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EUROPEAN COMMITTEE ON PHARMACEUTICALS AND PHARMACEUTICAL CARE
(PARTIAL AGREEMENT) (CD-P-PH)

# Methodological Guide to Select Medicines at Risk of Shortage - Terms of Reference

Adopted by the CD-P-PH

**Distribution**
**For action :**
CD-P-PH European Committee on Pharmaceuticals and Pharmaceutical Care

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# Elaboration of a Methodological Guide for Selecting Medicines at Risk of Shortage

## Terms of Reference (ToR) of the Methodological Guide Working Group

### Type of committee

Subordinate working group of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH)

**Terms of reference valid from:** 1 January 2024 until 31 December 2026

### Main tasks and expected results

Under the authority of the CD-P-PH, the Methodological Guide Working Group (hereinafter referred to as the Working Group) will draft a methodological guide for identifying and selecting medicines at risk of shortage that can be prepared as standardised stock preparations (deliverable no. 9 of the CD-P-PH 2024-2027 ToR). This guide will support national competent authorities and healthcare professionals in the identification and selection of medicines that can be in short supply under certain circumstances and that can be prepared in hospital and/or community pharmacy settings, taking into account applicable standards established by international and/or national organisations. In addition, the methodological guide may be used by the working group in charge of developing the European Drug Shortages Formulary (i.e. a compilation of texts (monographs) describing methods for the preparation and quality control of standardised, unlicensed pharmaceutical preparations that could be used as a temporary replacement when licensed medicinal products are unavailable and whose active substances are not affected by a shortage).

### Composition

*Members:* national competent authorities (NCAs) of the states parties and states with observer status to the Convention on the Elaboration of a European Pharmacopoeia were invited to nominate a representative belonging to relevant health authorities or institutions dealing with medicine shortages at national level. To ensure alignment and synergy with other authorities working on shortages, the Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) Task Force on Availability of authorised medicines for human and veterinary use (TF AAM), the Medicine Shortages Single Point of Contact Working Party (SPOC WP) and the EU Structured dialogue on security of medicines supply were also invited to nominate a representative. To ensure broad expertise and effectiveness, relevant healthcare professionals' associations and academia were also invited to do so.

*Desirable qualifications of the Working Group members*: ideally, Working Group members should have expertise in one of the following domains: public health, pharmaceutical regulation, medicine shortages or pharmacy preparations.

*Validation of the list of Working Group members*: the Working Group should be composed of up to 12 members. The EDQM Secretariat reviewed and approved the final list of members.

*Secretariat:* the EDQM will provide the technical, administrative and scientific secretariat for the Working Group.

**Working methods**

The Working Group should carry out its programme of activities using scientific and public health-oriented approaches.

With a view to avoiding duplication of work and taking advantage of synergies, the Working Group should take due account of initiatives carried out at international and European level in the area of medicine shortages and, where appropriate, will establish co-operation with stakeholders working in this field (such co-operation may also take the form of a consultation).

The Working Group should make use of virtual meetings and e-mail communication and, when needed, face-to-face meetings.

The Working Group appointed a rapporteur from among its members who is responsible for ensuring and contributing to appropriate co-ordination of the Working Group (in concert with the Secretariat) and for interacting and liaising with the CD-P-PH.

Where appropriate, progress towards the Working Group's goal should be presented by the rapporteur at meetings of the CD-P-PH for comment and endorsement. The final deliverable will be submitted to the CD-P-PH for approval prior to publication.

Where appropriate, the Working Group should liaise with and ensure alignment with the work of the working group in charge of developing the European Shortages Formulary.

**Budgetary information**

The EDQM should bear the travel and subsistence expenses for the Working Group members' participation in one face-to-face meeting per year. When an NCA or stakeholder designates more than one member, the travel and subsistence expenses of only one representative could be covered by the EDQM.