

**Working arrangements
between
the European Health Emergency Preparedness and Response
Authority (HERA)
and
the European Medicines Agency (EMA)**

**on
health emergency preparedness and response in the area of
medical countermeasures**

These working arrangements are established between the Commission's Health Emergency Preparedness and Response Authority, hereinafter referred to as HERA, and the European Medicines Agency, hereinafter referred to as EMA, collectively referred to in these working arrangements as the 'Sides'. DG SANTE, as the lead partner DG for EMA, will be kept informed of all relevant activities carried out under these working arrangements which fall under DG SANTE mandate. To this end, contact points will be established in DG SANTE, following the signature of the working arrangements.

1. PURPOSE AND SCOPE

The purpose of these working arrangements is to coordinate the work of the Sides in support of health emergency preparedness and response in the area of medical countermeasures.

As regards HERA, the present cooperation is intended to cover the mission and tasks of HERA as set out in Article 2 of Commission Decision C(2021) 6712.

As regards EMA, the present cooperation is intended to cover the mission and tasks of EMA as set out in Regulation (EC) No 726/2004 and Regulation (EU) 2022/13.

2. GENERAL MODALITIES OF COOPERATION

2.1 Meetings and contact persons

The Sides intend to organise meetings at management level, with the aim of ensuring the overall supervision and coordination of the activities carried out under these arrangements. Meetings at operational level may also be organised on a regular basis, where appropriate.

Each Side intends to designate a contact person responsible for the supervision and coordination of activities under this arrangement and to establish and update a list of contact persons with regard to the areas of cooperation referred to in point 3.

2.2 Identification and access to information systems and tools

The Sides intend to identify the information systems, and other IT tools of interest that support the work of the Sides in the determined areas of cooperation. Where appropriate, in particular in order to avoid duplication of efforts, the Sides aim at providing each other access to them. They intend to facilitate access by mutually identified means and methods, including interoperability.

2.3 Ad-hoc exchange of expertise

The Sides intend to exchange ad hoc scientific expertise related to the assessments of serious cross-border threats to health and intelligence with regard to medical countermeasures.

The Sides may arrange for a dedicated training program to exchange expertise.

3. AREAS OF THE COOPERATION AND INFORMATION EXCHANGE

The Sides identified the following areas of collaboration to fulfil the Sides' respective missions and tasks:

- Assessment of [serious cross-border] threats to health and intelligence gathering relevant to medical countermeasures
- Identification of medical countermeasures and priority research areas
- Identification of vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures
- Coordination, in relation to medical countermeasures, in the event of recognition of a public health emergency
- Contribution to reinforcing the global health emergency preparedness and response architecture

3.1. Assessment of serious cross-border health threats relevant to medical countermeasures

The Sides intend to share relevant data of their intelligence gathering and threat assessment activities in the area of medical countermeasures, including on priority health threats.

EMA intends to inform and involve HERA, as appropriate, in discussions and collaborations with international organisations or authorities of third countries regarding horizon scanning and threat assessment as well as the development and/or access to medical countermeasures. This may involve the sharing of information on serious cross-border threats to health and relevant medical countermeasures, where the Sides are in a position to share such information.

3.2 Identification of medical countermeasures and priority research areas

The Sides intend to exchange information that is relevant to identify the medical countermeasures that are deemed necessary to ensure a high level of preparedness and an appropriate response to serious cross-border threats to health. In this context, the Sides intend to cooperate in order to identify the clinical needs and priority research areas as well as exchange information resulting from their respective horizon scanning activities as regards identification of promising medicinal products and medical devices, authorised, CE marked or in development, which can be used during a public health emergency.

3.3 Vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical of medical countermeasures

The Sides intend to work closely on the availability of medical countermeasures to support their respective missions, aiming at avoiding redundancies or gaps.

In particular, EMA intends to provide assistance to HERA to identify risks of shortages for specific medical countermeasures.

The Sides intend to share with each other relevant information regarding the quality, safety or efficacy of medical countermeasures.

The Sides aim at mutual reliance on defined datasets from identified databases to avoid duplications.

The Sides intend to facilitate interoperability of their IT tools in accordance with the ambitions of the European Interoperability Framework. In particular, HERA aims at ensuring, to the extent possible and if applicable, the interoperability of its Intelligence Gathering Platform with existing or future EMA IT systems.

3.4 Coordination, in relation to medical countermeasures, in the event of the recognition of a public health emergency

The Sides intend to designate specific contact points and establish specific working methods for the coordination of their actions in relation to medical countermeasures in case of a public health emergency at Union level.

3.5 Contribution to reinforce the global health emergency and preparedness architecture in the area of medical countermeasures

The Sides intend to share information on exchanges with third country partners or international organisations on the matters relevant to the other Side's roles in preparedness and response to serious cross-border threats to health in the area of medical countermeasures, where the Sides are in a position to share such information.

In particular, HERA intends to inform EMA on its activities with regard to collaboration with global partners to address international supply chain bottlenecks and expanding global production capacities to contribute to the availability and accessibility of medical countermeasures. HERA intends to keep EMA informed on its actions to provide support to low- and middle-income countries to develop local manufacturing and distribution capacities of relevant medical countermeasures.

4. CONFLICTS OF INTEREST OF INDIVIDUAL EXPERTS

HERA acknowledges the principles of EMA's policy on handling competing interests of scientific committee members and experts and intends to respect that policy when interacting with EMA, and to take sufficient safeguards to avoid any perception of conflict of interest in view of EMA's role in the authorisation of medicinal products.

5. NON-BINDING NATURE

These working arrangements are not intended to create any legal rights or obligations in respect of either of the Sides and do not have any financial implications on either Side.

Done at Brussels

For HERA

For EMA

For DG SANTE as a partner DG of EMA