Open market consultation

Building a Horizon Scanning System (HSS)

12-11-2018
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
Aim open market consultation
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
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
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

Open market consultation – November 12th 2018
Data flow

HSS

Assessment bodies

National horizon scanning bodies

International organisations

Payers

Hospitals

Health insurers

Patient organisations

Tender organisations

Specialists

Commissioning groups

Data flow
Proposal for a database

Dataset 1 (baselist)

Dataset 2 (filtered list)

Dataset 3 (high impact)

Dataset 4

Dataset 5

Filter

- Originator pharmaceuticals (Phase II or phase III) / medical technologies grade 2b/3
- Biosimilars and generics (first to market only)
- Special status (e.g. Orphan, ATMP)

Defined variables

- Defined variables
- High impact
- Withdrawn / failed pharmaceuticals
- Registered pharmaceuticals

“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

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

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

- 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
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.)
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
Prior art analysis
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
Expectations
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

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

International database

Organisation – leading working groups (led by the Healthcare Institute Netherlands)

- Oncology & Haematology
- Metabolic diseases
- IMID
- Infectious diseases
- Lung diseases
- Neurological diseases
- Vascular diseases

National database (feedback on volumes, local impact, etc.)

- Risk identification
- Prioritisation
- Policy-making (national and local levels)

International Database

* IMID: Immune-mediated inflammatory disease
Benefits

Costs
- Funds
  - (Invest in national HSS)

Benefits
- Prioritisation
- Budget planning
- Efficiency gains
- Level playing field
- Early dialogue
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For more information go to:

www.beneluxa.org