BeNeLuxA

Pilots on joint HTA (Health Technology Assessment) and joint negotiations
1

Pilot requirements
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.
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

Pilot entry possibilities

BeNeLuxA guidance joint assessment & joint negotiations
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](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 2nd 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.*
Benefits for participation
Overall “win” situation

**Society:**
- Sustainable health care at affordable cost
- Better informed decisions

**Company:**
- Lower work load
- Negotiations at international level based on joint value setting
- High priority assessments - Faster access

**Patients:**
- Accelerated access

**BeNeLuxA:**
- Joint expertise
- Joint value setting
- Economy of scale
- Better informed decisions
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For more information go to:

www.beneluxa.org

Contact information for country coordinators:
http://beneluxa.org/contact