Annex A

EUROPEAN COMMISSION
EUROPEAN HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

The Director-General

Brussels, 9 November 2022
HERA.1/HH

MEETING OF THE HERA ADVISORY FORUM

9 SEPTEMBER 2022
14.00-16.00

DRAFT MEETING MINUTES

1. Introductions

HERA welcomed participants at the second Advisory Forum meeting, the first one focusing on technical matters, and explained that such meetings will take place regularly in the future.

2. Adoption of the draft agenda

The agenda was adopted [to be published with the Meeting minutes].

3. Intelligence gathering on MCMs

HERA provided details on four ongoing initiatives with the aim to inform HERA approach in the monitoring of critical MCMs during preparedness and crisis-relevant MCMs during crisis times.

3.1. Feasibility study on mapping the Covid-19 Therapeutics: HERA presented an ongoing feasibility study mapping the supply chain for select COVID-19 therapeutics, which serves as a basis for HERA's future IT platform on intelligence gathering and threat assessment related to medical countermeasures (MCMs). The objective of the study has been to identify the best possible options for the mapping platform, create a prototype and establish workflow. The project is planned to reach conclusion in mid-late October. In the context of the feasibility study, HERA has developed two questionnaires to request information on supply and demand from industry (see point 3.2). The need for a robust, agile and user friendlier approach for data collection was emphasised. These will need to be discussed further with Member States also based on outcomes from the feasibility study. To complement data collection and avoid duplication, HERA is working with EMA, and also consulting industry stakeholders to further develop the questionnaires.

3.2. Draft questionnaires to collect data on production, stocks and demand from producers: HERA collected feedback from Member States on the two corresponding questionnaires (for medicines/API manufacturers and to producers of medical devices, in vitro diagnostics and personal protective equipment, see also point 3.1.). Another, complementary questionnaire to national competent authorities will follow soon. During declared crisis situations, these questionnaires will be used in accordance with the draft Regulation on the emergency framework (Art 6.6.), in order to collect information on the MCM included in the list of crisis relevant MCM established through implementing acts (under Article 6.1) in agreement with the same Regulation. In agreement, the questionnaires are intended to be the core of templates in future implementing acts during a declared public health emergency at EU level. These questionnaires could be used also outside of declared crisis mode, to monitor access and availability of select, critical MCMs also during preparedness. Information would be provided on a voluntary basis in these cases. Main concerns raised by Member States were related to the legal basis and confidentiality of data collection from producers, and to the potential low response rates during preparedness phase where data collection, in contrast to crisis times, is on a voluntary basis. Possible duplication of data collection with EMA and national competent authorities during a declared crisis was raised as concern. Member States also stressed the need to reflect on how this exercise will be presented to industry in order to ensure their buy-in. The process for the drafting and the planned use of the questionnaires to minimise duplications between e.g. EMA and HERA data collections was explained. Comments from the written review were included and implemented. Post-meeting note: a follow-up meeting was organised to responding Member States (AT, BE, DE, FI, FR, GR, IE, NL, NO, PT, SE) to consolidate their comments for an overview to the Advisory Forum.

3.3. List of MCMs: the rationale for establishing a list of MCMs as well as a draft list for MCMs relevant for preparedness and response were presented together with a procedure to establish a refined list of critical MCMs with support from designated national experts. The MCM prioritisation exercise will build on the threat prioritisation exercise. Member States were asked to nominate experts to the MCM list working group by 15 September (the note on the MCM list with the call for experts was re-sent during the meeting). [post-meeting note: so far the following Member States nominated experts: AT, EE, FI, FR, DE, HR IE, NL, NO, PL, PT]

3.4. Mapping of MCMs for AMR and supply chain analysis: an overview on the two preparatory studies to establish a list of critical AMR MCMs and assess their access and availability was presented.

4. Feedback on Monkeypox

HERA summarised concluded and ongoing centralised purchases of MPX medicines (vaccines and therapeutics) and on planned and ongoing clinical trials with these products. There is ongoing work for the development of complementary European protocols for Jynneos/Imvanex. The protocol synopsis with contact details of MonkeyVax-EU was shared with the Advisory Forum experts.