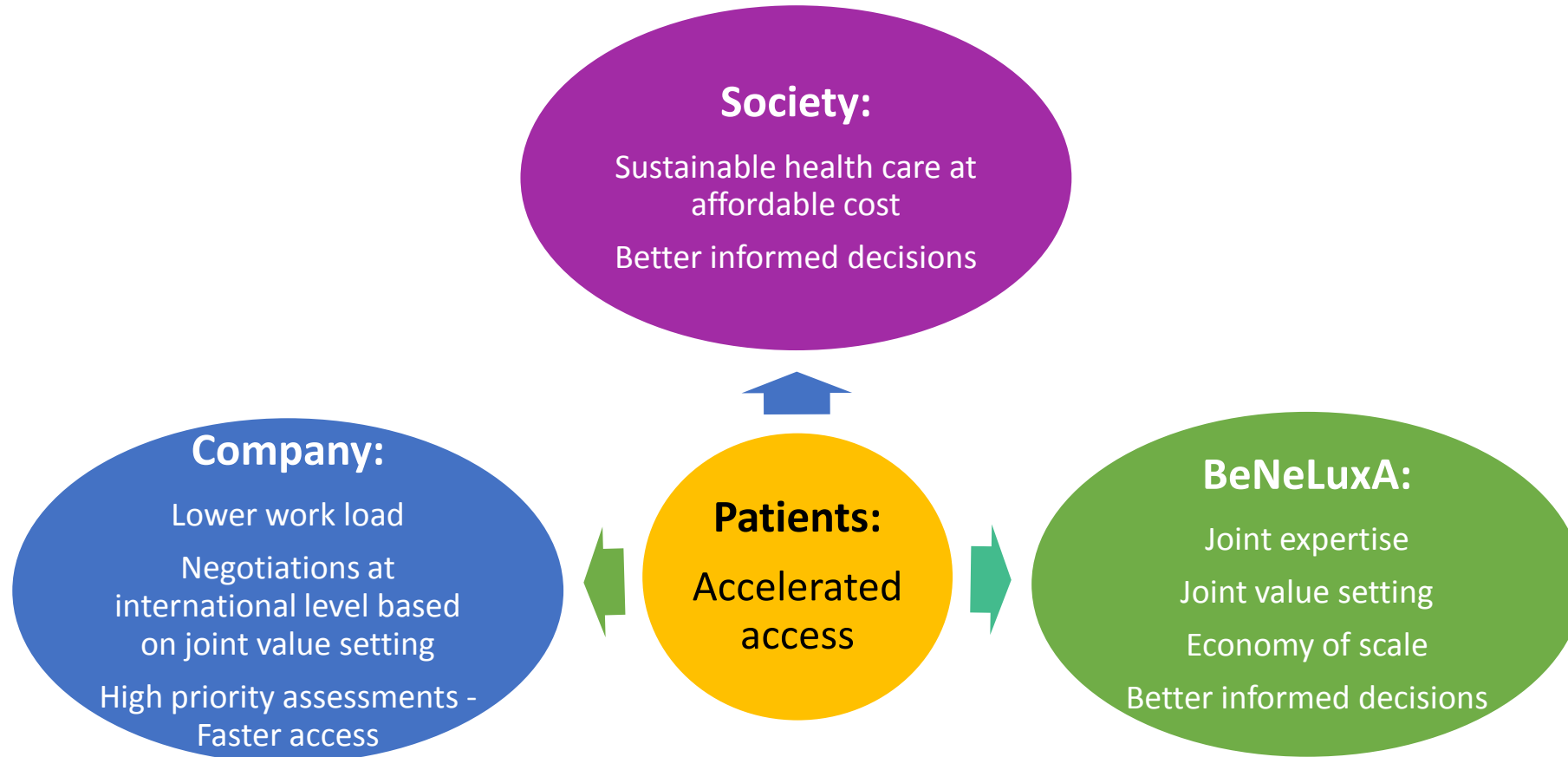
- **Approximately 1 month after finalized HTA report: Start of joint negotiations**
- **After successful completion of joint procedure: Reimbursement decision in all participating countries**  
*Note: Due to procedural reasons the exact starting date of reimbursement can differ in participating countries. This will be addressed in the orientation and kick-off meetings.*

# 4

## Benefits for participation



# Overall “win” situation



Contact:

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For more information go to:

**www.beneluxa.org**

Contact information for country coordinators:

<http://beneluxa.org/contact>