



***INFORMAL COMMISSION EXPERT GROUP ON
MEDICAL COUNTERMEASURES (MCM) EU CLASSIFIED INFORMATION (EUCI)
TERMS OF REFERENCE***

1. BACKGROUND

In 2021, the European Union established the EU4Health Programme¹ to complement the human health policies of EU Member States, including by improving the availability, accessibility and affordability of medical countermeasures (MCM) in the Union, and supporting innovation regarding such products. Under this objective, the Commission has recently reinforced its commitment to developing novel medical countermeasures (MCM) against chemical, biological, radiological and nuclear (CBRN) threats in light of the evolving geopolitical and security risks. That is why, under the EU4Health 2025 Work Programme², the Commission's Health Emergency Preparedness and Response Authority ('DG HERA') provided for a dedicated action³ to support the development and deployment of new medicinal products, diagnostics, and personal protective equipment to address CBRN-related challenges.

Unlike the Horizon Europe Regulation⁴, which establishes comprehensive security provisions applicable to all actions under the Commission's research and innovation programme, other funding instruments, such as EU4Health, do not include specific provisions in their basic acts governing the handling of projects that raise comparable security-related concerns. Therefore, and in line with Commission Decision (EU, Euratom) 2015/444⁵, it is now necessary to establish a dedicated expert group to assist the Commission with a view to ensuring that actions implemented outside Horizon Europe are subject to similar security standards.

Furthermore, the Commission adopted in July 2025, the EU Medical Countermeasures Strategy⁶, which sets out new initiatives on MCMs for dual purposes beyond research and

¹ [Regulation \(EU\) 2021/522 of the European Parliament and of the Council of 24 March 2021](#) establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014

² Commission Implementing Decision ([C\(2025\) 5148 final](#)) on the financing of the programme for the Union's action in the field of health ('EU4Health programme') and the adoption of the work programme for 2025

³ "CP-g-25-01 – Call for proposals to support innovative medical countermeasures for CBRN threats"

⁴ [Regulation \(EU\) 2021/695 of the European Parliament and of the Council of 28 April 2021](#) establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013

⁵ [Commission Decision \(EU, Euratom\) 2015/444 of 13 March 2015](#) on the security rules for protecting EU Classified Information

⁶ [COM\(2025\) 529 final](#)

innovation, including on the procurement of MCM products with civil–military potential and the preparation of a shortlist of essential medical countermeasures for armed aggression.

Considering the Commission’s expanding scope of activities related to MCM that may involve EU classified information (EUCI), this expert group will support the Commission in ensuring a robust security framework across the full MCM life cycle, including intelligence, research and innovation, manufacturing, procurement, stockpiling and market deployment. This expert group is expected to operate for unlimited duration.

2. SUBJECT MATTER

The group of experts on ‘Medical Countermeasures EU Classified Information’ (‘the group’) is set up.

3. TASKS

The group’s tasks shall be:

- 1) to assist the Commission⁷ in strengthening the security framework for the entire MCM value chain, which will ensure the safeguarding of Sensitive Non-Classified Information (SNC) and EU classified information (EUCI) throughout intelligence sharing, research and innovation, manufacturing, procurement, and logistics actions;
- 2) in the framework of the EU MCM Strategy, to assist the Commission in enhancing its capabilities, in synergy with other existing structures, in all security dimensions of MCM development and deployment;
- 3) to provide security guidance to the Commission regarding its efforts and initiatives to guarantee the availability and accessibility of MCM, such as the identification, assessment, and prioritisation of threats to health, as well as the development and deployment of MCM;
- 4) to provide the Commission with opinions on security aspects related to the coordination and cooperation with Member States and other relevant stakeholders on questions relating to the implementation of Union legislation, programmes and policies in the field of MCM for public health emergency preparedness and response;
- 5) to support exchange of security good practices and experiences regarding MCM, including dual-use MCM, development and deployment across the different sectors (e.g. civil, military, industrial, among others).

⁷ Such as DG SANTE, DG ECHO, DG DEFIS, DG HOME or DG RTD.

4. CONSULTATION

The Commission may consult the group on any matter relating to:

1. Conducting security scrutiny assessments:
 - for proposals for grants, tenders, or other implementation instruments under the EU4Health or other programmes for MCM and public health emergency preparedness and response-related actions, including advising on specific security and risk mitigation measures in relation to classified information and/or projects' results.
 - of private sector companies involved in, or set to be involved, in the implementation of EU-funded MCM initiatives (such as joint or central procurement or stockpiling actions, capacity reservation projects, or specific flagships, such as the RAMP UP⁸ initiative), or any other companies critical in the MCM value chain, such as actors involved in the development, production, or supply of MCM.
2. Providing, where needed, a resource pool of security authorities from which the Commission can draw experts to support specific activities within the scope of the group's tasks, including (apart from the security scrutiny assessment referred in point 1) security sensitive projects' monitoring and follow-up or pre-emptive consideration of security provisions in new initiatives.
3. Facilitating the secure exchange of information:
 - related to national and EU level procurement, capacity reservation, and stockpiling of MCM;
 - related to the Commission's 'Health Threat Prioritisation Assessment for Medical Countermeasures' and other MCM-related preparedness measures at Member State and EU levels;
 - on Member State response plans for serious cross-border threats to health, including CBRN and civil-military cooperation for public health emergency preparedness and response;
 - on MCM-related projects funded by Member States or by the Union, enabling data sharing and secure systems interoperability;
 - among Member States and the EU institutions and agencies on the availability and accessibility of MCM, including on supply chain and other dependencies' risks;
4. Informing and collaborating on MCM EU-level initiatives that may involve security risks, including any preparatory work (e.g. pipeline or market analysis).

⁸ Rapid Agile Manufacturing Partnerships for Union Protection, to be launched by DG HERA under the EU MCM Strategy

5. MEMBERSHIP

1. Members shall be Member States' authorities and national authorities from EEA/EFTA countries which have Security of Information Agreement with the EU.
2. Members shall nominate two representatives on a permanent basis, who shall:
 - provide high level expertise in the security domains related to public health, MCM research, development and/or deployment, industry, or civil-military affairs;
 - hold a valid Personnel Security Clearance (PSC) at the **SECRET UE/EU SECRET** level or an equivalent national security clearance, authorising them to access EUCI up to this level.
3. Members may replace nominated representatives at their own initiative, or at the request of the Chair, if the Chair considers that representatives do no longer meet the criteria referred to in paragraph 2.

6. CHAIR

1. The group shall be chaired by a representative of DG HERA.
2. DG HERA may delegate the chairing of the group to a representative of another Commission service when the group is requested to support or advise that service.

7. OPERATION

1. The group shall act at the request of the Commission, in compliance with the Commission's horizontal rules on expert groups⁹ ('the horizontal rules').
2. Meetings of the group shall, in principle, be held on Commission premises or virtually depending on the circumstances. When required, meetings shall be held in a secured environment.
3. DG HERA shall provide secretarial services. When acting at the request of another Commission service, it shall do so with the support of that service. Commission officials and other servants from departments with an interest in the discussions or the issues, and holding (when required) an appropriate PSC, may also attend meetings of the group.
4. Minutes on the discussion on each point on the agenda and on the opinions delivered by the group shall be meaningful and complete. Minutes shall be drafted by the secretariat under the responsibility of the Chair.
5. As far as possible, the group shall adopt its opinions, recommendations, or reports by consensus. In the event of a vote, the outcome of the vote shall be decided by simple majority of the members. Members who have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the opinions, recommendations, or reports.

⁹ C(2016) 3301, Article 13.1.

6. Appropriate communication and information systems (CIS) and encryption tools will be employed for the exchange and storage of SNC and EUCI.
7. Subject to the Chair's approval, deliberations on non-classified and non-sensitive matters may be made public. Conversely, for sensitive or classified topics, deliberations will be handled securely.

8. SUB-GROUPS

DG HERA may set up sub-groups for the purpose of examining specific questions on the basis of terms of reference defined by DG HERA. Sub-groups shall operate in compliance with the horizontal rules and shall report to the group. They shall be dissolved as soon as their mandate is fulfilled.

9. INVITED EXPERTS

1. DG HERA may invite experts with specific expertise with respect to subject matters on the agenda to take part in the work of the group on an *ad hoc* basis. These could be e.g. representatives of professional or scientific bodies or non-governmental organisations with recognised experience in disciplines related to their work, to cooperate in specific tasks and to take part in the relevant activities of the group.
2. Unless duly justified, such experts or representatives should hold a valid PSC at the SECRET UE/EU SECRET level or possess an equivalent national security clearance.

10. OBSERVERS

1. Individuals, organisations and public authorities other than Member States' authorities and national authorities from EEA/EFTA countries referred to under Point 5 may be granted an observer status, in compliance with the horizontal rules, by direct invitation.
2. Organisations and public authorities appointed as observers shall nominate their representatives.

Representatives may be asked to hold a valid PSC at the SECRET UE/EU SECRET level or possess an equivalent national security clearance, authorising them to access EUCI up to this level.
3. Observers and observers' representatives may be permitted by the Chair to take part in the discussions of the group and its sub-groups and provide expertise. However, they shall not have voting rights and shall not participate in the formulation of recommendations or advice of the group or its sub-groups.

11. RULES OF PROCEDURE

On a proposal by and in agreement with DG HERA, the group shall adopt its rules of procedure by simple majority of its members, on the basis of the standard rules of procedure

for expert groups, in compliance with the horizontal rules¹⁰. Sub-groups shall operate in compliance with the group's rules of procedure.

12. PROFESSIONAL SECRECY AND HANDLING OF CLASSIFIED INFORMATION

The members of the group and their representatives, as well as invited experts and observers, are subject to the obligation of professional secrecy, which by virtue of the Treaties and the rules implementing them applies to all members of the institutions and their staff, as well as to the Commission's rules on security regarding the protection of Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443¹¹ and 2015/444¹². Should they fail to respect these obligations, the Commission may take all appropriate measures.

13. TRANSPARENCY

1. The group and its sub-groups shall be registered in the Register of Commission expert groups and other similar entities ('the Register of expert groups').
2. As regards the group and sub-groups composition, the following data shall be published on the Register of expert groups:
 - the name of Member States' authorities;
 - the name of third countries' authorities;
 - the name of observers.
3. All relevant, non-sensitive or non-classified documents, including the agendas, the minutes and the participants' submissions, shall be made available on the Register of expert groups. In particular, DG HERA shall publish the agenda and other relevant non-classified and non-sensitive background documents in due time ahead of the meeting, followed by timely publication of minutes. Exceptions to publication shall only be possible where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001¹³.

Documents containing SNC or EUCI shall be communicated to the group members using appropriate communication and information systems (CIS) and encryption tools.

¹⁰ See Article 17 of the horizontal rules.

¹¹ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

¹² Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

¹³ These exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process.

14. MEETING EXPENSES

1. Participants in the activities of the group and sub-groups shall not be remunerated for the services they offer.
2. Travel and subsistence expenses incurred by participants in the activities of the group and subgroups shall be reimbursed by the Commission. Reimbursement shall be made in accordance with the provisions in force within the Commission¹⁴ and within the limits of the available appropriations allocated to the Commission departments under the annual procedure for the allocation of resources.

Done in Brussels, on 6 May 2026.

¹⁴ Commission Decision C(2007)5858