



# EDQM Network of experts from health regulatory authorities working on borderline products (“EDQM Network on Borderline Products”)

## Terms of Reference

Adopted by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) on 03.12.2025 by written procedure.

These Terms of Reference supersede the *Terms of Reference 2024-2025 – EDQM Network on Borderline Products*.

## 1) Background

Medicinal products are defined in EU legislation and in national laws, as are other product categories. According to established legal practice, the competent authorities in each member State, acting under the powers conferred upon them by national legislation or under the supervision of the courts, are to decide whether a product is a medicinal product or not. As their name suggests, borderline products can be difficult to assign to a specific product category. They are either already on the market or have been manufactured for sale and supply, but the legislative framework under which they are regulated is not clear. This makes it challenging to establish which national competent authority should take the lead at the regulatory level and be responsible for ensuring their safety and for enforcement actions, i.e. removal from the market if they are found to be non-compliant and/or deemed unsafe.

At the end of 2018, the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) and the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED) called for the launch of a joint PC/CMED workshop to address issues related to borderline products. The EDQM Network on Borderline Products was officially established in December 2021 and under the governance of the CD-P-PH in response to the need for a forum where experts working with borderline products could meet, discuss and share knowledge on this important area.

## 2) Governance

The EDQM Network of experts from health regulatory authorities working on borderline products (hereinafter “the Network”) is governed by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH).<sup>1</sup> The CD-P-PH was established by and reports to the Committee of Ministers of the Council of Europe. The CD-P-PH consists of senior officials in ministries and medicines agencies responsible for health policies and for ensuring that medical products are safe for use and effective. It accomplishes its tasks with the help of three subordinate committees of experts whose work focusses on the appropriate use of medicines and on preventing the falsification of medicines and similar crimes. The CD-P-PH’s core mission is to support national competent authorities of the Council of Europe member States in making the medication process safer, more responsible and accessible to all who need it.

The issues outlined above are observed in the context of the various activities for which the three subordinate committees are responsible, thus providing the logical basis for the Network to be governed by the CD-P-PH.

At its 17th meeting on 28-29 September 2021, the CD-P-PH agreed to designate a rapporteur acting as intermediary between the Committee and the Network. The CD-P-PH rapporteur and/or the Chair of the Network regularly reports to the Committee.

Finally, any opinions, agreements or recommendations expressed within the Network are not legally binding on any member.

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<sup>1</sup> See the Terms of Reference of the CD-P-PH, Main tasks, point viii: “maintain a network of experts in borderline products, establish framework to support Co-operation, to provide guidance on procedures of enforcement, and to facilitate the sharing of information”.

### 3) Objectives

The Network was established out of a need to better understand the phenomenon of borderline products and how it impacts the protection of public health and safety. Independently of the product categories involved, there are products that can represent a risk to public health, be it because of bad practices, ignorance or intentional criminal behaviour.

Questions around borderline products always involve at least two product categories – in view of its regulatory framework, the Network will work in the borderline between medicinal products and other categories of products. Borderline questions not including medicinal products are out of scope. In addition, the Network will focus on borderline issues related to compliance with and enforcement of national regulations applying to medicinal products.

It is not the responsibility of the Network to take decisions on classifications – the decision to establish that a specific product is medicinal or not is a national matter. Classification will, however, be discussed within the Network, since it is a prerequisite for any enforcement or supervision action.

Under the authority of the CD-P-PH, the core objectives of the Network shall be:

#### a. INFORMATION-SHARING

The Network shall be a forum for practical and operational information-sharing through open discussions – this can include:

- sharing information regarding borderline issues related to compliance and enforcement of national regulations of medicinal products;
- sharing expertise on specific borderline products or procedures (e.g. a particular group of products representing a risk for public health or a procedure representing a gap in ensuring product safety);
- encouraging exchanges of information/updates with experts from other fields (e.g. medical devices, substances of human origin, cosmetics, food, chemicals);
- sharing information regarding borderline products (e.g. new regulatory developments, innovative solutions, cases of interest);
- informing the CD-P-PH of major trends or changes in borderline matters that could impact its field of competence and alerting the CD-P-PH on issues that require action at committee level.

#### b. CO-OPERATION

- enabling the sharing of best practices, including identification of existing synergies and common practices on regulatory processes;
- establishing best practices and working towards the harmonisation of procedures;
- supporting co-operation between countries, if required with support from the CD-P-PH.

#### c. EXTERNAL ENGAGEMENT AND COMMUNICATION

- co-operating with relevant intergovernmental committees (at the EDQM) on matters of convergence, sharing of new developments and trends in fields other than medicines;

- raising awareness on risks related to borderline products and on new developments and trends that represent challenges to regulatory oversight from the borderline perspective.

#### 4) Composition of the Network

##### Members

Representatives from health regulatory authorities of Council of Europe member States with a background in medical products can become members of the Network (<https://www.coe.int/en/web/portal/46-members-states>). Each country is entitled to one vote, irrespective of the number of representatives appointed.

Considering the scope of competence of the Network, with focus on borderline issues involving medicines, members must have the relevant competence and preferably come from the relevant health authority. Members should have hands-on operational experience in order to be able to contribute constructively to the Network. Representatives may also belong to another relevant authority provided that they possess the relevant competencies and expertise as described above.

##### Invited guests

The Network may invite to its meetings and/or contribute to its activities, on an ad hoc basis, experts from fields of competence other than medicines or from other relevant groups or organisations.

##### Budgetary considerations

The sending authorities of the member States will bear the travel and subsistence expenses for their representatives' participation in the meetings of the Network. The travel and subsistence expenses of the Chair and the Advisory Group for participating in the meetings of the Network will be borne by the EDQM budget.

#### 5) Working methods

The official language of the Network shall be English.

The Network should hold at least one in-person and one online meeting per year. These meetings are not public, and attendance will be restricted to members and invited guests. The Secretariat shall ensure appropriate conduct of meetings and, in close consultation with the Chair and Advisory Group, shall draw up a draft meeting agenda.

With a view to reaching its objectives, the Network may arrange consultations, in particular with international and European organisations working in a field of competence other than medicines. The Network may also consider holding regular dedicated meetings with relevant organisations to facilitate interaction.

Invited guests may also be considered for ad hoc participation in working groups, should the need arise, and provided that the involvement of guests is of benefit to the overall goal of the activity.

Optimal use should be made of information technology, including between meetings. This includes for the purpose of exchanging information and best practices, working on and finalising documents and taking decisions.

All members may propose projects and work items to the Network for consideration. These proposals can come through formal submissions in writing or through presentations at meetings.

#### a. THE CHAIR

The Network shall elect a Chair with the following responsibilities:

- conducting proceedings and summing up the conclusions whenever he or she thinks necessary;
- when necessary, calling to order a speaker who departs from the subject under discussion or from the Network's Terms of Reference;
- providing leadership to the Network;
- representing the Network in meetings of intergovernmental bodies, at congresses and at other relevant fora.

The Chair also retains the right to speak and to vote in his or her capacity as a member of the Network.

If absent, the Chair shall be replaced by another member of the Advisory Group.

The term of office of the Chair shall be 2 years, renewable once.

#### b. THE ADVISORY GROUP

The Network shall appoint an Advisory Group to assist the Chair, consisting of four members of the Network.

The functions of the Advisory Group are to:

- ensure meetings are planned effectively and conducted according to objectives and that matters are dealt with in an orderly, efficient manner;
- regularly review the Network's performance and needs and encourage and support the enlargement of its geographical reach;
- ensure continuity between meetings as necessary;
- carry out other additional specific tasks delegated to it by the Network;
- assist/replace the Chair when required.

No decision on substantive issues shall be taken by the Advisory Group on behalf of the Network.

The term of office of the members of the Advisory Group shall be 2 years, renewable once.

#### c. ELECTIONS & DECISION-MAKING PROCESS

When taking decisions, every effort should be made to reach a consensus. Should a vote be required, each member country of the Network shall have one vote. Decisions shall be taken by a two-thirds majority of the votes cast. For the purposes of these rules, "votes cast" shall mean the votes of members cast for or against. Members who abstain shall be regarded as not having cast a vote. This applies to decisions in relation to the Network's work programme.

More specifically:

- Election of the Chair shall require a two-thirds majority of members entitled to vote at the first ballot, a simple majority of members entitled to vote at the second ballot and the highest number of votes at the third ballot.
- Members of the Advisory Group shall be appointed in the same manner as the Chair and elections shall take place every 2 years, where half (two) of the members shall be replaced, with each member being elected for a mandate of up to 4 years. In the event an Advisory Group member resigns from his or her post before the end of the full mandate (4 years), the position will be filled at the next regular election.
- Regarding other decisions, in exceptional cases and due to time constraints, the Advisory Group may have recourse to the tacit approval of all the members of the Network through electronic communication, in order to expedite decisions taken by the Network.

## 6) Secretariat

The Secretariat is provided by the EDQM's Intergovernmental Committees and Networks Department (ICND). The Secretariat shall provide all administrative support necessary to co-ordinate the activities of the Network. On behalf of the Network, it shall:

- liaise with the relevant national authorities and, where applicable, with international organisations and relevant bodies, groups or associations within the framework of the activities related to the Network;
- organise the annual meetings and any other specific meetings and be responsible for establishing meeting reports and taking any necessary follow-up measures ensuing from decisions taken during the meetings;
- assist in fulfilling the responsibilities of the Network.

## 7) Confidentiality status

Product and case data and related information exchanged within the Network via "information requests"<sup>2</sup> or during Network meetings is hosted on a secure EDQM server, accessible only to Network members. Authorised users are responsible for protecting their login information as well as any other data they may have downloaded or otherwise obtained from the Network.

Any documents shared within the Network or generated by the Network or the Secretariat or received from third parties in the context of the Network's activities and shared with the Network's members are not public, unless otherwise decided by the Network. These documents shall not be disclosed to any entity not involved in the Network's activities (e.g. not outside a member's own national authority), unless the Network decides otherwise, or unless they are in the public domain or have been received, without restriction, via other channels.

If all Network members involved in the production of a document agree unanimously, data and/or the document or parts thereof may be published on behalf of the Network or the working group concerned.

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<sup>2</sup> "Information requests" is the term used for cases when a Network member uses the Network contact list and sends out a request for information on a specific product or similar; the request is sent via e-mail, but the response is collected on a secured platform.

In such cases, the group concerned/Network shall determine whether it is necessary to anonymise data sets/parts of text depending on the forum for publication.

## 8) Review of Terms of Reference

The Terms of Reference will be reviewed and approved as needed following recommendations from the Network, the Advisory Group and/or the CD-P-PH.

The Secretariat will be responsible for co-ordinating the review of the Terms of Reference.

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