EFPIA and Vaccines Europe position on the European Health Emergency preparedness and Response Authority (HERA)

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COVID-19 has shown that coordinated action at EU level is necessary to effectively respond to health emergencies. While during the pandemic the EU reacted to issues as they arose, the creation of HERA is a first step to putting Europe on the front foot in addressing global health threats.

This paper outlines EFPIA and VE's views and recommendations on a number of elements included in the Commission's *Decision establishing the Health Emergency Preparedness and Response Authority (HERA)*[1] and in the *Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level*[2]. EFPIA and VE, their national associations and member companies, look forward to working with HERA and all stakeholders towards the shared goal of a safer, healthier and more resilient Europe.

1. General principles

Based on the lessons learned from COVID-19 crisis management, points which we believe require particular attention during planning and implementation of preparedness, as well as response activities by HERA, include:

- a **lean approach to decision-making**, with clear delineation of responsibilities of different institutions and agencies, avoiding overlapping remits, and duplicative or contradictory measures;
- **scenario planning and technology screening, in dialogue with developers** of medical countermeasures;
- **supply and deployment tools which leverage global supply capabilities** and do not create unintended vulnerabilities in the supply chain;
- a **clear legal framework and contracting terms**, to improve predictability, and therefore encourage industry's participation;
- a **no-fault compensation system** which provides the right level of protection and compensation in case of injuries related to medical countermeasures procured and deployed via HERA, to enhance public trust;
- **robust epidemiological data collection tools** underpinning HERA's decisions around procurement and deployment of medical countermeasures;
- **policies and structures to support equity in access to medical countermeasures** for priority populations around the world.

2. Scope

EFPIA and VE support HERA's end-to-end approach, from threat assessment and intelligence gathering, to promoting advanced R&D and ensuring the provision of medical countermeasures. In addressing

[1] C(2021) 6712 final, 16.09.2021 https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/hera_2021_decision_en.pdf
[2] 2021/0294 (NLE), 16.9.2021 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021PC0577&from=EN

market challenges, HERA should **concentrate its efforts on diseases with pandemic potential**, and **where existing incentives cannot ensure better results**.

While the proposed Council Regulation details the framework of measures to be activated "in the event of recognition of a public health emergency at Union level"[3], the EU needs also **fit-for-purpose tools to contract advanced research and development (R&D) into medical countermeasures in pre-pandemic and preparedness times**, while boosting "the Union's open strategic autonomy"[4]. As a starting point, scenario planning and prioritisation of needs, in consultation with stakeholders, would help map out potential gaps in assets and technologies.

3. Governance

To ensure seamless coordination, information exchange and the pooling of knowledge in both crisis and preparedness times, **greater involvement of the private sector will be instrumental to HERA's success**. The 'Joint Industrial Cooperation Forum'[5] should be set up as a permanent structure, allowing for continued interaction around, among others, scenario planning, science and technology opportunities, and resources. Where necessary and relevant, stakeholders could be invited to participate in the meetings of the HERA Board and of the Health Crisis Board. Furthermore, to avoid duplication and create the right level of synergy, the EMA representative in the Emergency Task Force should also be a member of the Health Crisis Board. Regulators play a central role in both identifying promising new medical countermeasures and enabling R&D thereof.

4. Operational and legal elements

4.1. Contracting

To attract long-term investments in high-risk R&D pandemic projects, and in sustainable surge capacity during health emergencies, **it will be critical for HERA to provide funding at scale with attractive funding rates**. **HERA should be able to partner with individual entities** (similarly to the European Innovation Council Accelerator) as opposed to multi-partner consortia, especially for late-stage development projects. This will help provide the flexibility for projects to adapt to an evolving context, and potentially correct the scope of activities based on the development of the public health situation. HERA should also ensure a high degree of flexibility, to adjust the budget to new needs and extend the scope of its existing activities.

4.2. Joint procurement

HERA's joint procurement facility should be underpinned by a clear process and be restricted to the purchasing of medical countermeasures in response to EU-wide health emergencies, for a time-limited period. It should apply only where purchase and supply of medical countermeasures cannot be ensured as efficiently by other means, notably via national procurement systems. It should not replace national procurement systems, and its scope and modalities should be clearly delineated. In addition, **joint procurement should not replace the much-needed push and pull incentives in areas where market failures exist**, such as antimicrobials, and where other types of economic incentives are required.

[3] 2021/0294 (NLE), Recital (3)
[4] C(2021) 6712 final, Article 2.2(c)
[5] C(2021) 6712 final, Article 7.4

Experience during the COVID-19 pandemic has shown that availability of consumables and other products in emergency situations is limited, and that access for patients will depend on a clear process for contracting, liability, indemnification and distribution[6]. **EU harmonization** would be required on these aspects, to help achieve equal EU-wide access to medical countermeasures. HERA should play a role in this respect, for example by negotiating **overarching standards on no-fault compensation and liability**, to create efficiencies in the context future EU negotiations with developers.

4.3. Stockpiling

Creating stockpiles of medical countermeasures raises important challenges (supply allocation, time to build, costs, shelf life of medical countermeasures stockpiled) **and should only be considered in very specific cases**, as one element of a broader strategy including **better, harmonised systems for demand forecasting, mechanisms to facilitate the transfer of medical countermeasures between Member States, as well as improved procurement practices**.

Stockpiling should focus on a limited number of critical products needed in response to public health emergencies, and the volumes requested should be proportionate and limited in time, to avoid unintended negative consequences on supply efficiency. To allow for optimal management of stocks through demand variability, these should be **managed at the European level, and at unfinished or unpackaged levels, or under common packaging with the use of e-leaflets**. Costs related with any request to build stocks at finished pack level should be borne by the authority requesting them. Management of stocks at EU level would increase supply flexibility and enable authorities to quickly allocate medical countermeasures where the patient need is, via appropriate regulatory measures and based on epidemiological data regarding actual patient needs in Member States.

Companies should be provided enough time to build and plan the stocks, keeping in mind product specificities and lead times, and the associated costs. Furthermore, with multiple EU Member States introducing unilateral stockpiling requirements, **HERA should prioritise solutions that ensure solidarity among Member States, while securing sustainability of supply**.

4.4. Intellectual property (IP)

During the COVID-19 pandemic, IP rules enabled collaboration between companies and governments, universities, and other research partners to speed up progress on finding, developing, and manufacturing COVID-19 treatments and vaccines.

With that in mind, **HERA should maintain a robust and predictable IP framework that incentivises industry to develop and commercialise medical countermeasures in a manner that promotes public health objectives**. Industry should retain ownership of background IP, and for the new IP rights generated with HERA funded projects. Additionally, developers should be assigned ownership of resulting IP, and as needed, have the ability to license IP rights to third parties. Clarity on IP ownership and control supports addressing public health needs, as it helps gain industry support and secure industry's participation, while advancing commercialisation and distribution goals.

The biopharmaceutical industry's record of engaging with multiple stakeholders through various innovative access initiatives and research collaborations during the COVID-19 pandemic, showcases that a strong IP incentive system supports rapid and robust response to a health crisis. **Voluntary licensing measures should therefore always be preferred over other measures**. However, should the contractor fail to take reasonable steps to commercialise a particular medical countermeasure, HERA

[6] in accordance with Article 5(2) of Directive 2001/83/EC

should define a **predictable and well-defined process under which HERA can take steps to exercise certain additional IP rights, to meet clearly defined public health needs**.

4.5. Cooperation with global actors and global supply chains

EFPIA and VE welcome HERA's intent to contribute to "reinforcing the global health emergency preparedness and response architecture"[7]. In doing so, and as recognised by the European Commission, HERA should "**contribute to ensuring close collaboration with global partners to address international supply chain bottlenecks, remove unnecessary restrictions and expand global production capacity**"[8], including the U.S Biomedical Advanced Research and Development Authority (BARDA), the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organisation (WHO). This will help avoid disruptions like those experienced during the COVID-19 pandemic, which have highlighted the need to support global supply chains, from raw materials to finished products. In addition, HERA should **contribute to equitable access to medical countermeasures for priority populations globally**. Collaboration with governments and other global partners will be key to achieve this objective.

4.6. No-fault compensation systems

While safety and efficacy remain key priorities for any measure taken, or medical countermeasure developed, the risk of serious adverse events will always exist, particularly when a new product or intervention is deployed rapidly, and when medical countermeasures are likely to be used by larger patient populations than usual. In those circumstances, there is a need to **ensure efficient access to adequate compensation for patients who have suffered serious adverse events**.

HERA should ensure that patients who suffer injuries because of medical countermeasures developed and supplied via HERA, can be compensated, and **setting up no-fault compensation systems in all EU Member States** is essential in this regard. In addition, an EU compensation fund should be created, to support Member States in this effort. Such measures would play a key role in **securing public trust in the medical countermeasures deployed** and would strengthen the EU's ability to effectively respond to health emergencies.

[7] C(2021) 6712 final, Article 1.2(c)
[8] COM(2021) 576 final, Article 7.4