Joint Horizon Scanning for pharmaceuticals

- KCE report and use of EMA data

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Introduction
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

Horizon Scanning

Health Technology Assessment

Information sharing

Specific information sharing

Joint negotiations
Horizon scanning
- a joint approach
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
The Horizon Scanning database: What is in it?
The database – ‘must haves’

**Database**
- Dataset 1 (baselist)
- Dataset 2 (filtered list)
- Dataset 3 (high impact list)
- Dataset 4
- Dataset 5

**Filter**
- Originator pharmaceuticals (Phase II or III)
- Biosimilars (first to market)
- Special status

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- Withdrawn / failed pharmaceuticals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

**Reporting**
- Real time access
- Publication of list (twice/year)
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

- 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

- 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

• 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

Dataset 7: Generics and biosimilars
The database – ‘nice to haves’

Dataset 6
- Patent related data

Dataset 7
- Generics and biosimilars

Dataset 8
- Medical devices and diagnostics

Dataset 9
- Other?

Loss of exclusivity of the main compound

Supplementary protection certificates, orphan exclusivity or data protection
Opportunities for data sharing
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?

- List of pharmaceuticals withdrawn from the registration process
- Registered pharmaceuticals: already publicly available
- Patent data: not available at EMA
- 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:

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