Terms of Reference 2024-2025 – EDQM Network on Borderline Products

Purpose

The importance of having a broad international network should be highlighted and the benefits of getting easily and timely relevant information through a contact network. Informal exchanges on best practices, new developments, good experiences, and other help finding alternative solutions to issues encountered on a national level and may even present the first steps towards harmonisation of procedures. With this in mind, it is of advantage to have a group bridging between different competences. Finally, it should also not be forgotten that this group covers countries under the Council of Europe, thus also countries outside the EU.

Scope

- The network is to work in the borderline between medicinal products and other categories of products. Issues not including the demarcation to medicinal products are out of scope.
- The network is primarily to work with borderline issues related to enforcement or supervision of the legislation for medicinal products.

Legal framework

- The network is established under the framework of European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) at EDQM and regularly reports to this committee.
- The decision to establish that a specific product is medicinal or not is a national matter. The network shall not express an official opinion on specific products.
- Opinions or recommendations expressed within the network are not legally binding to any member.

Tasks

- Sharing of information regarding borderline products (e.g. new regulatory developments, innovative solutions, cases of interest, other).
- Sharing of information regarding enforcement procedures for work with borderline products.
- Forum for discussions regarding specific borderline products or procedures (e.g. a particular group of products like cannabis products, for instance).
- Encourage information exchange / updates with experts from other fields (e.g. medical devices, chemicals, biocides, etc)
- Support cooperation between countries.

- Support CD-P-PH and its subcommittees in specific tasks related to borderline products (e.g. WG on "Best practices on borderline products in the enforcement of medical product legislations").
- Maintain an archive of information requests and resulting exchange of information
- Foresee ad-hoc workshops on topics of interest

Working methods

- Manage and maintain a list of contacts (email) for information sharing
- Physical and digital meetings, preferably yearly (i.e. one physical and one virtual meeting per year)
- For the beginning, the preferred way of interacting is via email (e.g. information request using dedicated request form sent to network contact list)
- the ACT platform (act.edqm.eu) is being used for archiving of information requests and other network related documents and information.

Members of network

Considering the scope of competence of this network (see above) 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 constructively contribute to this network. Representatives may also belong to another relevant authority provided that they possess the relevant competencies and expertise as described above. Working language is English.

Finally, representatives from all Council of Europe countries can become members of this network (https://www.coe.int/en/web/portal/46-members-states).

Management Team

The network agreed that for the good functioning of the group it would help to establish a Management Team. The **role** of this management team would be to:

- Plan the meetings, their chairing, and manage the group's work program
- Regularly monitor and assess the group's needs
- network towards external contacts of interest
- take up a representative role (i.e. to represent the network in other fora)

It is proposed that the management team should be composed of 5 members. Any member of the network can become part of the management team. The position should be held for a **duration of 2 years**. New candidates can be suggested when a position becomes vacant and should be confirmed through **approval by the network**.

For geographical balance, it is however recommended that not more than one person from one country should be part of the management team.

The Management team works as a group and no specific roles have been decided for the moment, except that **a Chair** should be identified. The other management team members act as Vice-Chair.

Members of the Management team as approved by the network for the period **2024/2025**:

Name	**Country**	**Authority**
Lisbeth Hemmingsen	Denmark	Danish Medicines Agency
Anne Vestrheim	Norway	Norwegian Medicines Agency
Tomas Nilsson - Chair	**Sweden**	**Swedish Medical Products Agency**
Myrtha Naef	Switzerland	Swissmedic
Lynda Scammell	UK	MHRA