



Intentions on collaboration on pharmaceutical policy between the Kingdom of Belgium, the Kingdom of the Netherlands, the Grand Duchy of Luxembourg, the Republic of Austria and the Republic of Ireland
(The Beneluxa Initiative on Pharmaceutical Policy)

Shared views on the benefits of voluntary collaboration

There are imbalances in the current pharmaceutical market which have been caused, to some extent, by the limitations of national policies on pricing, reimbursement and on the use of pharmaceuticals. At the same time, disproportionate stress is put on capabilities of individual authorities. Both elements could ultimately hamper timely access to medicines for patients. Joining forces and taking action on a voluntary basis to face common challenges resulting from these imbalances should support participating countries in fostering the sustainability of national healthcare systems and the affordability of medicinal products challenged by high prices, adverse consequences of incentives and the unfulfilled leverage potential of individual countries in negotiations with industry.

The countries co-signing this document agree that policies on pricing and reimbursement of pharmaceuticals benefit from collaboration between those countries.

Objectives of the collaboration initiative

Based on the current Beneluxa collaboration, four areas for potential collaboration were defined:

1. Horizon Scanning;
2. Health Technology Assessment;
3. Information sharing and policy exchange;
4. Joint price negotiations.

The initiative aims to further investigate how collaboration on these topics can be formalized, to determine the possible extent of cooperation and to define the desired outcomes, with due respect to current confidentiality agreements. Pilot projects are conducted in order to test and optimize collaboration methods.

Jointly composed Terms of Reference serve as a basis for execution and development of the current ongoing collaboration initiative, as well as for expansion to other countries.

The overall objective of the initiative is to actively collaborate on the aforementioned areas, thus contributing to affordable and better access to pharmaceuticals and appropriate use of pharmaceuticals:
to enhance the access of patients to high quality and affordable treatments;

- to allow for better anticipation on public health challenges more effectively due to a shared approach on horizon scanning;
- to increase efficiency in assessment, pricing and reimbursement of pharmaceutical products by exchanging expertise and the mutual recognition of Health Technology Assessments;
- to improve access by sharing policy expertise and by focusing on knowledge building;
- to improve the payers' position by:
 - increasing knowledge about products, usage and markets;
 - by allowing for joint negotiations;
- to increase transparency on pricing between the collaborating countries.

The collaboration initiative aims to offer a long term contribution towards sustainable access of pharmaceuticals in participating countries. When the current collaboration initiative is considered to be sufficiently mature, the collaboration initiative is open to other willing countries.



The agreement

By signing this document, the collaborating countries agree to the following:

- Collaboration remains voluntary and should allow for partial collaboration on selected areas.
- Countries will actively participate in areas in which they wish to collaborate, as deemed appropriate in accordance with their national specificities and available resources.
- Collaboration areas mentioned in this document shall be realised in accordance with the Terms of Reference applicable to each area.
- A technical working group consisting of delegates of all participating countries will further develop collaboration in the areas that were described.
- General Coordination of the collaboration initiative will be assigned yearly, at the time of signing being performed by the Netherlands.
- The Terms of Reference for the collaboration are presented to the ministers.
- Based on the proposals, current and new pilots covering the various domains of the collaboration and more specifically on price negotiations on pharmaceutical products shall be conducted.

Signed in five copies in Luxembourg on the 22nd of June, 2018.



Annex - Elements of the collaboration initiative

1. Horizon Scanning

General - shared opinion

The participating countries underline the importance of consolidated and validated information on new products entering the market in the short- to mid-term. A 'Horizon Scan' can serve as a tool to provide such information. The benefit of Horizon Scanning is two-fold: It allows for national planning and allocation of funds, but it will also enable international collaboration on pricing, reimbursement and usage of pharmaceuticals.

The instrument could facilitate early dialogues with pharmaceutical companies on the price and positioning of their drugs, allow for (reimbursement) decisions at an early stage, including the conditions in which pharmaceuticals can be made available to patients and ultimately facilitate (shared) price negotiations with companies.

Countries are aware of the fact that the use and outcomes of Horizon Scanning could lead to a change of strategic behavior of stakeholders.

Collaboration on Horizon Scanning

All countries commit to investing in the on-going development and validation of a shared method ('Horizon scanning') that allows for proactive generation of aforementioned information. They therefore agree to the following:

- The Dutch methodology on Horizon Scanning will be used as an interim instrument. The outcomes will be shared among participating member states.
- Horizon scanning activities of international and national initiatives will be explored and if appropriate, integrated in the shared approach.
- Countries will determine how (and by whom) a permanent cycle of horizon scanning will be carried out through the International Horizon Scanning Initiative (IHSI).
- The intent is to share outcomes of horizon scanning exercises with the public in the future. It will be further discussed whether and how results of Horizon scanning should be communicated to interested third parties or countries.

2. Health Technology Assessment

General- shared opinion

Countries recognize the importance of an active participation by payers regarding Early Dialogues/Scientific Advice in the respective platforms (e.g. at EMA level, EUnetHTA). The added value of early exchange of opinions and where necessary, formulating a shared point of view on these subjects, is recognised. In order to optimize the investment of all countries in these initiatives, a structural dialogue will be initiated among the relevant national bodies.

Collaboration within EUnetHTA

In order to facilitate international collaboration on HTA within the EUnetHTA Joint Action, participating countries will actively participate and coordinate efforts within EUnetHTA.

Collaboration on HTA reports

Given the resources and expertise invested in HTA in the respective countries, and in order to share existing expertise as well as building further relevant expertise, countries agree to the following:

- If available, HTA bodies of all countries shall share their yearly work planning where such planning is in place, describing the current and planned assessments.
- If so desired, national competent authorities on HTA and/or payers in the respective countries are willing to act as external expert for other countries, taking into account the availability of relevant expertise and human resources.



- HTA bodies will improve comparability of reporting formats, in order to facilitate the exchange and mutual recognition of work.
- These formats should allow for the production of joint assessments (in the case of an expansion of participating EU Member States, or for use within EUnetHTA).
- An analysis shall be performed by all participating countries to determine required legal changes in their national context in order to accept 'non-national' HTA reports in decision making processes.
- The possibilities to actively promote the results of EUnetHTA joint assessments among other Member States will be explored.

3. Information sharing

General - shared opinion

The current pharmaceutical market is a globalised one. The pricing strategies of multinational companies, the increasing complexity of the use of newly introduced medicines and the shift towards products that target smaller patient populations pose policy dilemmas in a national context. A less fragmented approach to address these dilemmas can improve affordability, quality of care and ultimately access to medicines. Pharmaceutical policies in the collaborating countries can benefit greatly from sharing information and expertise.

Collaboration on information sharing

Participating countries agree to the following:

- Collaboration on Information exchange consists of several areas:
 1. Exchange of policy issues such as best practices and knowledge of pricing and reimbursement systems that help improve the efficiency of national policies
 2. Sharing general information on markets, volumes and prices of specific products or indication areas (so far as current confidentiality agreements allow).
 3. Interpretation of the outcomes of a joint Horizon scanning exercise by exchanging information on the expected impact of new products on individual markets and the focus of national efforts to contain the impact.
 4. Discussion on the possibilities of collaboration on cross-country registries, data sharing and appropriate use, allowing for a life-cycle approach towards medicines.
- Participation of countries can vary according to their needs and possibilities.
- By actively engaging in one or more areas of information sharing, countries commit to active participation, in accordance with available resources and means.
- Current participating countries will commit to participation on all areas of collaboration, in accordance with available resources and means.
- A platform to share information is to be created to facilitate information sharing.

4. Collaboration on Pricing

General - shared opinion

Participating countries agree that there are specific markets in which collaboration on price negotiations will improve the strategic position towards industry. By pooling patient volumes, a more efficient and sustainable use of resources will be possible.

Collaboration in this respect falls into two categories:

1. The structured exchange of strategic information before, during and after negotiations with companies;
2. Performing joint price negotiations and setting shared goals and conditions on pricing and reimbursement beforehand.



Collaboration on pricing

Belgium, the Netherlands, Austria and Ireland will seek collaboration on price negotiations. Given the complexity of collaboration on pricing, countries recognize the importance of a step by step approach. They agree to the following:

Ad 1. Exchange of strategic information:

- Strategic information sharing is on-going. All countries agree on increasing and improving this dialogue.

Ad 2. Joint price negotiations:

- Countries will continuously exchange information on current and planned national negotiations, within their respective legal frameworks, including confidentiality of information where relevant.
- Suitable candidate products for a pilot for joint negotiations are selected based on a joint horizon scanning exercise.
- An assessment of all national pricing and reimbursement procedures is being carried out in order to evaluate how decision making processes can be synchronized.
- Authorities of all participating countries aim to take necessary measures in order to facilitate and allow for joint negotiations based on the assessment.
- All elements of price negotiations will be explored further in a structured dialogue on a technical and political level between the collaborating countries.