



Minister van Sociale Zaken en Volksgezondheid
MAGGIE DE BLOCK



Ministerie van Volksgezondheid,
Welzijn en Sport



THE GOVERNMENT
OF THE GRAND DUCHY OF LUXEMBOURG
Ministry of Health



BUNDESMINISTERIUM
FÜR GESUNDHEIT

The BeNeLuxA Initiative - Collaboration on pharmaceutical policy

- Terms of Reference -

Version 1

Adopted by Belgium, the Netherlands, Luxembourg and Austria

Effective as of March 1st, 2017

Table of Contents

1	Prerequisites.....	3
2	Context.....	3
3	Vision	3
4	Scope and objectives of the Collaboration Initiative.....	4
5	Membership	4
5.1	Participation: Mandate and expansion	4
5.2	Membership options and expectations	5
5.3	Responsibilities and resources	5
6	Internal transparency: Definition and expectations.....	6
7	Public Access	6
8	Review and planning.....	6
9	Conflict resolution.....	7
10	Working Methods	7
10.1	Introduction.....	7
10.2	Overall coordination.....	7
10.2.1	Setup.....	7
10.2.2	Appointed representatives.....	7
10.3	Initiative Steering Committee	8
10.3.1	Role.....	8
10.3.2	Responsibilities.....	8
10.3.3	Political Mandate.....	8
10.3.4	Setup.....	8
10.4	Domain Task Forces.....	9
10.4.1	Role.....	9
10.4.2	Responsibilities.....	9
10.4.3	Setup.....	10
11	General Assembly	10
12	Communication	10
13	Adoption	10

1 Prerequisites

All the decisions and activities of the Collaboration Initiative will be taken, and performed, in accordance with the present Terms of Reference, the EU and national regulations and legislation and the EU Council Conclusions. As these EU and national regulations and legislation prevail, Members of the Initiative will refrain from participating in decisions and/or activities/projects/pilots if there is a conflict between these and said national regulations or legislation. If deemed necessary, this reservation will be clearly stated beforehand in an appropriate way.

Participating countries should clearly state the topics they wish to collaborate on, and the extent to which they will be able to do so according to the working agreements of those topics.

The Initiative is committed to ensuring that there is external transparency, unless specific aspects of the collaboration require confidentiality. However, participants will ensure that they exhibit discretion regarding ongoing projects and dialogues in so far as (country-) specific transparency requirements allow.

2 Context

Currently, there are imbalances in the 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, a disproportionate emphasis has been put on the capacities of individual national authorities. Both elements could ultimately hamper patients' timely access to medicines. Joining forces to face the common challenges created by these imbalances should support participating countries in fostering the sustainability of their national healthcare systems and the affordability of medicinal products challenged by high prices, the adverse consequences of incentives and the unfulfilled leverage potential that individual countries have in their negotiations with the industry.

The countries co-signing this document agree that policy initiatives on the pricing and reimbursement of pharmaceuticals will benefit from collaboration between participating countries.

3 Vision

The Collaboration Initiative should make a long term contribution towards the sustainable access to, and appropriate use of, medicines in the participating countries. The current focus of this Initiative is on pharmaceuticals. In light of - for instance – the emergence of personalised medicine, a collaborative approach regarding issues such as treatment 'packages' (medicines ± medical devices) should be possible.

The Initiative aims to achieve this goal by:

- enhancing patients' access to high quality and affordable treatments;
- enabling national health challenges to be anticipated more effectively by adopting a shared approach to the horizon scanning of new pharmaceutical products and to new indications of existing products coming to the market;

- increasing efficiency in the assessment, pricing and reimbursement of pharmaceutical products by exchanging expertise and the mutual recognition of Health Technology Assessments;
- improving access by sharing policy expertise and by focusing on knowledge building;
- improving the payers' position in the market:
 - by improving knowledge about products, usage and markets;
 - by allowing joint (price) negotiations for specific products to be made;
- increasing transparency on pricing between the collaborating countries.

4 **Scope and objectives of the Collaboration Initiative**

The Collaboration Initiative consists of a Steering Committee which oversees the overall collaboration, aided by Domain Task Forces for each specific area of collaboration.

There are four domains where potential for collaboration exists:

1. Horizon scanning
2. Health technology assessment
3. Information sharing and policy exchange
4. Pricing and reimbursement (among which joint price negotiations).

The Collaboration Initiative will define the extent of the collaboration on these domains. For each of those, the Initiative will determine the following:

- A clear overall goal for collaboration;
- A definition of the desired outcomes;
- The extent of collaboration on specific topics;
- A formalised organisational structure in which collaboration will take place;
- Pilot projects will be conducted in order to test and optimise collaboration methods ('proof of concept').

The Collaboration Initiative is responsible for the execution of the current ongoing collaboration initiatives, the development of new initiatives, and for expanding the current collaboration initiative to other countries.

The working language of the Initiative is English.

5 **Membership**

5.1 Participation: Mandate and expansion

The political mandate for collaboration within the Initiative is to be given by the formal signature of the Minister(s) responsible for pharmaceutical policy.

Participation is, therefore, preceded by the signing of a letter of intent by the Minister(s) of the candidate country who is responsible for pharmaceutical policy regarding 'Cross Border Collaboration on Pharmaceutical Policy' explicating/stating the scope and nature of the participation.

Participating countries can end their membership at any time, but must continue to respect the

explicit and implicit confidentiality conditions and agreements which were applicable during their membership.

Participating countries will consider the current collaboration as an open partnership. Membership of the Initiative is open to EU Member States and other interested countries. The conditions of expansion are as follows:

1. Consensus among the current participating countries is a prerequisite for expansion should a positive response be made towards a membership application;
2. The current Collaboration Initiative should, therefore, be considered to be sufficiently mature and robust in its functioning by the current participating countries to absorb the expansion;
3. Given the nature and extent of the collaboration, there are several aspects to be taken into account:
 - A shared view on the current threats to affordability and access to innovative medicines;
 - A shared view on the added-value of international collaboration in the domains targeted by this Initiative;
 - The economic position, average income and/or purchasing power of the potential new participating country compared to that of the current participants;
 - The degree to which the pharmaceutical markets and overall policy frameworks (overall health care and pharmaceutical systems) are comparable;
 - Willingness to provide sufficient resources according to the capacities of the Member.

5.2 Membership options and expectations

Members are expected to operate within their political mandate as agreed upon in the Letter of Intent. This implies responsibility, loyalty and accountability regarding the activities of the initiative, joint communication and outcomes.

This holds particularly true for investments made and/or promised by the participating country, for instance in terms of human resources.

The Members can determine the scope of their voluntary participation to include one, several or all four areas of collaboration. The extent and role of the participation in the specific collaboration with individual participating countries will be clearly stated in the co-signed letter of intent.

In accordance with its political mandate, each member can determine the nature (or role) of its participation: from active contribution/participant to observer. This role can change over time, preceded by a signed amendment to the letter of intent.

Voting power in the Steering Committee is limited to both the four founding Members and to those Members who have committed to collaborating within the Initiative to the fullest extent. Members participating in selected Domain Task Forces can be invited to attend as Observing Members of the Steering Committee.

All Members have voting powers in the Domain Task Forces that they participate in.

5.3 Responsibilities and resources

Although the nature of the participation is voluntary, it will still require active participation in the fields that the countries participate in. Participants will confirm the extent of their contribution of resources (financially and/or in-kind) at the beginning of each calendar year. This confirmation will be documented in the minutes of the first meeting held by the steering committee in that year. If needed, adaptations during the year will be documented.

Member States will cover the travel and/or accommodation costs incurred for attending meetings.

Resources that could be made available to the Initiative:

- Brain power: active participation in meetings;
- Labour: in principle, participants will contribute in kind;
- Meeting space: meetings will be hosted by participating countries.
 - The Member State hosting the face to face meeting will provide the necessary infrastructure (meeting rooms, technical/logistic support and catering) for the meeting;
- Communication: Member States will cover their own communication costs;
- Financial contributions: participation in certain projects may require a voluntary financial contribution to be made to cover operational costs, e.g. costs of additional research or IT infrastructure. The division of these costs will be determined among the participants.
 - No financial contributions will be required until further notice.

6 Internal transparency: Definition and expectations

In the spirit of the collaboration, transparency between members is, and remains, an essential goal. Each Member State is, however, entitled to request that confidentiality be maintained in regard to any oral statements, or any written material, that concerns the collaboration's activities, projects and procedures or those of individual Member States.

7 Public Access

Members of the Initiative value public access to documents that are composed and shared by the Initiative. Therefore the General Terms of Reference are publicly available.

However, given the delicate nature of the collaboration, all meeting agendas, minutes, working plans and working documents are considered to be of strategic importance to the Members of the Initiative. They are, therefore, confidential and only to be shared among partner institutions of the collaboration until the Steering Committee has decided whether they are to be published.

Countries will agree on separate confidentiality agreements for those aspects of the Collaboration Initiative which, because of the nature of the work, require confidentiality.

8 Review and planning

The Initiative will regularly review its progress and results in order to both critically reflect on the process/outcome balance and make recommendations for adjusting the work accordingly. The Initiative will chart its progress against agreed timelines.

- The first meeting of each new calendar year will be used to reflect on the outcomes and to set milestones for the upcoming period;
- Each Domain Task Force will perform a review based on the previous annual work planning;
- A review and planning document will be drafted by the Steering Committee according to written reviews provided by each Domain Task Force;
- This document is to be approved by the participating countries of the Steering Committee.

9 Conflict resolution

Incidents, jeopardizing, harming or violating the general principles as described in the Terms of Reference, the Working Agreements of the Domain Task Forces and/or specific agreements on confidentiality, will be reviewed by the Initiative Steering Committee. If deemed necessary, and specifically if the functioning of the Initiative is likely to be compromised, the conclusions of the review and recommendations of the Initiative Steering Committee will be submitted to the appropriate political level.

10 Working Methods

10.1 Introduction

The Initiative Steering Committee will be responsible for the overall governance of the Initiative.

The activities/projects/pilots within the four different areas of the Initiative will be performed by dedicated Domain Task Forces. These Domain Task Forces can be supported by ad hoc Working Groups if necessary (for instance for the elaboration of a Joint HTA report or a joint negotiation).

10.2 Overall coordination

10.2.1 Setup

The overall, day to day coordination of the Initiative will be rotated among participating countries within the Initiative Steering Committee. The duration of this coordination will be decided by the Initiative Steering Committee.

Each country will appoint a Country Coordinator (CoCo) who will be the single point of contact in that country for any matters regarding the Initiative.

The Country Coordinator of the coordinating country carries out the daily operations of the Collaboration Initiative assisted by his or her fellow Country Coordinators. This coordination team prepares meetings, handles day-to-day issues and provides external communication.

The Coordinator chairs the meetings of the Initiative Steering Committee, and the plenary meeting, and assumes the responsibilities of the Secretariat for the Initiative Steering Committee by providing the formal invitations for the meetings, lists of attendees (and affiliations), formal agendas for the meetings and minutes of the meetings.

10.2.2 Appointed representatives

One of the representatives of each Member State will function as a Country Coordinator for that Member State and be responsible for the coordination of the internal communication (within the Initiative).

This Country Coordinator will guarantee the availability of an updated list of all the participants (names and contact details) of the Member States in the different Domain Task Forces and in the

Initiative Steering Committee, to allow efficient communication between participants on issues and topics that specifically concern them.

The Country Coordinator will also be the custodian of organisational information related to common projects, such as the calendar/timeframe and/or milestones of an ongoing project.

The Country Coordinator is, therefore, not responsible per se for the dissemination of all information within the Initiative. In this regard however, the Initiative Steering Committee can charge the Country Coordinator, with a specific task.

The Country Coordinator of each Member State will also be the public contact point for companies and for any external solicitations made to that Member State.

10.3 Initiative Steering Committee

10.3.1 Role

The Initiative Steering Committee will ensure that the overall scope, the objectives, the deliverables, the functioning and the Terms of Reference of the Initiative are adhered to. It does this on a technical, as well as a political mandate. It also coordinates the Domain Task Forces.

10.3.2 Responsibilities

The Initiative Steering Committee has the following responsibilities:

- Overall decision making power, based on a political mandate;
- Integral oversight of the initiative;
- Adoption of the Terms of Reference, the activities/projects/pilots of the Domain Task Forces and their prioritisation and timing;
- Setting timeframes and milestones for the collaboration as a whole;
- Coordination, mandate and progress monitoring of the Domain Task Forces;
- Preparation of decisions to be made at a (national) political level;
- Maintaining a Communication Protocol for external communication on matters concerning the Initiative;
- Decisions about expansion of the Initiative.

10.3.3 Political Mandate

The Initiative Steering Committee acts on a clear political mandate of the participating Member States. This mandate is derived from the Letters of Intent, signed by the responsible Minister of each Member State.

For all matters which require explicit political approval or which exceed the agreed political mandate contained in the Letters of Intent, the Steering Committee will prepare a joint proposal to be approved by all the Ministers of the countries represented in the Initiative Steering Committee. Examples of these situations are:

- Change of structure, methodology or scope of the Collaboration Initiative;
- Expansion of the Initiative;
- Outline of Communication Protocols;
- A significant demand for (financial) resources;
- Any matters which directly impact policies at a national level.

10.3.4 Setup

The Initiative Steering Committee consists of all four founding countries, complemented by countries which commit to all the collaboration areas of the Initiative. Countries that partly commit to the collaboration will be appointed as Observing Members.

The Steering Committee is set up as follows:

- Chair, performed by the Coordinating Country;
- Two representatives per participating country ('Member'). Representatives will ensure that the limitations/extent of the political mandate of the Member is respected. These Member representatives have decision-making power within the Steering Committee;
- The Chair of each Domain Task Force. Chairs only act as a liaison between the Steering Committee and the respective Domain Task Forces and have no decision-making powers.

The Steering Committee will convene at least three times a year, physically or via video-conferencing. Additional meetings can be organised, in a format which is judged to be best suited for the purpose of the meeting (teleconference, Web based meetings etcetera). The scheduling, timing and agenda of these meetings will be agreed upon by the Initiative Steering Committee.

External experts may be invited by the Initiative Steering Committee to attend meetings on a temporary, ad hoc basis. These external experts will not be considered 'members' of the Initiative Steering Committee; they will contribute as 'advisors' and not participate in decisions taken by the Initiative Steering Committee.

10.4 Domain Task Forces

The activities developed within the four different areas of the Initiative described above will be performed by dedicated Domain Task Forces. This involves the project launch, execution, follow up, closure (results and deliverables) and the reporting.

These Domain Task Forces will function within their own specific Working Agreements, in addition to adhering to the overall Terms of Reference of the initiative. The Working Agreements will be monitored by the Steering Committee.

All Member representatives have an equal vote within the range set by the Working Agreements.

10.4.1 Role

Each Domain Task Force performs its activities according to a clear mission and predefined goals. Their role is to actively set up and carry out collaboration on specific themes.

10.4.2 Responsibilities

The Domain Task Forces have the following responsibilities:

- Performing tasks according to the Working Agreements;
- Defining the goals and deliverables;
- Building collaboration;
- Assessing inter-country limitations and possibilities;
- Carrying out collaborative work;
- Reporting on activities (state of play, deliverables, milestones, Key Performance Indicators, results) and on their functioning (assessment of the processes) in the Initiative Steering Committee;
- Providing the Initiative Steering Committee with proposals for topics for potential collaborative activities, in the format of a prioritised long-list;
- Proposing improvements to facilitate thematic collaboration.

10.4.3 Setup

The Domain Task Force is set up as follows:

- Chair (also member of the Steering Committee);
- The nationally appointed experts from each participating country to take part in the activities/projects/pilots performed within the Domain Task Forces that the Member has chosen to participate in;
- Meeting frequency will be determined by the members of the Domain Task Force;
- Each Member commits to the participation as agreed on in the letter of intent signed by its country.

11 General Assembly

The General Assembly of the Initiative consists of all members of all Domain Task Forces and the Steering Committee. The purpose of a General Assembly is to inform the delegates of members about developments that are taking place within the Collaboration Initiative as a whole. The plenary meeting will be organised at least once a year by the Initiative Steering Committee and presided over by one of the Members of the Steering Committee. The timing and agenda of the plenary meeting will also be decided by the Initiative Steering Committee.

External experts, stakeholders, EU Member States, other countries and interested third parties can be invited by the Initiative Steering Committee.

12 Communication

Communication on the content of the Initiative, the processes within the Initiative, its outcomes (results and deliverables) and the outcomes of the annual review of the Initiative will be coordinated by the Initiative Steering Committee.

Communication on specific topics, in the appropriate formats and with the appropriate tools, can be addressed to the general public, to national and international stakeholders, EU Member States and other countries, and to the pharmaceutical industry as well as individual pharmaceutical companies and interested third parties.

Communication at a technical as well as political level will be conducted according to a consensus-based Communication Protocol. This protocol will be updated by the Initiative Steering Committee at regular intervals.

13 Adoption

These General Terms of Reference were adopted by all participating countries:

- the Kingdom of Belgium
- the Kingdom of the Netherlands (Coordinator)
- the Grand Duchy of Luxembourg
- the Federal Republic of Austria