EUROPEAN COMMISSION
EUROPEAN HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

Meeting of the Joint Industrial Cooperation Forum

22 November 2023 – Brussels, Belgium

Meeting minutes

1. Introduction

Olivier Girard (HERA) and Giacomo Mattino (GROW) thanked JICF members for participating in the meeting.

2. Incentives for the development of medical countermeasures

- **AMR pull incentives**

HERA presented ongoing work on the procurement-based pull incentives for AMR that would be complementary to the incentive proposed in the revision of the pharmaceutical legislation. HERA informed about its work to develop an EU multi-country revenue guarantee model based on a service requirement and inspired from the Swedish pilot model. Discussion on the selection of drugs and way forward is ongoing with Member States in the expert group established by HERA under the Advisory Forum.

BEAM, Medicines for Europe, EFPIA outlined the need to support both pull incentives which support access to antimicrobials and the pull incentives that favour innovation. BEAM, Medicines for Europe also indicated the possibility to use joint/centralised procurement. Vaccines Europe highlighted the need to support additional approaches such as phage therapies, antifungals and vaccines was stressed.

- **Pull incentives for other medical countermeasures**

HERA presented existing pull incentives, including existing EU funding mechanism for innovation, joint procurement mechanisms and alternative incentives for procuring innovative medical countermeasures such as Advance Purchase Agreement (APA), Advanced Market commitment (AMC) or target product profiles (TPP).

COCIR and Vaccines Europe highlighted the need for projects to be commercially viable. EUCOPE and EFPIA mentioned the link between the implementation of the mechanism and the product development stage. Moreover, COCIR stressed the need to cover all MCMs beyond pharmaceutical products and EUCOPE mentioned the need for a specific mechanism to addressed MCMs that counter CBRN which may lack commercial viability. Furthermore, participants turn

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the attention to the importance of adjusting regulatory processes to support the swift launch of innovative products and differences between EU and US (FDA vs. EMA).

HERA was opened to discuss initiatives proposed by the industry but recalled that innovation should be needs driven.

- **Possible gaps in incentives**

EFPIA shared their insights on the current incentives for late-stage development of MCMs. EFPIA proposed to launch a HERA pilot programme under the current MFF and deploy a fit for purpose bio-preparedness funding tool under the next MFF. Industry stressed the need to support a single beneficiary, significant grants (more than 50%) and need to abandon geographic restrictions. EFPIA also proposed to set up a dedicated JICF working group.

- **HERA Invest**

HERA presented the initiative to JICF Members and updated them on the state of play. Members were informed that the EIB was identifying the first relevant projects, with aim for the first loans to be signed in 2024. HERA also informed about the establishment of a new matchmaking platform. Project funded under HERA Invest need to be commercially viable.

3. Communication on Addressing medicine shortages in the EU

- **Short-term measures**

HERA presented the short-term measures announced in the Communication. HERA commended the good collaboration with industry in the EMA/HERA pilot project and that close collaboration should continue to monitor supply and identify possible bottlenecks. Participants welcomed the Communication.

AESGP, Vaccines Europe, CEFIC recalled the need to be prudent in communicating about shortages to avoid panic behaviours (e.g. suggestion to avoid mentioning concrete medicines such as paracetamol and cough syrups unless they are identified as critical medicines prone to critical shortages) and that prevention was key. Vaccines Europe stressed the benefits of e-leaflets and regulatory flexibility to face surge in demand and provide update in real life in case of fast changing situations like pandemics. Medicines for Europe indicated the need for trading requirements and signalled that the EMVS could be used to provide real-time information on medicines availability. CEFIC mentioned that prevention is not addressed in the Communication.

- **Mid-to-long term measures**

HERA presented the Critical Medicines Alliance and informed about its launch in early 2024. JICF members were invited to contribute to the work of the Alliance. HERA also informed of the first steps taken towards a possible future Critical Medicines Act. DG GROW presented the skills partnership for the European health industry, which will be launched on December 1st by signing the Partnership Agreement. This agreement was prepared in close cooperation between DG GROW and JICF industry representatives. DG GROW also provided an update on the development of a methodology for monitoring vulnerabilities in the supply chains of critical medicines and informed JICF members that a separate meeting on this topic will be organized early next year.

In response to a question from EFCG, DG GROW confirmed that the development of the methodology has taken account of existing monitoring systems within the Commission, e.g. for critical raw materials. Vaccines Europe highlighted the potential consequences of the PFAS legislation on continued manufacturing and availability of medicines in the EU given the lack of alternatives and called for a derogation for the pharmaceutical and medical devices industries.

HERA finally presented the international dimension of the work of the Critical Medicines Alliance.

Medicines for Europe and Vaccines Europe supported the need to make production more sustainable. Medicines for Europe indicated that manufacturing flexibility was key for the scale up of production. On skills, Medicines for Europe stressed that vocational trainings were important.

4. Update on the JICF WG on data collection

HERA and the EMA gave an update on the JICF Working Group on data collection which was created in January 2023. JICF members were updated on the objectives of data collection for medical devices. HERA expected discussions on data collection for medicines to take place in the context of the joint HERA/GROW action to map supply chain vulnerabilities. HERA was still expecting feedback on the medical devices questionnaire.

Members stressed that reporting requirements should be streamlined to avoid duplication between different for at the EU level and between the EU/national level. COCIR also referred to commercial sensitivities of sharing such data.

5. AOB

Medicines for Europe shared their views on preparedness for demand surge caused by epidemic prone infectious diseases (EPIDs).

COCIR asked for an update on the stockpiling strategy.

6. Conclusions

Olivier Girard (HERA) and Giacomo Mattino (GROW) thanked JICF members for their participation. Olivier Girard reminded participants about the 2nd HERA Conference which will take place on 5 December 2023. He informed about the HERA review. He looked forward to continuing to work closely with JICF members as part of the establishment of the Critical Medicines Alliance and invited JICF members to contribute to this work.