International Horizon Scanning Initiative
2. The database
"A pessimist sees the difficulty in every opportunity; an optimist sees the opportunity in every difficulty."

Winston Churchill
International Horizon Scanning Initiative (IHSI)

- Aim of a joint HSS:
  - To inform decision-makers on emerging and new pharmaceuticals 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)
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

International Horizon Scanning Initiative (IHSI) 2019
Data flow

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Proposal for a database

Baselist

Filter

Originator pharmaceuticals (Phase II or phase III)

Biosimilars and generics (first to market only)

Special status (e.g. Orphan, ATMP)

Filtered list (defined variables)

High impact reports

List of withdrawn or failed pharmaceuticals

Archive of 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)
Baselist and filtered list

- Baselist: a list of pharmaceuticals 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 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
  - Data is public data

- Database includes tracking of withdrawn or failed products
- Database includes keeping the information on registered products available, however without updates
High impact reports

- Enables prioritisation
- Scientific method to determine high impact
- 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
  - Aim to publish KOL list
- Reports published twice a year
  - Intention to publish these to the general public

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Proposed 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 referenced 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
- The role of potential input from industry is to be decided on by IHSI members
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.)
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