

## **CALL FOR APPLICATIONS FOR THE SELECTION OF MEMBERS OF THE CIVIL SOCIETY FORUM AS A SUB-GROUP OF THE HERA ADVISORY FORUM**

### **1. Background on the Civil Society Forum**

In accordance with Article 7 of HERA Decision (Commission Decision C(2021) 6712 establishing HERA), the **HERA Advisory Forum** ('Forum') "*shall constitute a mechanism for an exchange of information on preparedness and response in the area of medical countermeasures and the pooling of knowledge. It shall ensure close cooperation between HERA and the competent bodies in the Member States, in particular on the planning and implementation of scientific, health and industrial activities of HERA*".

The HERA Advisory Forum is not a Commission expert group in the sense of Commission decision C(2016)3301. It will follow, where appropriate, the horizontal rules on expert groups<sup>1</sup>. In accordance with those rules and as foreseen in Commission Decision C(2021)6712, sub-groups could be created. The members of the Advisory Forum will be, in accordance with Article 7 (2) and 7 (4) of HERA Decision, the representatives designated by each Member State (from technically competent bodies), therefore Type D members.

In accordance with Article 14 of Commission Decision C(2016)3301, the Commission or its departments may establish sub-groups for the purpose of examining specific questions on the basis of terms of reference defined by the Commission or its departments.

#### **1.1. THE LINK WITH THE ADVISORY FORUM**

The Civil Society Forum sub-group will help to ensure that the HERA Advisory Forum will receive regular input on the views and opinions of the civil society stakeholders.

Along with Joint industrial Cooperation Forum sub-group, it will provide the HERA Advisory Forum with observations and assessments from a diverse range of stakeholders.

This will facilitate the work of the Forum and contribute to its informed opinions and conclusions.

#### **1.2. MIRRORING THE SUBGROUP ON "JOINT INDUSTRIAL COOPERATION FORUM"**

The HERA Decision in its Article 7 (4) created a sub-group called "Joint Industrial Cooperation Forum" that will be composed of the representatives of the industry and Member States.

In order to mirror the engagement of industry in the work of the HERA Advisory Forum, the civil society should be also represented, in order to examine specific questions, which have impact on Europeans. As stated in Commission Decision C(2016)3301, the members of sub-groups that are not members of the expert group to which they belong shall be selected via a public call, in compliance with the rules on the selection process (Article 10)

#### **1.3. TASKS OF THE CIVIL SOCIETY FORUM**

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<sup>1</sup> Commission expert groups are subject to the horizontal rules established by Commission Decision C(2016)3301.

The sub – group’s tasks shall be:

- (a) to facilitate interactions and serve as a liaison between HERA and stakeholders representing patients, consumers and healthcare professionals;
- (b) to provide the forum with exchange of information and views;
- (c) to provide, where appropriate, recommendations and particular point of view of the represented civil society groups to the Advisory Forum on matters of health preparedness and response, with particular focus on medical countermeasures;
- (d) to deliver, where appropriate, opinions on specific matters and obtain expertise in a structured way;
- (e) to monitor research, industrial and policy developments in in areas relevant to HERA’s activities<sup>2</sup>.

The Commission is calling for applications with a view to selecting members of the sub- group.

## **2. Features of the Civil Society Forum**

### **2.1. COMPOSITION**

The group shall consist of up to 30 members.

Members shall be European organisations, possibly with the widest geographical coverage, with a specific focus on patients’, consumers and healthcare professionals’ interests.

Members are expected to actively contribute to the tasks of the sub-group, which may range from strategic policy-related topics to technical issues, for example relating to the development and stockpiling of medical countermeasures.

Organisations shall nominate a permanent representative at senior level and may nominate an alternate representative. Organisations shall be responsible for ensuring that their representatives provide a high level of expertise. The HERA may refuse the nomination of a representative by an organisation if it considers this nomination inappropriate in light of the requirements specified in section 4 of this call (see below). In such case, the organisation concerned shall be asked to appoint another representative.

### **2.2. APPOINTMENT**

Members shall be appointed by the Head of HERA from applicants complying with the requirements referred to in section 4 of this call.

Members shall be appointed for three years. They shall remain in office until replaced or until the end of their term of office. Their term of office may be renewed.

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<sup>2</sup> According to the Article 2 of the C(2021) 6712, HERA shall be responsible for the following tasks: (a) assessment of health threats and intelligence gathering relevant to medical countermeasures; (b) promoting advanced research and development of medical countermeasures and related technologies; (c) addressing market challenges and boosting the Union’s open strategic autonomy in medical countermeasures production; (d) swift procurement and distribution of medical countermeasures; EN 3 EN (e) increasing stockpiling capacity of medical countermeasures; (f) strengthening knowledge and skills in preparedness and response related to medical countermeasures

The Commission retains the right to remove any member selected through this call, should any conflict of interest arise, or any other circumstance that may make them unfit for the task.

The individuals appointed by the organisations act as their representatives for the purpose of the sub-group activities and not on their own individual capacity. Therefore, the appointed representative is responsible for liaising with their organisation in order to provide the organisation's position on the topics to be addressed. In parallel, they should report back on the activities of the sub-group.

Registration in the Transparency Register is required in order for individuals representing organisations to be appointed.

HERA shall appoint alternate members, who shall automatically replace any members who are absent or indisposed. The same conditions would apply to the alternate members as to the members of the subgroup.

### **2.3 RULES OF ENGAGEMENT AND OPERATION OF THE CIVIL SOCIETY FORUM**

The sub-group shall be chaired by a representative of the Commission.

Meetings of the group shall, in principle, be held in Commission premises or via secure electronic communication tools. HERA shall provide the secretariat. The sub-group shall report to the HERA Advisory Forum.

Members' representatives should be prepared to attend meetings systematically, to contribute actively to discussions in the group, to participate in preparatory work ahead of meetings, to examine and provide comments on documents under discussion, and to act, as appropriate, as 'rapporteurs' on an *ad hoc* basis.

As a general rule, working documents will be drafted in English and meetings will be also conducted in English.

In principle, if there is a case where it is appropriate for the sub-group to adopt its opinions, recommendations or reports, then it shall be done by consensus. In exceptional cases, the Chair may decide that the sub-group shall adopt its opinions, recommendations or reports by voting. 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 shall have the right to have a document summarising the reasons for their position annexed to the opinions, recommendations or reports.

The Commission will reimburse travel and subsistence expenses incurred by organisations (Type C members) and invited experts attending meetings in person and not based in Brussels.

The sub-group will follow the rules of procedures adopted for the Advisory Forum.

### **2.4. TRANSPARENCY**

As concerns the sub-group composition, HERA shall publish the following data:

- the name of member organisations; the interest represented shall be disclosed;

HERA shall make available all relevant documents, including the agendas, the minutes and the participants' submissions, via a link to a dedicated website. Access to this dedicated website shall not be submitted to user registration or any other restriction. In particular, HERA shall ensure the publication of the agenda and other relevant background documents in due time ahead of each meeting of the subgroup, followed by timely publication of the minutes of the sub-group

meetings. Exceptions to publication shall only be foreseen 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° 1049/2001.

Personal data shall be collected, processed and published in accordance with Regulation (EU) No 2018/1725.

### **3. Application procedure**

Interested organisations are invited to submit their application to the European Commission, HERA.

Applications must be completed in one of the official languages of the European Union. However, applications in English would facilitate the evaluation procedure. If another language is used, it would be helpful to include a summary of the application in English.

Organisations shall indicate the name of their main and alternate representatives in the group.

An application will be deemed admissible only if it is sent by the deadline and includes the documents referred to below. All documents submitted by applicants should be duly filled in, legible, signed and numbered sequentially.

#### Supporting documents

Each application shall include the following documents:

- a cover letter explaining the applicant's motivation for answering this call and stating what contribution the applicant could make to the group and how it meets the selection criteria laid down in section 4 (below);
- a classification form duly filled in specifying the member category for which the application is made (Annex I);
- a selection criteria form duly filled in documenting how the applicant fulfills the selection criteria listed in chapter 4 of this call (Annex II).

For nominated representatives of the organisations, a *curriculum vitae* (CV) shall also be provided, not exceeding three pages. All CVs shall be submitted in the European format (<https://europass.cedefop.europa.eu/en/documents/curriculum-vitae/templates-instructions>).

Additional supporting documents (e.g. publications) may be requested at a later stage.

#### Deadline for application

The duly signed applications must be sent electronically by 19/04 17:00:00 Brussels time at the latest to the following e-mail address: [hera-advisory-forum-secretariat@ec.europa.eu](mailto:hera-advisory-forum-secretariat@ec.europa.eu).

The date of submission will be the date on which the email was sent.

#### 4. Selection criteria

HERA will take the following criteria into account when assessing applications:

- 1) affiliation to one of the following groups:
  - a) Patients and their representatives
  - b) Consumers and their representatives
  - c) Healthcare professionals and their representatives
- proven and relevant competence and experience, including at European and / or international level, in areas relevant to HERA's activities;<sup>3</sup>
- proven capacity to represent effectively the position shared by patients, consumers or healthcare professionals;
- competence, experience and hierarchical level of the proposed representatives;
- good knowledge by the proposed representative of the English language, allowing active participation in the discussions.

The organisation shall be formally established in one of the Member States of the EU/EEA. Organisations not formally established in an EU/EEA Member State may apply to become eligible organisations if they provide additional information that they have specific focus and carry out activities in the EU.

#### 5. Selection procedure

The selection procedure shall consist of an assessment of the applications to be performed by HERA against the selection criteria listed in section 4 of this call (above), followed by the establishment of a list of the most suitable applicants, and concluded by the appointment of the members of the group.

When defining the composition of the sub-group, HERA shall aim at ensuring, as far as possible, a high level of expertise, as well as a balanced representation of relevant know-how, position in the value chain, size of organisation and areas of interest (patients, consumers, healthcare professionals), as well as geographical balance.

For any further information please contact the secretariat of the HERA Advisory Forum at [hera-advisory-forum-secretariat@ec.europa.eu](mailto:hera-advisory-forum-secretariat@ec.europa.eu)

#### ANNEXES:

- Annex I: Application form
- Annex II: Selection criteria form
- Annex III: Privacy statement

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<sup>3</sup> Please see the footnote 2