KCE REPORT 283Cs

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

SYNTHESIS

HORIZON SCANNING FOR PHARMACEUTICALS: PROPOSAL FOR THE BENELUXA COLLABORATION

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HEALTH SERVICES RESEARCH

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HORIZON SCANNING FOR PHARMACEUTICALS: PROPOSAL FOR THE BENELUXA COLLABORATION

ISABELLE LEPAGE-NEFKENS, KARLA DOUW, GERTJAN MANTJES, GIMON DE GRAAF, ROOS LEROY, IRINA CLEEMPUT

KEY MESSAGES

- In 2016, the Belgian, Dutch, Luxembourg and Austrian governments declared their intention to collaborate on pharmaceutical policy (BeNeLuxA Collaboration). KCE was asked to lead a task force responsible for developing a **Horizon Scanning methodology** for pharmaceuticals and a possible model for a joint horizon scanning system (HSS).
- We propose to create a **central "horizon scanning unit"** to perform the joint HS activities (a newly established unit, an existing HS unit, or a third party commissioned and financed by the collaborating countries). The unit will be responsible for the **identification** and **filtration** of new and emerging pharmaceutical products. It will maintain and update the HS database, organise company pipeline meetings, and disseminate the HSS's outputs.
- The HS unit works closely together with the designated **national HS experts** in each collaborating country. The national HS experts will collect country-specific information, liaise between the central HS unit and country-specific clinical and other experts, coordinate the national **prioritization** process (to select products for early assessment), and communicate the output of the HSS to national decision makers.
- The **outputs** of the joint HSS are published in the format of Lists, with links to the database entry with the most extensive information available at that time.
- **Access** to the HS database is restricted to registered parties within the collaborating countries.
- The establishment of an HSS requires **human resources** with specific skills as well as **facilities and equipment** to collect, manage, store and secure sensitive data.

SYNTHESIS

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AHRQ	The Agency for Healthcare Research and Quality (Québec)
EMA	European Medicines Agency
FDA	Food and Drug Administration (USA)
HS	Horizon scanning
HSS	Horizon scanning system
HTA	Health Technology Assessment
KCE	Belgian Health Care Knowledge Centre
MA	Market authorisation
NICE	The National Institute for Health and Care Excellence (UK)
NIHR HSRIC	National Institute for Health Research Horizon Scanning Research & Intelligence Centre, UK
RIZIV – INAMI	Rijksinstituut voor ziekte- en invaliditeitsverzekering / Institut National d'Assurance Maladie-Invalidité
UKmi	UK Medicines information

1. BACKGROUND, OBJECTIVES AND SCOPE

In 2016, the Belgian, Dutch, Luxembourg and Austrian governments declared their intention to collaborate on pharmaceutical policy, more precisely on horizon scanning (HS), health technology assessment (HTA), information sharing and policy exchange, and pricing and reimbursement. It is the goal of the collaboration to avoid duplication of efforts by dividing tasks and sharing data. The collaboration is currently known as the "BeNeLuxA Collaboration". KCE was asked to lead a task force responsible for **developing a HS methodology for pharmaceuticals and a possible model for a joint horizon scanning system** (HSS).

The scope of this study is **limited to horizon scanning for pharmaceuticals**.

2. PROPOSAL FOR A JOINT HORIZON SCANNING SYSTEM

The proposed model for a joint HSS for the BeNeLuxA collaboration was based on the lessons learnt from an international comparison of eight HSSs and the input from several stakeholders (representatives of the minister of health in the different countries and country experts in HS) about their needs and objectives with the HSS. HSSs differ in their goals, time horizon and customers. They make different methodological choices for the identification, filtration and prioritization of new or emerging products.

2.1. Objectives of the collaborative HSS

The joint HSS should enable the participating countries to make their local decisions based on the jointly collected information, as well as allow the collaborating countries to identify possible topics on which they could work together.

The BeNeLuxA collaboration needs a HSS that serves a broad range of objectives relevant for different policy making processes in different countries:

- to inform decision makers on emerging and new pharmaceuticals for reimbursement decisions and policy development;
- to inform decision makers on issues that are relevant for the managed introduction and monitoring of drugs;
- to facilitate estimation of budget impact and budget planning;
- to allow the selection of pharmaceuticals for (international collaboration on) early dialogue with industry, price negotiations, HTA and registers;
- to plan health services.

2.2. Organization of a collaborative HSS

Internationally, HS is performed by diverse organizations: academic institutions (England), independent research institutes (US, Wales and Scotland), (local) health authorities (Italy and the UK), and public policy makers (the Netherlands, Sweden). Customers are national or regional health authorities (the Netherlands, Sweden and Wales), HTA agencies (England, the US and Italy) or health service providers or managers (the UK and Scotland).

For the BeNeLuxA collaboration, we propose to create a **central "HS unit"** to perform the joint HS activities. This could be a newly established unit within an existing agency in one of the countries, or the expansion of the HS activities of an existing HS unit in one of the countries, or a third party commissioned and financed by the collaborating countries.

The HS unit should be commissioned for a certain period (for example at least 5 years), in order to safeguard the continuity of the system and the expertise built up in the system.

2.3. Scope of the HSS

The four countries agreed on the following scope of the joint HSS: "both **inpatient and outpatient pharmaceutical products** with a potentially **high financial, clinical and/or organizational impact** on the health system". The first biosimilar for a biological product, cellular therapies and/or gene therapies that will be licensed as medicinal products by the European Medicines Agency (EMA), are included in the scope. Prophylactic vaccines, generics and medical devices are out-of-scope for the time being.

2.4. The HS process

The main activities of a HSS are:

- the **identification** of new and emerging pharmaceutical products that could enter the market within a pre-defined period of time;
- the **filtering** of identified products, based on the scope and time horizon of the HSS;
- the **prioritization** of filtered products for early assessment;
- the **early assessment** of the prioritized products or groups of products based on available data or predictions.

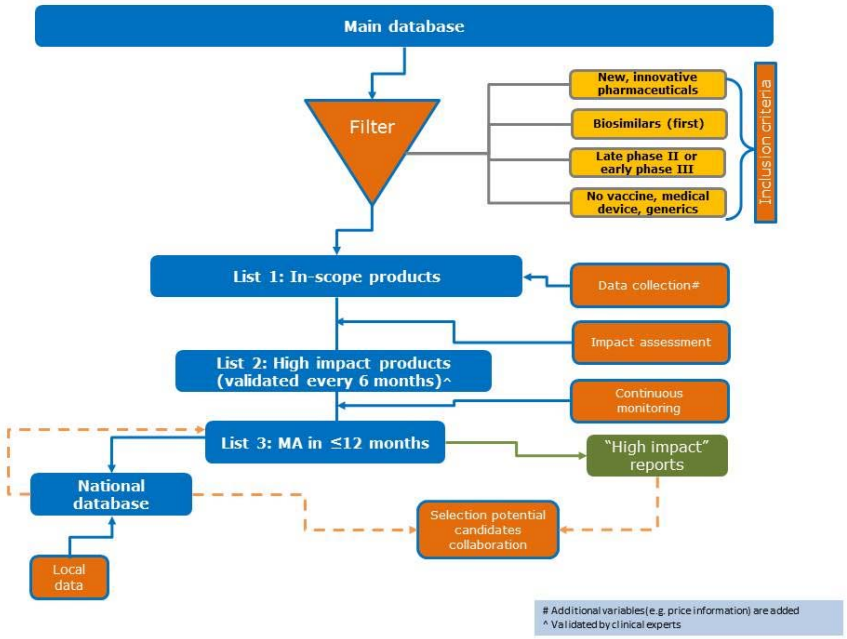
The proposed joint HS process and its outputs are graphically presented in Figure 1. We suggest to perform the identification as well as the filtration on the international level (within the collaboration), and the prioritization on the national level.

The result of the joint **identification** process is the 'main database', which consists of all new or emerging pharmaceuticals that fall within the chosen time horizon for the HS. The time horizon is expressed in terms of the development phase of the product of interest (e.g. late phase II), rather than in months.

During the **filtration** phase, only the products that are within the pre-defined scope of the HSS are selected from the main database for further follow-up. The filtration reduces the number of technologies on which collect in-depth information. In the proposal several rounds of filtration are suggested, based on emerging new information on the products when time moves on (see also section 2.7). The filtration rounds result in a set of lists, which contain products that are far (list 1) or less far (list 3) away from expected market authorization (MA).

The **prioritization** phase requires an assessment of the relative urgency of action on each of the products in the filtered database. As this urgency may be country-specific, additional national information may be needed for this purpose. The result of the national prioritization is relevant for the selection of products on which to collaborate on an international level. Hence sharing of prioritization outcomes amongst the collaborating countries would be desirable.

Figure 1 – Proposed methodology for a joint HSS



Based on an informally shared viewpoint on a possible international HS database from the Bureau Financial Arrangements for Pharmaceutical Products of the Dutch Ministry of Health, Welfare and Sport (Buro Financiële Arrangementen Geneesmiddelen, Ministerie van Volksgezondheid, Welzijn en Sport, Nederland). MA: market authorization

2.5. Time horizon and outputs

In HS there is a trade-off between early information, with more uncertainty, and late information with less uncertainty. The longer before MA, the higher the uncertainty about the products. The goal of the HSS and the context of the health system determine the most appropriate time horizon for the HSS.

To accommodate for the different objectives and associated time horizons among the four countries, the proposed system produces **three lists**:

- **LIST 1**: A list of products at the end of phase II *OR* early phase III *OR* having obtained orphan drug status *OR* having applied for or obtained fast track status through other means (e.g. conditional MA[a]). Drugs with orphan drug or fast track status will already be identified in phase I. The list includes a brief description of the product, such as the name of the molecule, the manufacturer and the target indication(s).
- **LIST 2**: A list of products at the end of phase III, with an expected high financial, clinical or organisational impact on the health care system.
- **LIST 3**: A list with expected high impact pharmaceuticals in the final stage of development, i.e. about 12 months before MA application; phase III studies are finalized. Timelines and EMA/FDA status of these products are followed until they either have approval or are denied approval.

[a] Conditional market authorization (MA) refers to the approval of a medicine that addresses unmet medical needs of patients on the basis of less comprehensive data than normally required. The available data must indicate that the medicine's benefits outweigh its risks and the applicant should be in a position to provide the comprehensive clinical data in the future.

List 1 gives the customer an idea of what is in the pipeline and can be useful for decision makers to identify products for which early dialogue or drug policy development may be desirable (early dialogue should take place before phase III or combined phase II/III trials in order to allow companies to take into account the comments made). This is particularly important for countries with a negative reimbursement list[b], such as the UK and Austria, because they preferably dispose of a finalised HTA as soon as the product comes to the market. List 2 can be useful for national budgetary planning, as it encompasses products that are potentially important but not yet too close to MA, so that anticipation is feasible. In the US, for instance, the Agency for Healthcare Research and Quality (AHRQ) therefore uses a time horizon for the identification of new or emerging products between 24 and 36 months before MA. List 3 allows countries to set priorities for early assessment and to highlight possibilities for collaborations on HTA, registries and/or price negotiations.

The three lists are to be considered as the outputs of the HSS. Lists 1 and 2 would be shared annually with the customers, while List 3 would be shared twice a year. The desired format of the lists can be customized: it could be shared as a database or a customized report could be drawn from the database. For example, the Dutch system produces a database with information on the products, including a one-sentence advice on whether a product should go into the price negotiation procedure or not, while the Swedish, US, Italian and UK systems produce early assessment reports on fixed time intervals (quarterly, twice a year or annually).

In the scientific report it is extensively described which information could be collected for the respective lists and which sources could be used for that purpose. We refer the interested reader to section 5.8.

[b] Health systems with a negative reimbursement list apply a policy of reimbursement by default once the product has received market authorization from the European Medicines Agency or the national Regulatory Authority. Products can be taken out of the reimbursement package, but only after a political appraisal process informed by HTA.

2.6. Database content and sources

2.6.1. Active scanning

For the BeNeLuxA collaboration an active scanning approach is proposed, i.e. the HS unit actively scans information sources instead of using the output of another HSS. This ensures that the scanning process is in line with the pre-defined scope and time-horizon of the joint HSS. Sources could be scanned weekly or monthly. A list of sources that could be used for the identification of products is included in the Appendix of the scientific report.

2.6.2. Main database

First of all it is important that appropriate measures are taken for an **optimal protection** of the database with the information on the identified products.

In addition, the collaboration should explore the opportunities of **data collection automation**, as a semi-automated search could significantly improve, accelerate and simplify the identification and data collection process of new pharmaceuticals. Such automated searches will, however, not replace input from human expertise. Input from companies and clinical experts may improve the filtration process (cf. infra). In this context, it should be investigated if and under which circumstances the **pre-submission data gathered by EMA** (and currently not accessible to non-regulatory bodies) can be shared with the HS unit.

Over time, the database should evolve to a **real-time** database, meaning that every time an entry in the internal database is updated and validated by the analyst team, the collaborating countries are informed about the update.

Access to the full database is restricted to the designated HS experts in each country (for example in Belgium this could be designated experts from the RIZIV – INAMI and/or the Ministry of Health). By granting access only to those who are paying for the system, sustainability of the joint HSS is enhanced, and inappropriate interpretations or expectations by lay people are avoided. Although the database should not be disseminated to a broader audience, dissemination of some findings to specific target groups (e.g. clinicians) in a specific user-friendly format may be considered. The format and frequency of such **outputs** depend on the output timing (i.e. how long before MA) and the needs of the customer. The closer to MA, the more information is available and hence the more in-depth the assessment can be. We recommend to explore the need for such assessments first and pilot several models (e.g. "info sheet" (1 to 2 pages, can be done within 24-48h) over "brief" (4-6 pages, can take 0.5 to 2 weeks) to "in-depth" (up to 40 pages, can take 4-6 months)) before investing in their systematic production.

2.6.3. Company pipeline meetings

The HS unit could organize annual face-to-face company pipeline meetings to obtain input for the HS database, similar to the English and Swedish HSSs. During these meetings companies are asked to pro-actively share a list of upcoming products, provide information on estimated launch dates and estimated price ranges, and filter out products which are no longer relevant, e.g. because the company has discontinued the research. Other information, such as target population, indications or possible extension of indications, clinical trial results etc. collected from other sources, can also be verified with the companies and compared with the information provided to financial analysts.

For this communication with companies to be really effective and relevant for the HSS, genuine commitment from companies is required. Enforcement may not be the best way to reach the goal of the pipeline meetings. For example, the UK PharmaScan is a secured central database organised and managed by NICE, which contains information on all products that will be launched in the UK. In an ideal world, all pharmaceutical companies would proactively fill in UK PharmaScan, but in reality companies often need prompting for completion of UK PharmaScan. Despite these efforts, the data are still considered not up-to-date and incomplete.[c]

Within the scope of the present study a Belgian feasibility study was performed. From the six companies invited for an information exchange meeting on specific products in their pipeline, only three participated in a meeting. Yet, the companies that participated in the feasibility study provided useful information on, for instance, companies' development priorities, product discontinuation, place in therapy, expected EMA submission and outcomes of unpublished trials, but were unable to provide country-specific prices[d].

The Belgian Society for the Pharmaceutical Industry, Pharma.be, expressed its willingness to engage in a collaborative HS effort, be it under a number of conditions.[e] These conditions should be further discussed at the European level, more precisely it should be investigated whether the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Biotechnology Enterprises (EBE) share the view of Pharma.be.

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[c] Scottish Medicines Consortium. Guidance on Horizon Scanning Process. July 2015. Accessed on https://www.scottishmedicines.org.uk/About_SMC/What_we_do/Horizon_Scanning/Guidance_on_Horizon_Scanning (1st February 2017)

[d] For prices, alternative sources, such as investor's websites or prices of comparators, should in this case be used.

[e] First, Pharma.be wants information supplied by companies that is not publicly available to remain confidential (unless if contained in financial analyst reports). Second, they would not support the principle that participation in the HSS becomes a condition for reimbursement or that implicit decisions about reimbursement are made before a reimbursement request has been submitted to the Drug Reimbursement Committee. This is the case in England, where inclusion in the UK PharmaScan database is a pre-requisite for getting reimbursement. The HSS is used to select pharmaceuticals for

2.7. Filtration

For the filtration process, it is recommended to use explicit criteria, based on the scope of the HSS. A set of possible questions which can help in this phase (i.e. to determine whether an identified product fits within the scope of the HSS and should hence be included in List 1) is presented in the scientific report. The filtration can be performed internally by the HS unit, or can involve consultation of external experts, as in the Dutch and US HSS.

When products on List 1 are in late Phase II (or phase I for orphan drugs) or early Phase III, it is assessed whether they have a potential financial, organizational and/or clinical impact, based on the collection of additional (minimal) data. This is the second filtration step. For example, in order to be filtered into the Dutch system, products need to exceed the explicit threshold on one of the pre-defined cost parameters (estimated annual macro cost, cost per patient per year, volume risk and potential savings).

In case of an estimated high potential impact, a product is selected for List 2. Finally, for inclusion in List 3, the third filtration step, the explicit criteria used are 'phase III finalized' and '<12 months to MA request'.

more in-depth HTA by NICE. Third, they state that the HSS should not lead to a separate budget for new medicines. Fourth, they emphasize that all companies should get the opportunity to participate.

2.8. Prioritization

After filtration, products have to be prioritized for assessment. This happens at the national level. Each country will need to set up a systematic approach to use the HSS's outputs in their policy cycle or research agenda. It can start based on List 2 or List 3, depending on the objective of the decision maker. Some products that have been selected by the central HS unit can be filtered out at the national level if they do not serve the national customer's objective.

National data collection

Most information necessary to perform a country-specific prioritization process will already be included in the joint HSS's database, but national prioritization may also require country-specific information (for example about the national incidence and prevalence, the expected proportion of patients eligible for the treatment, existing guidelines and current standard of care, costs, unmet medical and societal need, impact on current care and health services). Involvement of national clinical and other **experts** (health system specialists, HTA experts, hospital managers, payers, insurers and patient associations) in this process will be needed. This creates transparency and supports subsequent decisions, but also helps to obtain information from different perspectives. The possible downside of it is that it may be time consuming and comes with a cost. Our feasibility study in Belgium showed that it was not easy to engage clinical experts, but once involved, they provided useful information on the context of the novel treatment (e.g. current standard-of-care, the medical need in (specific) patient population(s) and the estimation of the volume of patients in each treatment line) and the products' place in therapy (i.e. appropriate target patient population, first, second or third line, substitution of other product(s)). Expert involvement can be organized through written forms and/or group meetings.

Also the involvement of an **investor** should be considered in this phase. Some investor's websites or commercial news sites provide data on costs without a reference. In that case, an investor could help in assessing the reputation of the website.

Although the prioritization process itself it not a collaborative effort, it is wise to **share the country-specific information and priorities** with the central HS unit in order to facilitate further collaboration downstream of the HS process.

Prioritization process

Prioritization processes can be explicit, quantitative processes or consensus-based processes or something in between. A set of **explicit priority setting criteria** increases the transparency and consistency of the prioritization process.

Impact on health care expenditures and impact on the organisation of health care (e.g. utilization, infrastructure, system of care delivery) are the main explicit prioritization criteria used in current systems. Other explicit criteria are health benefits, innovativeness, volume of patients and impact on access. Besides explicit criteria, also implicit prioritization criteria could play a role, such as policy priorities and advice given by medical societies or clinical experts. While similar prioritization criteria may be used across countries, the respective weights assigned to these criteria will depend on the context, preferences and goal of the decision makers.

More details on the prioritization process are provided in the scientific report section 5.11.

2.9. Establishment of the collaborative system

2.9.1. Start-up investment

The initial investment depends on how the system is established: as a new HS unit or as a collaboration with an existing HS initiative with prior experience.

For the establishment of a new unit, an initial investment is needed for training people in the HS process, methodology and communication skills. In case a new HS unit is established in one of the collaborating countries, it is important to ensure that this unit closely connects to the relevant decision-making agencies in the other collaborating countries. Therefore, a HS representative should be appointed in each of these agencies.

Resources are needed for the development of the database and the web-based interface. As explained before, functionalities to make the process as efficient as possible should be explored, but also data security should be guaranteed. It can take up to 6 months to create an initial database, while it should take less time in case of collaboration with an existing initiative. Alternatively, an initial database can be acquired from AHRQ, NIHR HSRIC or UKmi or the Ludwig Boltzmann Institute (oncology products only), but then still additional development will be needed to customize the database to the BeNeLuxA Collaboration's needs.

Contacts need to be made with pharmaceutical companies and medical societies at the country level to explain their role in the process and set up productive relationships. This effort should not be underestimated: it is time consuming but important to obtain the right information.

A pilot phase is proposed to test the proposed HSS with its different outputs, data sources and stakeholder input procedures, and to develop practical output formats. The pilot phase is estimated to take about 1.5 year (or at least two "List 2" cycles). During this pilot phase it can be evaluated whether the involvement of a financial analyst is an added value in the validation of the (cost) data or in the development of new methodologies for cost and budget estimations.

2.9.2. Annual cost

The annual cost of the HSS will depend on the extent of the HS activities. For a complete system, covering all types of health technology and not just pharmaceuticals, it is estimated that up to 10 full-time equivalents with diverse competences would be needed. A system with a limited scope, such as the one described in the current proposal, could do with less. The HS unit requires services from

- a medical librarian
- HS analysts with HTA and/or health economics expertise or with background in pharmacoeconomics
- a pharmacologist
- a HS analyst with medical background (medical doctor)
- a data manager
- a communication specialist (for the production of “high impact reports”)
- an ICT specialist
- a manager or coordinator

Also for the subscription to sources, rent and facilities an annual budget will be needed. Outsourcing to a for-profit third party might require a premium above the costs.

2.10. Summary of the proposed joint HSS

The features of the proposed HSS are presented in Figure 2.

Figure 2 – Features of the proposed joint HSS

Identification	International collaboration	Yes	No
	Active scanning	Yes	No
	Company input	Yes	No
	Expert input	Yes	No
Filtration	International collaboration	Yes	No
	Criteria	Explicit	Implicit
	Company input	Yes	No
	Stakeholder input	Yes	No
Dissemination	Early assessment	Yes	No
	Public availability	Yes	No

The proposal suggests to collaborate on the identification and filtration. A central HS unit could perform the HS tasks for the collaboration, including the maintenance and update the HS database, the organization of the company pipeline meetings and the support of national HS experts. The outputs of the joint HSS are three lists, with links to the database entry with the most extensive information available at that time. Access to the database is restricted to registered parties within the collaborating countries.

The current proposal describes a quite extensive system, which is to be envisaged in the long term. However, for the short term, suggestions are made on how to start with an operational HSS that serves quite some needs of the collaboration. If, in the longer term, more countries wish to step in or use the HSS’s outputs, the scope can be enlarged. For maximal relevance, the described HS process should be adopted in a flexible way, taking the specific needs of the customers into account. Therefore, continuous communication with the collaborating countries is of utmost importance as well as regular evaluation of the HSS.

RECOMMENDATIONS

To the BeNeLuxA collaboration

- **Set up a central horizon scanning unit to perform the horizon scanning activities for the collaboration. This could be a newly established unit within an existing agency in one of the countries, the expansion of the HS activities of an existing HS unit in one of the countries or a third party.**
- **Provide resources to support the activities of the horizon scanning unit.**
- **Pilot test the methodology proposed.**
- **Develop an evaluation framework for the joint horizon scanning system.**
- **Perform an evaluation of the horizon scanning system and make adjustments where needed.**

To the national governments

- **Support the integration of horizon scanning in your national health policy processes.**
- **Appoint a national horizon scanning expert, that is the single point of contact in the country for all matters relating to horizon scanning. The national horizon scanning expert can coordinate the national prioritisation process and liaise with the central horizon scanning unit.**

COLOPHON

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