RULES OF PROCEDURE OF THE HERA ADVISORY FORUM

THE HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY ADVISORY FORUM (hereafter ‘Forum’),

Having regard to Commission Decision C(2021) 6712 of 16 September 2021 on establishing the Health Emergency Preparedness and Response Authority 1, and in particular Article 7 thereof,

HAS ADOPTED THE FOLLOWING RULES OF PROCEDURE:

Point 1

Operation of the group

The Forum shall be chaired by a representative of the Commission appointed with the agreement of the Head of HERA.

Point 2

Convening a meeting

1. Meetings of the HERA Advisory Forum are convened by the Head of HERA either on its own initiative, or at the request of a simple majority of members.

2. Joint meetings of the Forum with its sub-groups may be convened to discuss matters falling within their respective areas of responsibility.

3. In principle, meetings of the Forum shall be held physically at Commission premises but may also be held virtually or in a hybrid form, depending on the circumstances.

Point 3

Agenda

1. The secretariat, as referred to in point 10, shall draw up the agenda under the responsibility of the Chair and send it to the members of the Forum.

2. The agenda shall be adopted by the Forum at the start of the meeting.

Point 4

Documentation to be sent to members of the Forum

1. The secretariat shall send the invitation to the meeting and the draft agenda to the members of the Forum no later than five calendar days before the date of the meeting.

2. The secretariat shall send documents on which the Forum is consulted to the members of the Forum no later than five calendar days before the date of the meeting.

3. In urgent or exceptional cases, the time limits for sending the documentation mentioned in paragraphs 1 and 2 may be reduced.

Point 5

Opinions of the Forum

1. As far as possible, the Forum shall adopt its opinions, recommendations, advice or reports by consensus.

2. In the event of a vote, the outcome of the vote shall be decided by simple majority of the members. The members that have voted against or abstained shall have the right to have a

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1 C(2021) 6712; OJ C 393I, 29.9.2021, p. 3–8
document summarising the reasons for their position annexed to the opinions, recommendations, advice or reports.

**Point 6**

**Sub-groups**

1. The HERA Board may set up sub-groups of the Forum for the purpose of examining specific questions on the basis of terms of reference and after agreement of the Chair. Sub-groups shall report to the Forum plenary. They shall be dissolved as soon as their mandate is fulfilled.

2. In case of the sub-group named “Joint Industrial Cooperation Forum” the members of the sub-group that are not members of the Forum shall be selected via a public call for applications.²

**Point 7**

**Invited experts**

HERA may invite experts or representatives of professional or scientific bodies, or non-governmental organisations with recognised experience in disciplines related to HERA’s work, to cooperate in specific tasks and to take part in the relevant activities of the Forum. Specific expertise is required with regard to subject matters put on the agenda. The participation shall be on ad hoc basis.

**Point 8**

**Observers**

The European Centre for Disease Prevention and Control and the European Medicines Agency, as well as any other EU decentralised agency, may participate as observers in the meetings of the Forum.

The Chair may invite other observers.

Organisations and public entities appointed as observers shall nominate their representatives.

Observers and their representatives may be permitted by the Chair to take part in the discussions of the Forum and sub-groups. However, they shall not have voting rights and shall not participate in the formulation of recommendations or advice of the Forum and its sub-groups.

**Point 9**

**Written procedure**

1. If necessary, the Forum’s opinion or recommendation on a specific question may be delivered via a written procedure. To this end, the secretariat shall send the members the document(s) on which the Forum is being consulted.

2. However, if a simple majority of members asks for the question to be examined at a meeting of the Forum, the written procedure shall be terminated without result and the Chair shall convene a meeting of the Forum as soon as possible.

**Point 10**

**Secretariat**

HERA shall provide secretarial support for the Forum and any sub-group.

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² C(2016) 3301, Articles 10 and 14.2.
**Point 11**

**Minutes of the meetings**

Minutes on the discussion on each point on the agenda and on the opinions delivered by the Forum shall be meaningful and complete. Minutes shall be drafted by the secretariat under the responsibility of the Chair.

**Point 12**

**Attendance list**

At each meeting, the secretariat shall draw up, under the responsibility of the Chair, an attendance list also specifying, where appropriate, the organisations, Member States’ authorities or other public entities to which the participants belong.

**Point 13**

**Correspondence**

1. Correspondence relating to the Forum shall be addressed to the secretariat of the Forum for the attention of the Chair.

2. Correspondence for the Forum members shall be sent to the e-mail address which they provide for that purpose.

**Point 14**

**Transparency**

1. The Forum and its sub-groups are listed on a dedicated subsection of HERA’s website.

2. As concerns the composition of the Forum, the following data shall be published on the website:
   
   (a) the name of Member States’ authorities;
   
   (b) the name of observers;
   
   (c) the names of organisations other than Member States’ authorities that are members of any sub-groups;

3. The secretariat of the Forum shall make available all relevant documents, including the agendas, the minutes and the participants’ submissions, on a subsection of HERA’s website. In particular, HERA shall publish the agenda and other relevant 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° 1049/2001.

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3 The names of the representatives of organisations, Member States’ authorities or other public entities may be included only subject to their prior freely given, specific, informed and unambiguous consent, in compliance with Article 3(15) and Article 7 of Regulation 2018/1725.

4 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.
**Point 16**

**Access to documents**

Applications for access to documents held by the group shall be handled in accordance with Regulation (EC) No 1049/2001.

**Point 17**

**Deliberations**

In agreement with the Chair, the Forum may, by simple majority of its members, decide that deliberations shall be public. In sensitive matters, the Chair may decide that the required majority is three quarters of the members.

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