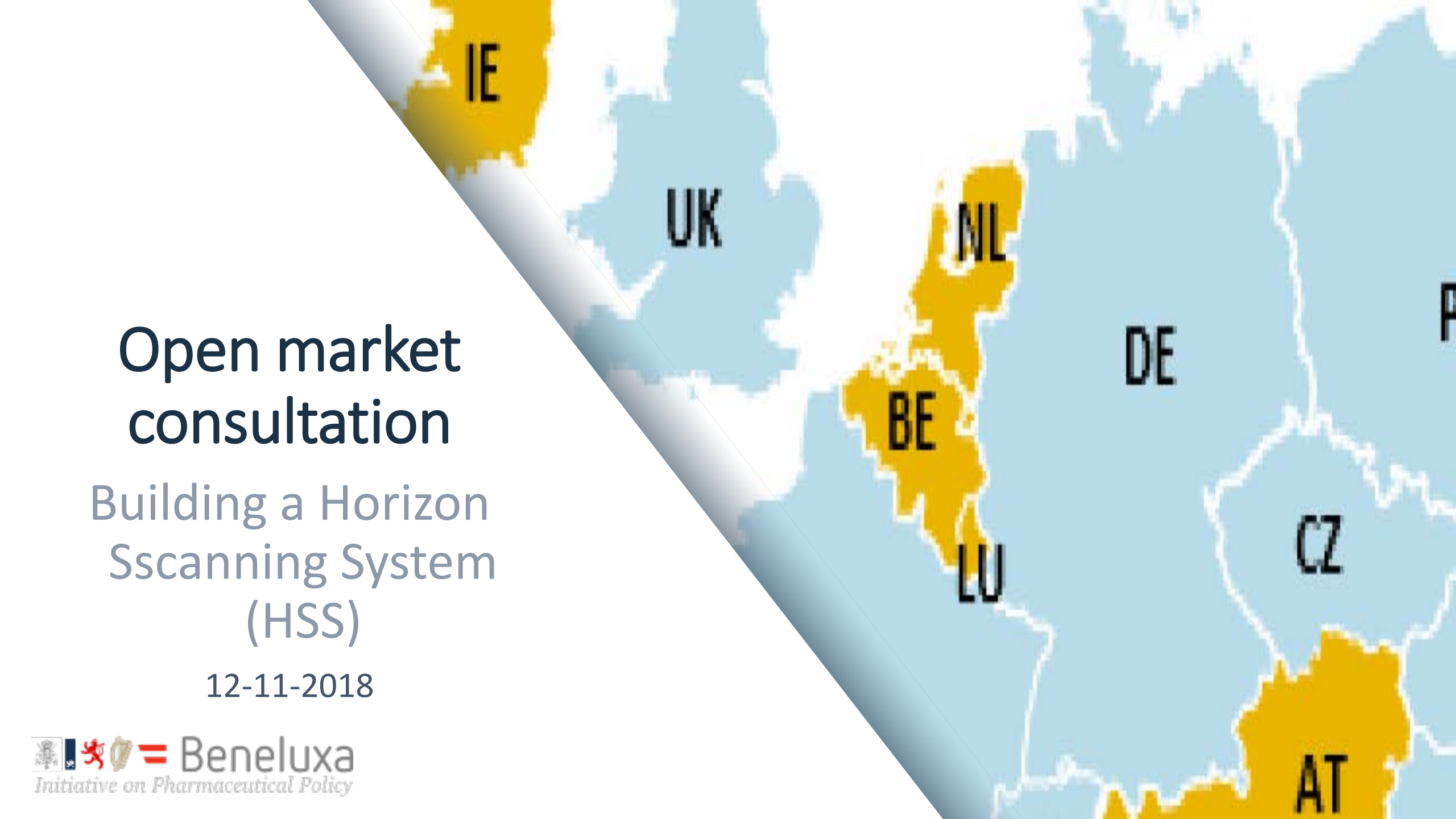
Open market consultation

Building a Horizon Sscanning System (HSS)

12-11-2018



Beneluxa
Initiative on Pharmaceutical Policy

Today - agenda

- Welcome
- Aim of this open market consultation
- Introduction to the International Horizon Scanning Initiative (IHSI)
- Scope of the Horizon scanning system (HSS)
- Prior Art analysis
- Expectations
- Questions to the market

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Aim open market consultation

Graslei, Gent (B)

Aim open market consultation (OMC)

- To inform market operators of the initiative to procure a horizon scanning system by the Beneluxa Initiative and other public procurers
- To understand capabilities of existing market operators
- To see if market operators are able to meet our needs for a HSS
- To obtain input from market operators on the feasibility of such an initiative
- To understand what cost may be involved in building such a system

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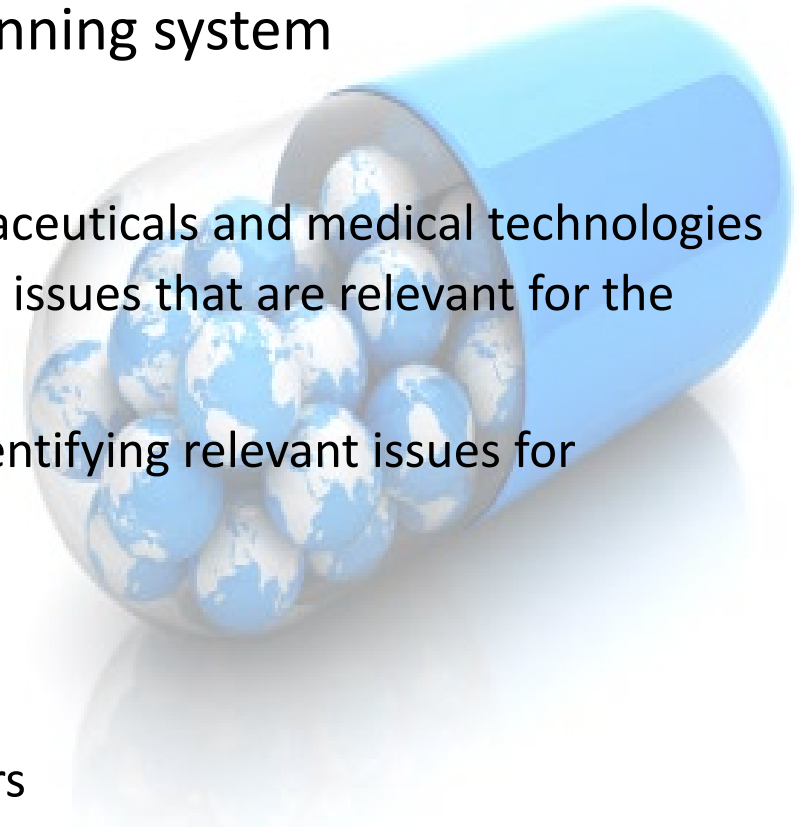
Introduction International Horizon Scanning Initiative

Keizersgracht, Amsterdam

International Horizon Scanning Initiative (IHSI)

- 10+ countries interested in procuring a horizon scanning system
- Aim of a joint HSS:
  - To inform decision-makers on emerging and new pharmaceuticals and medical technologies for reimbursement decisions and policy development on issues that are relevant for the managed entry and monitoring of new products
  - To enhance collaboration between member states by identifying relevant issues for collaboration
  - To level the playing field
  - To enable prioritisation according to potential impact
  - To allow for early dialogue between relevant stakeholders
- Countries see potential in working together because of similar information needs and thus central data collection (HSS)



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Scope of the HSS

Christ Church Cathedral, Dublin

End-users and how they use the data

Payers

- To inform negotiations
- To estimate budget impact
- To allow for early dialogue based on a level playing field
- To inform policy-making

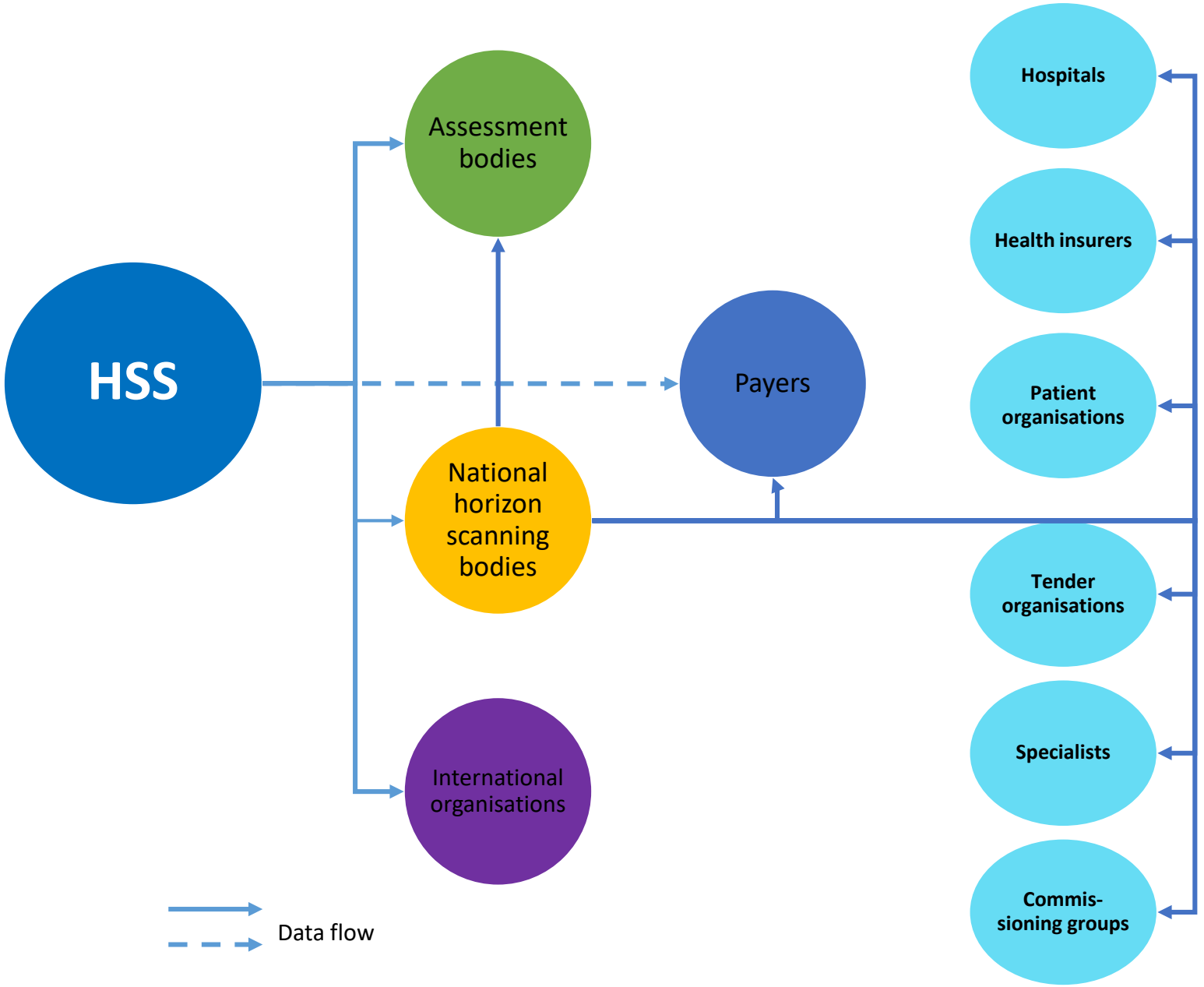
Assessment bodies

- To prioritise assessments
- To plan assessments to ensure minimal waiting time for patients
- To allow for early dialogue based on a level playing field

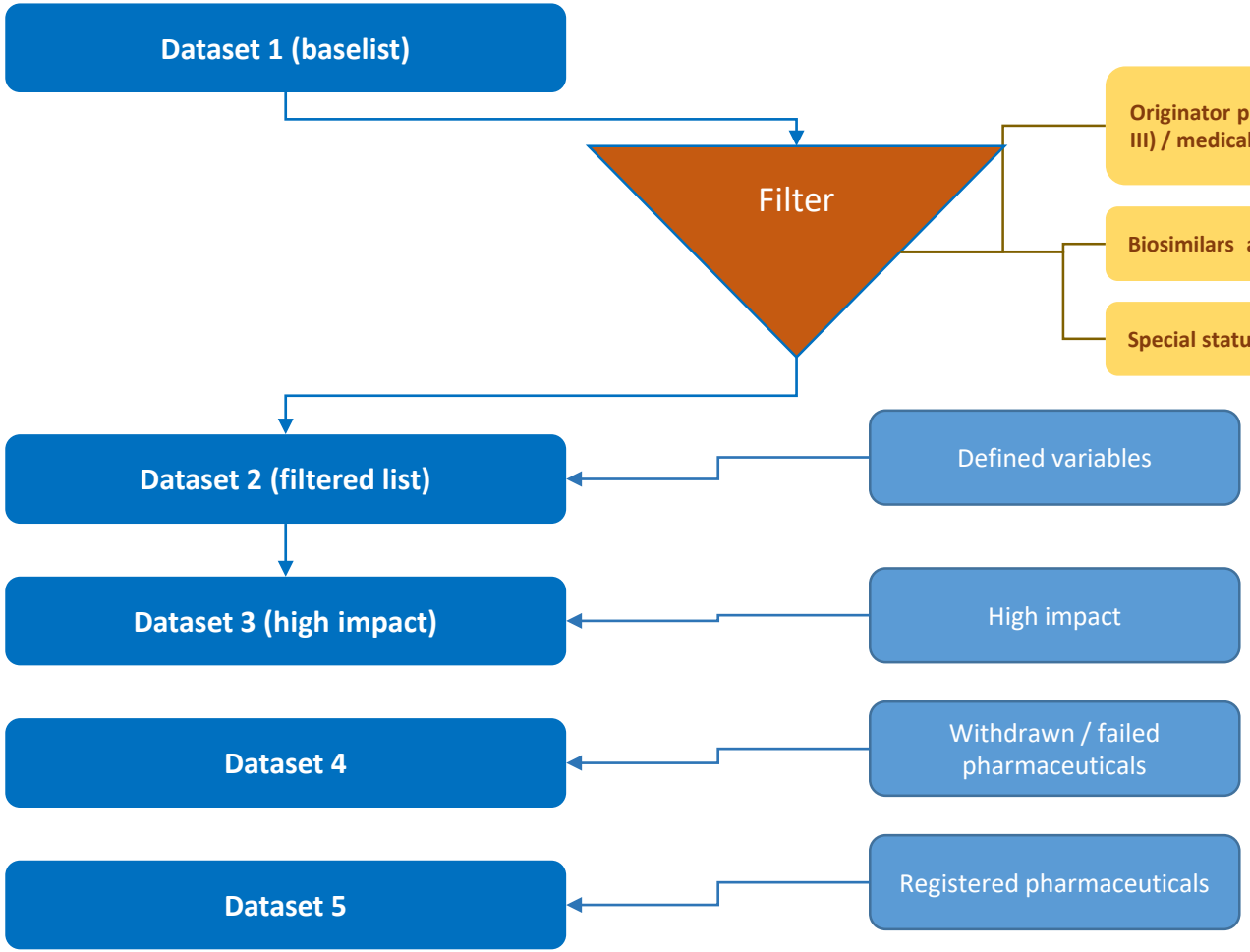
National horizon scanning bodies

- To focus on adding national relevant data
- To inform local decision-makers, health services, and hospitals of future products and their impact
- To have one consistent source of information

Data flow


HSS
Assessment bodies
National horizon scanning bodies
International organisations
Payers
Hospitals
Health insurers
Patient organisations
Tender organisations
Specialists
Commis-sioning groups
Data flow

Proposal for a database



"HSS aims 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)

Datasets 1 & 2

- Dataset 1: a list of pharmaceuticals and medical technologies in development
  - Aim: to provide insights in the industry pipeline and to enable insights into possible gaps of research
  - From early phase one for pharmaceuticals or early research for medical technology with limited data collection
  - Aligns with the European clinical trial register
- Dataset 2: a filtered list with
  - Aim: to provide insights into products expected in the short-run
  - an overview of all originator pharmaceutical products in development from phase II / phase III and
  - Also includes first to enter biosimilar and generics and pharmaceuticals with a special status
  - An overview of grade 2b and grade 3 medical technologies from 2.5 years before market entry
  - Data is public data and (mostly) open

Dataset 3

- Dataset 3: high impact reports
  - Enables prioritization
  - Requires a sound method to determine high impact with a
  - Requires a network of KOLs for assessing the potential impact on upcoming products
    - Minimum of ten disease areas
    - Minimum of 5 years of relevant experience as medical specialist
    - Policy for conflict of interest
    - KOL list is public or at least can be seen by paying members
  - A number of aspects for this method have been defined
  - Reports published twice a year
- Database includes tracking of withdrawn or failed products
- Database includes keeping the information on registered products available, however without updates

Dataset 3 – parameters for high impact

Health care costs
- Population level
- Patient level
- Volume risk

Organisation consequences
- Health care use
- Infrastructure
- Impact on services delivery
- Impact on disease management

Innovativeness
- First in class / availability of alternatives
- Unmet clinical need
- Patients / clinical demand

Prevalence / incidence of disease
- Patient population
- Orphan designation

Health benefits
- Therapeutic value
- Life expectancy

Data sources

- Data needs to open or can be made public
- Data always needs to be references to appropriate sources
- Data collection can be (partly) automated with prior approved algorithms
- Following sources are relevant:
  - Registries of clinical data
  - Regulatory authorities including FDA and EMA
  - Scientific reports and journals
  - Input from clinical experts and industry

Variables

- The tender will include a list of variables that need to be included in the database
- These can roughly be divided into:
  - Clinical variables: relevant clinical data on pharmaceuticals and medical technologies, e.g.:
    - Trial data
    - Comparator products
  - Timeline data: data relevant to tracking to where products are in their development trajectory
  - Cost data: data related to the costs and pricing of the product
  - Data related to the disease area, e.g.:
    - Prevalence and incidence data, and other relevant epidemiological data
    - Place in treatment
    - Guidelines
  - Product specific data (e.g. company, compound, INN, ATC, etc.)

Functionalities

- The tender will include a list of functionalities that the database needs to have, however flexibility is key with the option that needs and possibilities change overtime
- Amongst these (see also annex II):
  - Searchability:
    - Complex filters / queries
    - Search by field
    - Progressive results
  - Update alerts
  - Exporting data in different formats
  - Archive
  - Continuous updates of records (real-time)
- Agreement on number of users and downtime and evaluations

What does the database not do

- The HSS does not prioritise for countries
- The HSS does not make any decisions on pricing and reimbursement or market entry
- Data collected is not tailored to specific countries
- Data collected is factual with the exception of the high impact reports

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Prior art analysis

Domkirche St. Stephan zu Wien, Vienna

Prior art analysis

- KCE report (2017)
  - There is no existing system meeting the requirements
  - Current initiatives are inconsistent and not comprehensive at EU level
  - Existing databases, including those at national level are not public

- Corvers / Vtrek analysis and report
  - Performed in order to gain insights into available technologies and methodologies to perform horizon scanning
  - To identify active and innovative market players
  - Some patents and current standards identified, but none directly relevant to IHSI

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Expectations

'Waves of the Donau', Vienna

Expectations from “builder”

- Knowledge on pharmaceuticals and medical technologies
- Experience in designing and performing maintenance of a database
- Experience in analysis and writing of reports
- Scientific – methods should be based on scientific grounds and variables need to be referenced using appropriate sources
- A flexible approach – it will be key to develop a database that meets the evolving needs of the procuring countries
- To enable users to use the data in an easy and accessible way

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Questions to the market

Along the Alzette, Luxembourg

Questions to the market

#	Question	#	
1	Do you have any reservations regarding te availability of het HSS database	**12**	Do you foresee barriers to establishing a KOL network
2	Do you have the expertise to deliver the services described in this document (may also be through the use of consortia)	**13**	Can you suggest other relevant functonalities
3	Do you have any suggestions regarding the scope of te HSS	**14**	Are there any advertencies that have not been described in the consultation
4	What would you consider an appropriate budget	**15**	Do you commercalise automatic search egines or semantic search, which could make searches more efficient
5	Do you have knowledge of any suitable methodology / approach to identify the products	**16**	Could you provide a modern interface for the database
6	Do you have knowledge on performing a high impact analysis	**17**	Can you indicate whether the listed patents and standards in section 6 (Table 4) of the prior art analysis (Annex 3) are relevant ?
7	Could you suggest a way to classify the different disease areas	**18**	Can you name additional relevant standards and patents? Are you aware of other relevant rights or trade secrets ? If so, please provide reference to the revelant patent registration and details, as well as a general description of any relevant rights or trade secrets.
8	Could you suggest a classification for medical technologies		
9	Can you describe an approach for using data from industry	**19**	Do you own any relevant IPR to the HSS ?
10	Do you foresee barriers to partially restricting access to the database	**20**	Are you aware of any patents that may constitute a barrier to your delivering a solution in the envisaged HSS procurement ?
11	Do you foresee barriers to offering different degrees of access		

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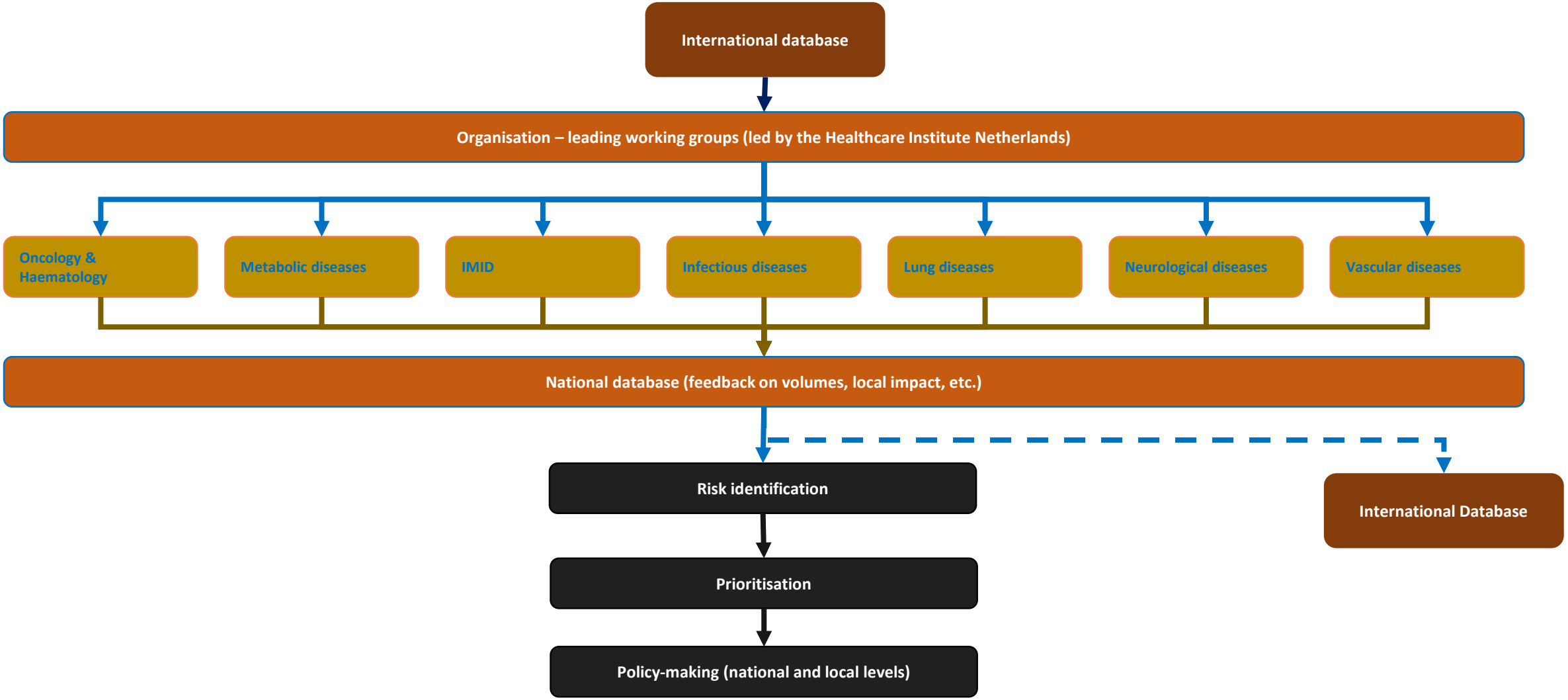
HSS examples and benefits

Samuel Becket bridge, Dublin

National horizon scanning

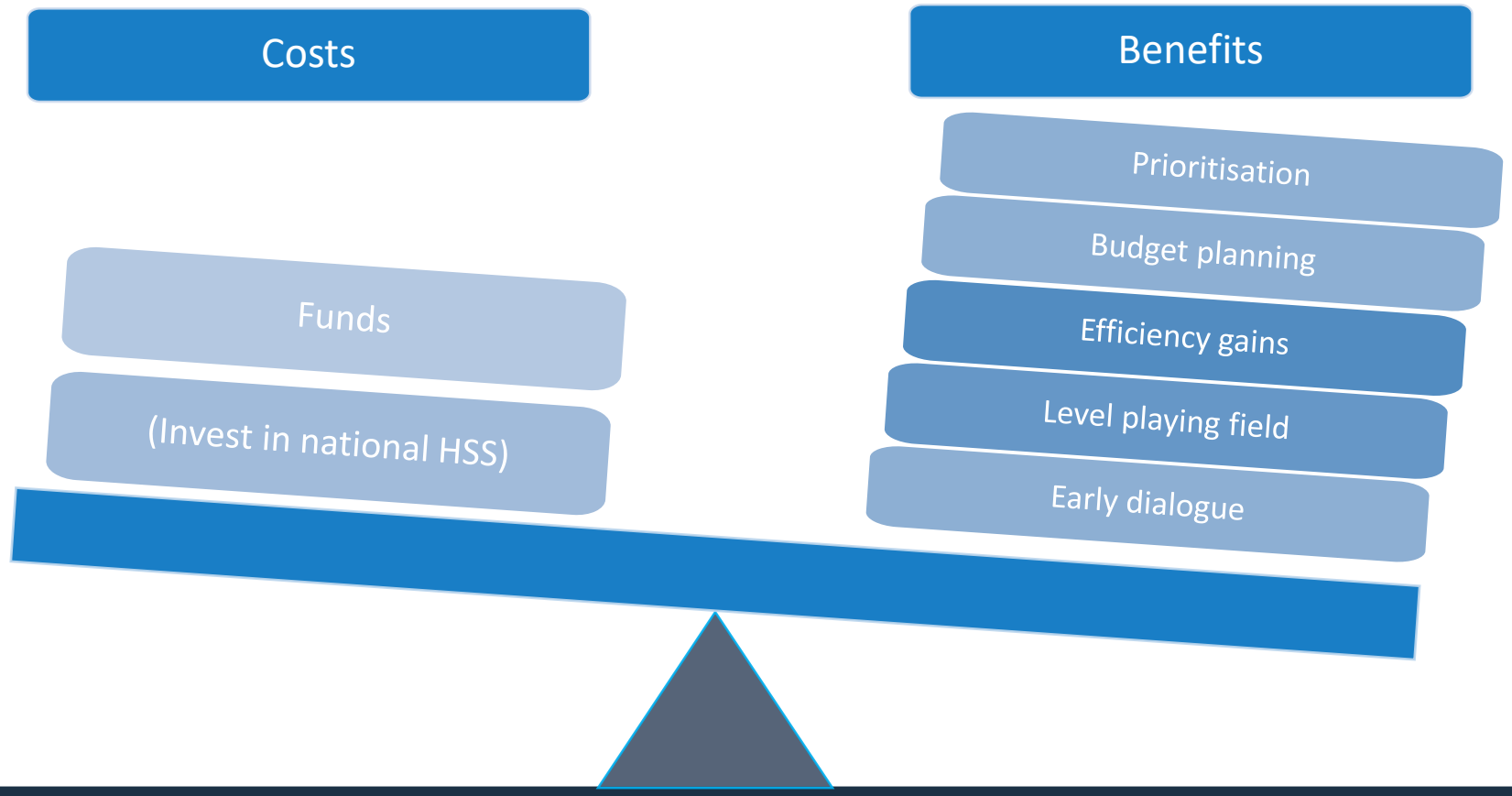
- Some countries have national horizon scanning systems, e.g. Sweden, Austria and the Netherlands
- The international database has the potential to contribute to these national systems or to the setting up of national horizon scanning in countries
- The data collected in the international database is not tailored to:
  - National guidelines
  - Epidemiology on a national level
  - Volume of patients qualifying for treatment
  - National registries
- There is enormous potential in using the international database to enhance data collection on a national level
- In the future there is also the potential to feed national data back into the central database

The Netherlands - example



* IMID: Immune-mediated inflammatory disease

Benefits


Costs
Benefits
Funds
(Invest in national HSS)
Prioritisation
Budget planning
Efficiency gains
Level playing field
Early dialogue

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For more information go to:

www.beneluxa.org

Beneluxa
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