Joint Horizon Scanning for pharmaceuticals

- KCE report and use of EMA data

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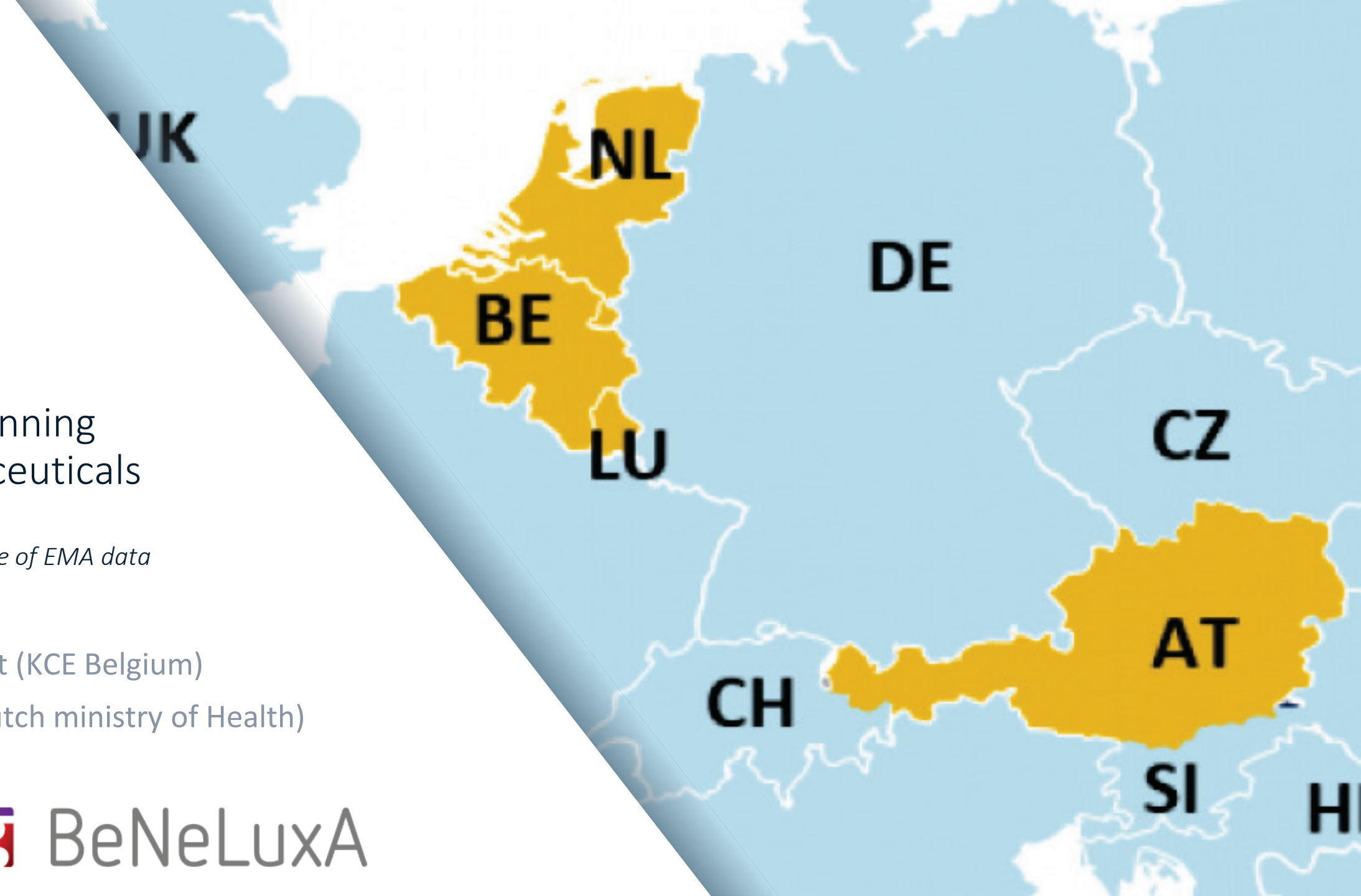

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Introduction

Brood hal, Brussels

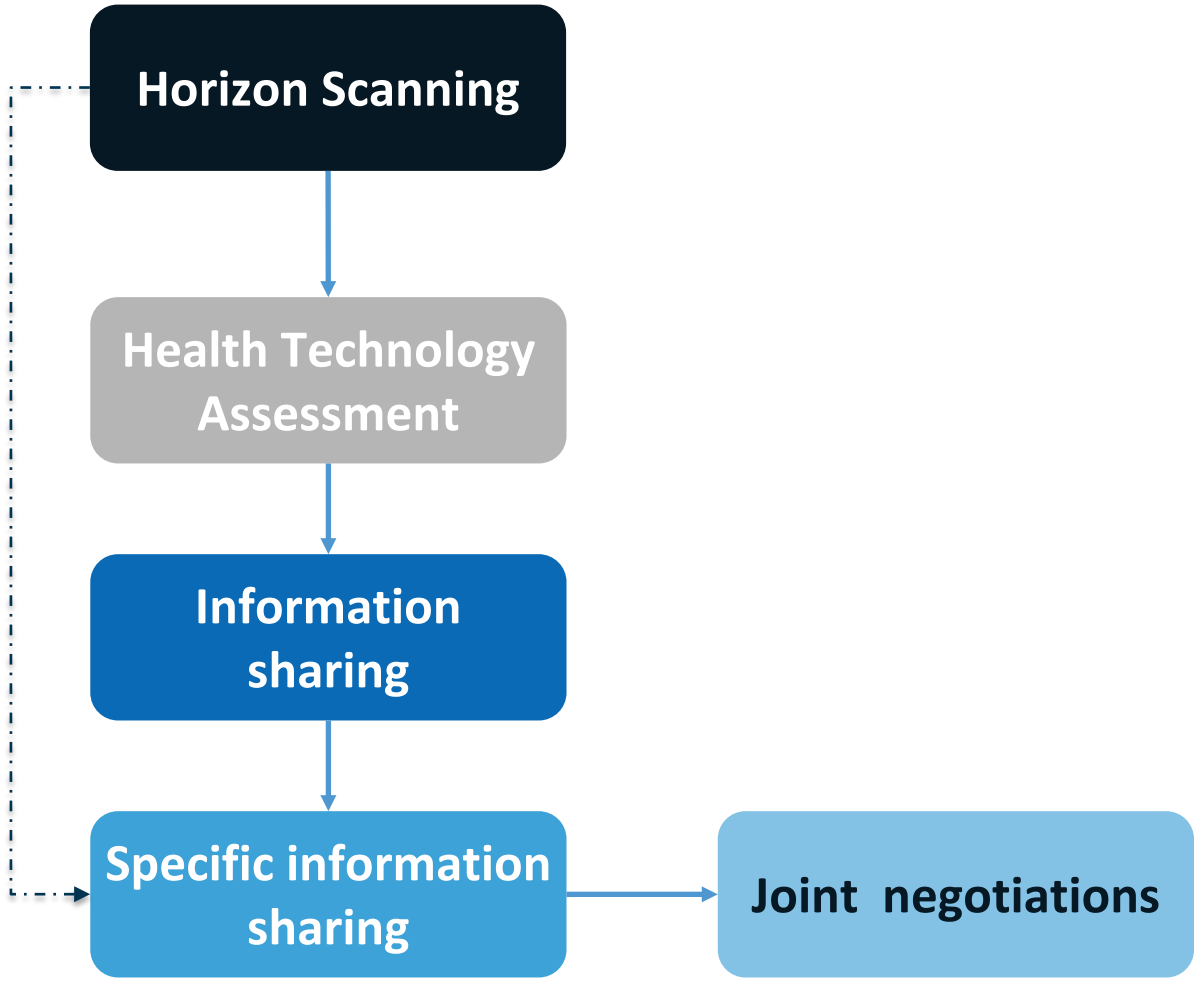
BeNeLuxA – what is on the menu?

Collaborative approach to gathering information

- Mutual recognition
- Joint HTA

- Best practices
- Registries
- Policy dilemmas

- Horizon scan interpretation
- Strategic information exchange
- Input for joint negotiations



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Horizon scanning

- a joint approach

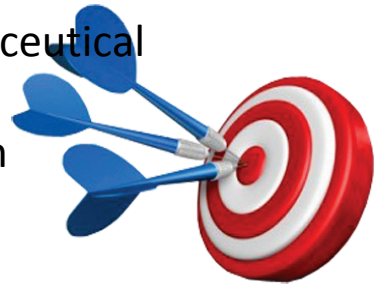
Keizersgracht, Amsterdam

1/2 Horizon Scanning – Benefits of joint efforts

- *"Horizon scanning systems aim at **identifying**, **filtering**, and **prioritising** new and emerging health technologies with a considerable predicted impact on health, costs, society and the health care system in order to inform policymakers, purchasers, and health care providers or facilitate early access"**

* KCE report 2017

- Aim of a joint horizon scanning database:
  - To inform decision-makers on emerging and new pharmaceuticals for reimbursement decisions
  - Policy development on issues that are relevant for the managed entry and monitoring of pharmaceutical products
  - To enhance collaboration between member states by identifying relevant issues for collaboration



National Horizon Scanning

- The data collected in the international database is not tailored to:
  - *National guidelines*
  - *Epidemiology on a national level*
  - *Volume of patients qualifying for treatment*
  - *National registries*

- The international database has the potential to:
  - *contribute to setting up national horizon scanning in countries*
  - *Enhance systematic data collection on a national level*

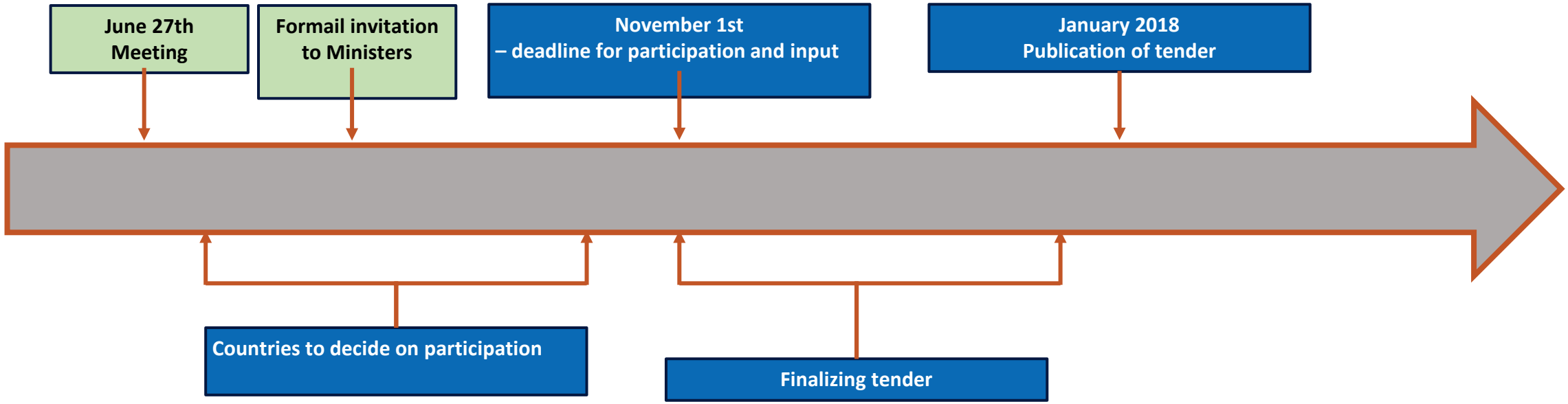
- In the future there is also the potential to feed national data back into the central database

Basic principles of a joint Initiative on Horizon Scanning

- Participation in Horizon Scanning is voluntary
  - The Initiative does not obligate to further participation in the BeNeLuxA collaboration
- Based on publicly available information and data (non-confidential)
- Data collected is owned by paying participants
- Solidarity principle in calculating financial obligations
  - Purchase Parity as a measure
- All participating countries have an equal vote
- Organisational structure should be lean: no ’bureaucracy’
- The Initiative aims to gather internationally relevant data. Countries are responsible for the use in the national context

Planning

- The aim is to start the database in 2018



Collaboration with other parties - data

- European Medicines Agency (EMA)
  - There is the potential to work more closely with EMA for input into the database
  - Mostly for input of trial data using the European clinical trial registry
  - For timelines of registration

- Pharmaceutical industry
  - It needs to be identified how the pharmaceutical industry can potentially play a role without issues of confidentiality

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The Horizon Scanning database

What is in it?

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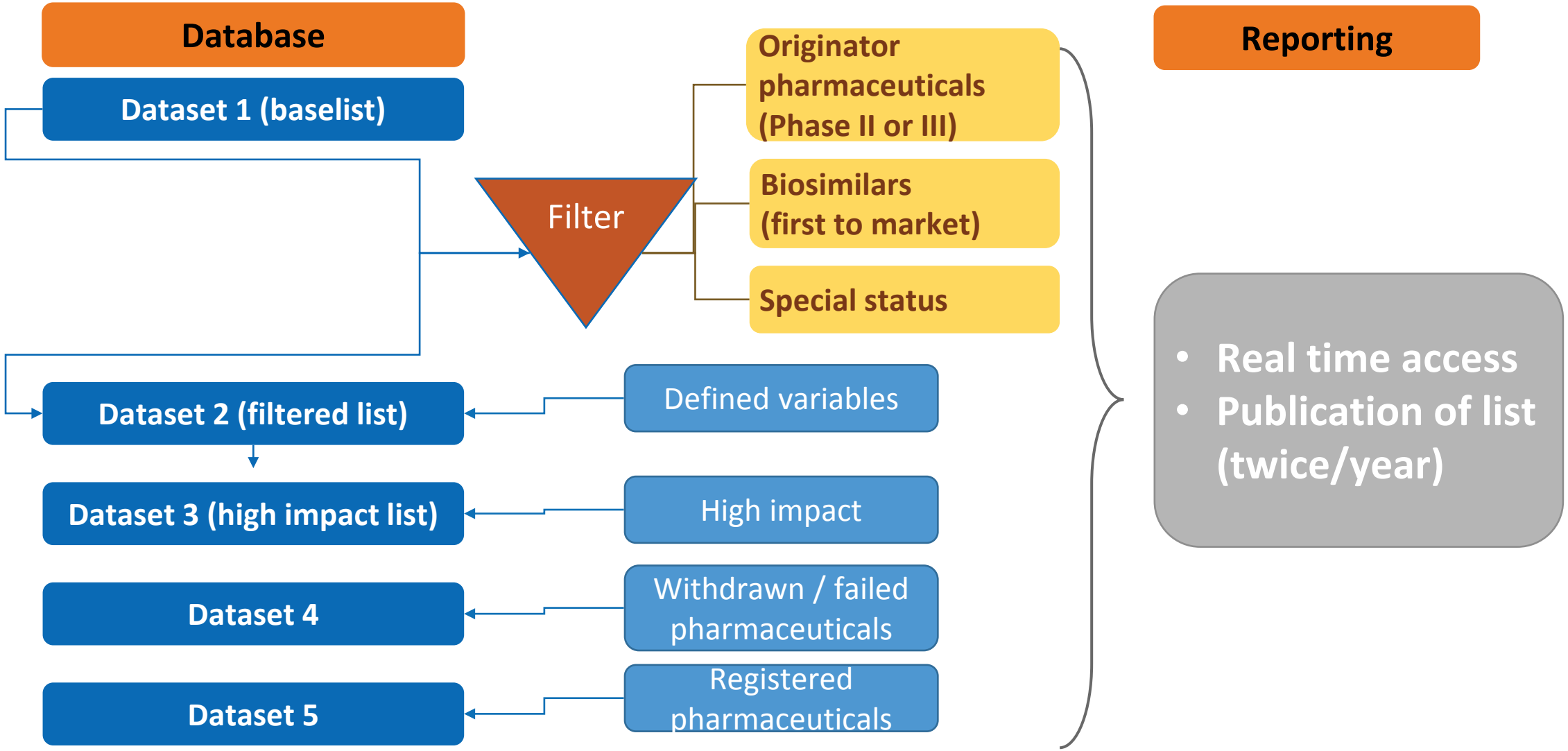
Along the Alzette, Luxembourg

The database – ‘must haves’



Dataset 1 & 2

Dataset 1 :
Baselist

- All pharmaceuticals in development from **phase I**
  - Insight in the industry **pipeline**
  - Enables to identify **gaps** in research
  - Ties in with the **European clinical trials register**

Dataset 2 :
Filtered list

- All originator pharmaceuticals in development from **phase II /phase III**
  - Possibility to focus on products likely to come to market **within the next 1-2 years** with a **potential high impact**
    - Originator pharmaceutical products PhII/PhIII
    - First to enter biosimilars
    - Pharmaceutical products with a **special status** (e.g. Accelerated assessment, orphan, breakthrough, etc.)
  - Continuous monitoring : collection of data to assess **likely impact**

Dataset 3

Dataset 3 :
High impact list

- Pharmaceutical products with a **potential high impact**
  - Useful for **prioritization** and identification of **opportunities to collaborate**
  - Impact will be assessed using a **validated methodology**
    - Pharmaceutical products classified into **disease areas**
    - Parameters used to assess impact
      - ➢ Potential importance of the **unmet need** it intends to address
      - ➢ Potential to **improve** patient **health**
      - ➢ Potential for **acceptance/adoption** by patients and clinicians
      - ➢ Potential impact on health care **costs and expenditures**
    - A questionnaire will be developed for asking medical experts to assess the impact of pharmaceutical products

Datasets 4 & 5

Dataset 4: Withdrawn / failed pharmaceuticals

- Pharmaceutical products that, at any stage, have failed or are withdrawn from FDA / EMA registration procedures
  - **Data** collected on these withdrawn or failed pharmaceutical products will **migrate into this dataset**
  - Allows to identify disease areas where pharmaceutical products fail and investment potentially high

Dataset 5: Registered pharmaceuticals

- Data collected for pharmaceutical products once registered
  - Data will no longer be updated

Dataset 6

Dataset 6:
Patent data

- Patent data for pharmaceutical products
  - When pharmaceutical products come off-patent
  - Loss of exclusivity of the main compound
  - Additional protection certificates, orphan exclusivity and data protection
- Adding this data could be very **resource-intensive**, since it also includes all existing pharmaceutical products

  Alternative option

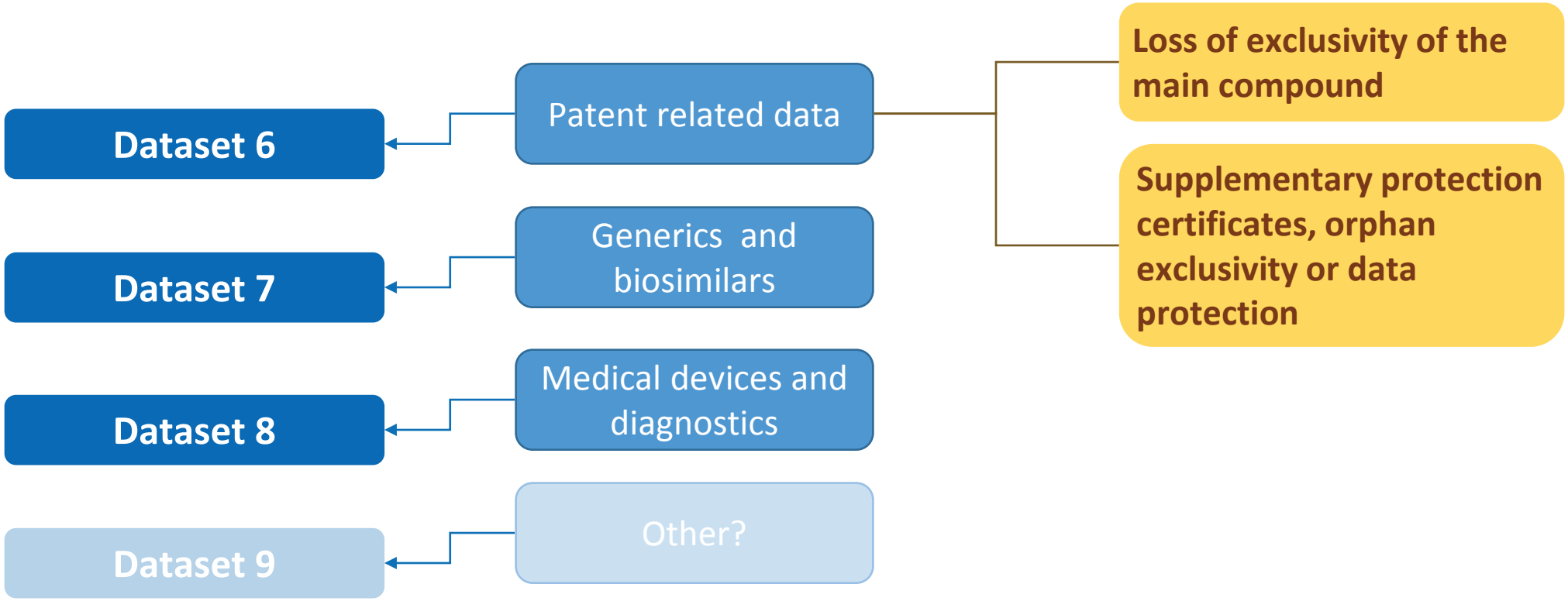
  Collect patent data only for current high impact products
  - If included, **legal issues** may have to be dealt with

Dataset 7

Dataset 7: Generics and biosimilars

- All generics and biosimilars coming to market
  - First to enter biosimilars are already included in dataset 2
  - Is add-on to dataset 1 (adds expected launch)
  - Enables users to identify early on **when** generics or biosimilars are **expected**
  - Enables users to identify **gaps** in the development of generics and biosimilars

The database – ‘nice to haves’



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Opportunities for data sharing

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Domkirche St. Stephan zu Wien, Vienna

Data available at EMA?

Dataset 1 : Baselist

- Business pipeline meetings / disease areas
- European Clinical Trials Register
- PRIME (non-industry products)

Dataset 2 : Filtered list

- Clinical studies in Phase II or III
- Special status products (orphan designation, accelerated approval, …)
- Early dialogues: outcomes included in studies
- Medical need evaluation?

Dataset 3 : High impact

- List of products under evaluation
- Draft assessment reports

Data available at EMA?

Dataset 4: Withdrawn / failed pharmaceuticals

- List of pharmaceuticals withdrawn from the registration process

Dataset 5: Registered pharmaceuticals

- Registered pharmaceuticals: already publicly available

Dataset 6: Patent data

- Patent data: not available at EMA

Dataset 7: Generics and biosimilars

- Generic products and biosimilars: could be identified at the same time as new compounds (dataset 1)

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For more information go to:

www.beneluxa.org