

**Working arrangements between
the Health Emergency Preparedness and Response Authority
(HERA)
and
the European Centre For Disease Prevention and Control
(ECDC)**

**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 Centre for Disease Prevention and Control, hereinafter referred to as ECDC, collectively referred to in this working arrangement as the 'Sides'. DG SANTE, as the partner DG for ECDC, 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 threat detection and health emergency preparedness and response in the area of medical countermeasures.

With regard to HERA the cooperation is intended to cover only the mission and the tasks set out under Article 2 of Commission Decision C(2021) 6712.

With regard to ECDC the cooperation is intended to cover its mission and tasks under Article 3 of Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control, as amended by Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 in particular to identify and assess current and emerging threats to human health from communicable diseases and related special health issues including reporting and presenting information thereon, and providing science-based recommendations and support in coordinating the response to such threats. In pursuing its mission, the Centre shall respect the responsibilities of the Member States, the Commission and other Union bodies or agencies, and the responsibilities of third countries and international organisations active within the field of public health, in particular the WHO, in order to ensure that there is comprehensiveness, coherence and complementarity of action and that actions are coordinated.

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 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 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 and, where appropriate, provide access to them in full compliance with the relevant Union legislation. They intend to facilitate access by mutually identified means and methods, including interoperability.

3. AREAS OF COOPERATION

The Sides identified the following areas of collaboration, in order to assist each other in the fulfilment of their mission and tasks.

- Intelligence gathering and assessment of health threats relevant to medical countermeasures;
- Modelling, forecasts and foresight activities relevant to medical countermeasures;
- Promoting advanced research and development of medical countermeasures and related technologies
- Strengthening knowledge in preparedness and response related to medical countermeasures
- Contribution to reinforcing the global health emergency preparedness and response architecture.

3.1. Intelligence gathering and assessment of cross-border health threats relevant to medical Countermeasures

3.1.1 Threat prioritisation relevant to medical countermeasures

HERA intends to draw up and regularly update a list of priority health threats relevant to medical countermeasures, drawing on many sources, inter alia, on ECDC infectious disease threat assessments and epidemic intelligence, and make the list available to ECDC.

ECDC detects, assesses, and communicates emerging and ongoing infectious disease threats and disease threats of unknown origin, and intends to make this information available to HERA.

HERA intends to invite ECDC to contribute to its prioritisation work by providing scientific and technical advice on threat prioritisation of threats from communicable diseases.

3.1.2 Epidemic intelligence relevant to medical countermeasures

ECDC has established an epidemic intelligence system to rapidly detect and assess public health events, notably novel threats from communicable diseases or threats of unknown origin.

HERA, to fulfil its tasks of assessing health threats and gathering intelligence relevant to medical countermeasures, intends to use, where relevant, the epidemic intelligence from ECDC together with information that HERA collects on cross-border health threats and the availability of relevant medical countermeasures, including information related to their characteristics, stockpiles, manufacturing capacities and the supply chains.

Both Sides intend to share information and coordinate their activities in the area of epidemic intelligence relevant to medical countermeasures, and in particular, to share the signals, events and threats each side identifies, in particular before their publication.

ECDC also intends to share with HERA scientific data and information on diagnostics and vaccines which would enable HERA to fulfil its task of assessment of health threats and intelligence gathering relevant to medical countermeasures.

In addition, the Sides intend to cooperate and coordinate their activities in relation to gathering intelligence on the preparedness level in Member States insofar as this cooperation and coordination is relevant to the task of assessment of health threats and intelligence gathering relevant to medical countermeasures.

3.1.3 Epidemiological surveillance relevant to medical countermeasures

ECDC intends to share with HERA, at an early stage, epidemiological data and analyses resulting from its dedicated surveillance networks that could be relevant for the availability of critical medical countermeasures.

Such data may include, in particular

- unexpected disease trends,
- emergence of a new cross-border health threat (e.g. new communicable diseases, pathogens, mechanism of antimicrobial resistance),
- information on disease outbreaks,
- results of the assessment of the burden of cross-border health threats,
- results of epidemiological surveillance activities.

The Sides intend to agree on the means and methods of transmission of such data.

3.1.4 Laboratory activities

Each Side intends to inform the other Side of the laboratory activities that they coordinate respectively, with the aim of ensuring coordination and avoiding duplication.

In particular, ECDC intends to inform HERA on the support provided to the nominated networks of national laboratories by the European Union Reference Laboratory (EURL) network in terms of diagnosis, detection, identification and characterisation of infectious agents.

In particular, HERA intends to inform ECDC of the studies to be carried out by laboratories supported by HERA, on the characterisation of emerging pathogens, and of their results. Where relevant, HERA intends to consult with ECDC on the design and outcome of these

studies. HERA informs ECDC of the result of the epidemic intelligence gathered at global level through HERA laboratory initiatives.

3.2. Modelling and forecasting activities relevant to medical countermeasures

The Sides intend to cooperate with regard to modelling and forecasting of serious cross-border threats to health and provide mutual support through the sharing of data, expertise, tools and outputs related to modelling and forecasting.

ECDC intends to provide support to HERA in particular as regards the modelling and forecasting of:

- likelihood of outbreaks of health emergencies and their consequences,
- scenario based analysis,
- forecast of the determinants of health and their potential impact on health,
- consequences of serious cross-border threats to health.

HERA intends to share, or provide support, where relevant, to ECDC as regards of the modelling and forecasting of relevant medical countermeasures capacities, including data, models and development scenarios.

ECDC intends to share with HERA the epidemiological data, models and development scenarios that it provides to the Medicine Shortages Steering Group (MSSG) established within EMA, following the recognition of a public health emergency or the recognition of a major event, to help HERA to fulfil its task of assessment of health threats and intelligence gathering relevant to medical countermeasures

3.3. Risk assessment relevant to medical countermeasures

ECDC intends to share its risk assessment with HERA insofar as it is relevant to fulfil its task of assessment of health threats and intelligence gathering relevant to medical countermeasures.

HERA intends to contribute to ECDC risk assessments, when relevant and feasible, with information on medical countermeasures availability and capacities.

3.4. Risk communication relevant to medical countermeasures

The Sides intend to establish a mutual process to coordinate, where possible, their communication on risks relevant to the availability of medical countermeasures.

3.5. Foresight activities relevant to medical countermeasures

The Sides intend to actively contribute to foresight consultations of the other Side, and share the results of their foresight activities which are relevant to the availability of medical countermeasures.

3.6. Promoting advanced research and development of medical countermeasures and related technologies

ECDC identifies knowledge gaps and provides input to research priorities relevant to the prevention and control of infectious disease, in consultation with Member State partners, and intends to share its findings and conclusions with HERA insofar as it is relevant to promoting advanced research and development of medical countermeasures and related technologies.

3.7. Strengthening surveillance, diagnostic and capacity relevant to medical countermeasures

Taking into account the relevant regulatory Union framework applicable for the award of direct grants to support capacity building for Member States, the Sides intend, to the extent possible, to share content and operational responsibilities in relation to grants to Member States for preparedness and response for serious cross-border threats to health in the area of medical countermeasures, where appropriate.

In such cases, the Sides may decide to lay down the repartition of tasks and responsibilities as regards the preparation, evaluation, selection and management of grant agreements in a common document.

3.8. Strengthening health security coordination within the Union during preparedness and crisis response times in the area of medical countermeasures

Where appropriate and relevant, the Sides intend to coordinate their activities on preparedness and response planning in the area of medical countermeasures, notably with the aim of ensuring that the data collection system they establish for this purpose do not lead to double reporting in Member States, and that the indicators they use for assessing preparedness and response in the area of medical countermeasures are coherent.

3.9. Strengthening knowledge and skills in preparedness and response related to medical countermeasures

ECDC intends to provide support to HERA to fulfil its task of strengthening knowledge and skills in preparedness and response related to medical countermeasures.

The Sides intend to inform each other and coordinate their activities as regards trainings, exercises, evaluations, after action reviews and other relevant activities which strengthen preparedness and response related to medical countermeasures. They intend to organise joint exercises and trainings in that area, where appropriate.

In particular, HERA intends to support ECDC as regards its training, exercises and evaluation.

The Sides intend to open the trainings that they organise to the staff of the other Side.

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

The Sides intend to establish Standard Operating Procedures (SOPs), including means of communication, for the coordination of their actions in case of a public health emergency.

These SOPs notably aim to ensure close coordination of ad-hoc collaboration with international partners, especially WHO and national and regional CDCs, also coordinating, where relevant, a possible intervention of the EU Health Task Force. HERA plans to launch actions at global level, notably with the aim to contribute to global surveillance and improve the global availability and accessibility of crisis-relevant medical countermeasures, as well as support low- and middle-income countries to build expertise and develop local capacities for manufacturing and distribution of relevant medical countermeasures, and to access to EU funded or procured medical countermeasures.

The Sides intend to keep each other informed about their collaboration in global projects with their partners, in particular with WHO and the CDCs from third countries, in order to contribute to reinforcing the global health emergency preparedness and response architecture.

4. CONFLICT OF INTEREST

HERA acknowledges the principles of ECDC's revised Independence Policy for Non-Staff approved by the ECDC Management Board on 21 March 2018 and intends to respect that in accordance with the policy when interacting with ECDC. HERA intends to obtain and submit declarations of interest to ECDC from any experts, country representatives and other stakeholders participating in joint activities and/or acting on behalf of HERA where the outcome involves publishing guidelines, recommendations or any other form of official position on a subject, in order to avoid conflicts of interest.

5. AMENDMENTS

The terms of this working arrangements can be amended at any time by a written agreement of all the Sides.

6. 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 ECDC

FOR DG SANTE as a partner DG of ECDC