European Parliament

HERA, the EU's new Health Emergency Preparedness and Response Authority

SUMMARY

The outbreak of the coronavirus pandemic exposed the weaknesses in the EU's preparedness and planning capacities as well as its lack of funding, with much of the EU's initial response being on an ad-hoc basis. Coordination and cooperation between EU Member States was initially often difficult, and took time to get established and start functioning in a structured way.

The EU's Health Emergency Preparedness and Response Authority (HERA) was established by a Commission decision of 16 September 2021, as part of the European health union initiative that also includes legislative proposals reinforcing the roles and mandates of the European Centre for Disease Prevention and Control and the European Medicines Agency.

Set up within the European Commission and endowed with €6 billion from the EU's long-term budget, the 2021-2027 multiannual financial framework, HERA is expected to strengthen EU health security coordination during the preparedness phase, shorten crisis response times, and reinforce the EU's overall health emergency preparedness and response architecture.

While the creation of HERA has been welcomed by European stakeholders active in research, innovation and healthcare, they stress their preference for inclusive governance, and the need to harness the activities so that they reflect the public good dimension of HERA investments.

Since HERA is a European Commission entity and not an EU agency, the European Parliament's role, and in particular that of its relevant committees, in assessing and monitoring HERA's effectiveness and efficiency has yet to be defined.

IN THIS BRIEFING

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Introduction

The coronavirus pandemic has revealed structural weaknesses in the EU's preparedness and its ability to respond coherently, rapidly and appropriately to protect citizens from health crises. It has also demonstrated the need for and value of coordinated EU-level action. In this context, in November 2020, the European Commission adopted the European health union initiative to step-up the fight against the coronavirus pandemic and future health emergencies. The newly established Health Emergency Preparedness and Response Authority (HERA) aims to enable the EU and its Member States to strengthen preparedness and rapidly deploy the most advanced medical and other counter-measures in the event of a health emergency. Endowed with €6 billion from the EU's 2021-2027 multiannual financial framework (MFF), HERA is expected to drive forward preparedness efforts across many issues, ranging from clinical research to production and distribution of medical counter-measures.

Context

European health union

HERA was first introduced as part of the European health union initiative, presented by European Commission President Ursula von der Leyen in her 2020 State of the Union address, and laid down in the November 2021 communication 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats'.

The health union initiative draws on the lessons learned from the pandemic. It aims to strengthen the EU's health security framework, as well as reinforcing the crisis preparedness and response role of key EU agencies. It is composed of a set of legislative and non-legislative acts that are all directly relevant to HERA's tasks and governance:

- a proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health, repealing Decision No 1082/2013/EU (proposal based on Article 168(5) of the Treaty on the Functioning of the European Union (TFEU);[1]
- a proposal for a regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency (EMA) in crisis preparedness and management for medicinal products and medical devices (based on Articles 114 and 168(4)(c) TFEU);
- a proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control (ECDC) (based on Article 168(5) TFEU);
- a proposal for a Council regulation on the emergency framework of measures for ensuring the supply of crisis-relevant medical counter-measures in the event of a public health emergency at Union level (based on Article 122(1) TFEU);[2]
- a Commission decision of 16 September 2021 establishing HERA.

According to the Commission, HERA was set up to strengthen the EU's ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical counter-measures.[3] The authority will continue the work launched by the biodefence preparedness plan set up in February 2021 (the HERA incubator), to rapidly detect and characterise new coronavirus (Covid-19) variants, adapt vaccines as necessary, and scale up existing production capacities.

Set up within the Commission as a shared resource for Member States and the EU, HERA will have different modes of operation; these will reflect its scope that ranges from preparedness planning to crisis management. HERA will be operational from 2022, and is set to be endowed with €6 billion from the EU budget over a six-year period, according to the Commission communication

of 16 September 2021 'Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union'.

US Biomedical Advance Research and Development Authority

HERA shows similarities with a United States authority, the Biomedical Advanced Research and Development Authority (BARDA), founded under the 2006 Pandemic and All Hazards Preparedness Act Bill. The act notably established a new post of assistant secretary for preparedness and response within the federal administration, and a programme – BARDA – that aims to provide an integrated, systematic approach to the development of the necessary counter-measures for public health medical emergencies.

Following the outbreak of the pandemic, the US launched Operation Warp Speed as an inter-agency partnership between the Department of Health and Human Services and the Department of Defence, to coordinate federal efforts to accelerate the development, acquisition and distribution of medical counter-measures. According to a Congressional Research Service report, BARDA is currently supporting six vaccine candidates through funding for research and development, and increased funding in manufacturing capacity and/or advance purchase contracts, for an amount of at least US$29 billion. The Pfizer/BioNTech, Janssen, and Novavax vaccine candidates participated in Operation Warp Speed through federal purchase of doses only.

European Parliament position

While supporting the aims of HERA in general terms, the Parliament – in its October 2021 resolution on EU transparency in the development, purchase and distribution of Covid-19 vaccines – criticised the Commission's decision to refrain from using the ordinary legislative procedure through Article 168 TFEU in setting up HERA, thus failing to establish HERA as a fully fledged independent agency subject to the same scrutiny requirements as other agencies, such as the EMA and the ECDC. The Parliament 'regrets the fact that the Commission's approach, which has led to Parliament being excluded from designing and overseeing the work of HERA, can be regarded as yet another shortcoming that has undermined transparency and accountability for public spending and decision-making in the area of public health'.

The Parliament has also stressed the importance of accountability, including parliamentary monitoring of HERA, for instance in its November 2021 resolution on a pharmaceutical strategy for Europe.[4] None of the European health union proposals and initiatives has been subject to a formal impact assessment. In this context, the Parliament's monitoring competence, such as budgetary control, will be key to assessing the effectiveness and efficiency of the European health union's implementation, including HERA's activities. However, the evaluation framework developed under the health union differs significantly from that established under the US Preparedness and All Hazards Preparedness Act mentioned above. While the US legislator ensures Congressional oversight of the evaluation by including several provisions that require the assistant secretary for preparedness and response also to report annually to the 'relevant committees of Congress', the European Parliament committees are not mentioned in connection with a review of HERA. Article 8 of the Commission decision establishing HERA only mentions an obligation for the Commission to report to the European Parliament, to the Council and to the HERA Board on a review of the implementation of HERA's operations by 2025.

In terms of HERA's mandate, the Parliament has adopted various resolutions with either direct reference to, or relevant guidance on, HERA. In its July 2021 resolution on trade-related aspects and implications of Covid-19, Parliament emphasises the key role played by public-sector resources, allowing pharmaceutical companies to de-risk the whole vaccine value chain; it also considers that a multilateral intellectual property rights (IPR) framework can provide protections and incentives that are critical for preparedness against future pandemics. In its May 2021 resolution on accelerating progress and tackling inequalities towards ending AIDS as a public health threat by 2030, Parliament encourages the Commission and the Member States to explore the decoupling of research and development spending from the price of medicines, for instance through the use of

patent pools, open source research, and grants and subsidies. In its above-mentioned November 2021 resolution on a pharmaceutical strategy, the Parliament considers that HERA should initiate and support the development of innovation, establish at EU level a list of medicinal products of major therapeutic interest, facilitate their production within the EU, promote their joint purchase, and build up strategic stocks of these medicines.

In November 2021, Parliament reflected further on HERA when adopting its first-reading position on the proposal for a regulation on serious cross-border threats to health. In particular, Parliament adopted several amendments aimed at ensuring HERA's visibility in different key processes and schemes established,[5] and at facilitating the coordination with the set of bodies to be established under the proposal for a regulation on the emergency framework of measures for ensuring the supply of crisis-relevant medical counter-measures.[6]

Stakeholder positions

An October 2021 EPRS pre legislative synthesis briefing summarises national, regional and local organisations' views on the European Commission's HERA initiative. On the preparedness activities, comments from the Netherlands and Sweden insist on the advisability to include research and development activities on antibiotic resistance within HERA's scope, and on the need to design open and inclusive research and innovation agendas and activities, particularly with a view to gathering all actors, including small and medium-sized enterprises (SMEs) and local communities.

HERA was also commented on by several stakeholder organisations. The European Public Health Alliance (EPHA) stresses the global relevance of HERA's activities; according to EPHA, HERA's results should, where relevant, reflect the public good dimension, as well as ensuring affordability, accessibility and availability. A network of 19 pan-European organisations representing patients, consumers, health professionals, and civil society,[7] coordinated by the European Alliance for Responsible R&D and Affordable Medicines, voiced their preference for an inclusive and transparent governance scheme, to allow for the involvement of all interested actors, including patients.

Under the Conference on the Future of Europe, European Citizens' Panel 3: 'Climate change and the environment / Health' adopted several recommendations relevant to HERA, including for instance recommendation 43, which will be taken forward to the Conference Plenary:

> *We recommend that the European Union increases its budget dedicated for joint research and innovation projects in the area of health (without budget cuts in other EU health-related programs). This would also strengthen European scientific and research institutions overall.*

Governance, mission and budget

Governance

Unlike in other similar previous instances, in which the need for additional planning and execution capacities for EU policies led to the formation of stand-alone EU agencies, HERA remains an entity within the European Commission.

As of January 2022, HERA's organisational chart shows a structure based only on four units (policy and coordination; intelligence gathering, analysis and innovation; medical counter-measures; emergency office). Similarly, the governance bodies have yet to be installed, and their members appointed.

The Commission decision establishing HERA sets up specific bodies, and provides guidance on how to facilitate the interplay between EU institutions and the relevant agencies active in health preparedness and emergencies. The decision introduces one individual role, the Head of HERA, and three collegial bodies: the Coordination Committee, the HERA Board, and the HERA Advisory Forum.

The **Head of HERA** is appointed by the Commission and ranked as director-general. He or she 'shall take all measures necessary for the efficient functioning of HERA, in close coordination with the

Directorate-General for Health and Food Safety'. Pierre Delsaux was appointed to this function on 1 December 2021.

The **Coordination Committee** is composed of the Vice-President of the Commission overseeing the health portfolio, and the Members of the Commission in charge of Health, the Internal Market, Innovation and Research, and Crisis Management.[8] It provides the political steer for the planning and implementation of HERA's tasks.

The **HERA Board** is composed of one high-level representative from each Member State, appointed by the Commission based on nominations by the relevant national authorities. The board members are appointed for a two-year (renewable) term. A European Parliament representative may participate as an observer in the board meetings, as well as a representative of the ECDC and EMA, respectively. The board assists and advises the Commission in formulating strategic decisions that concern HERA and have regard to the need to develop close cooperation between HERA and Member States, thereby ensuring that Member States' resources and capacities are leveraged as much as possible towards HERA's joint goals.

The HERA **Advisory Forum** is composed of members from competent bodies designated by each Member State who are not members of the board. The forum facilitates an exchange of information on preparedness and response in the area of medical counter-measures and the pooling of knowledge. It will ensure close cooperation between HERA and the competent bodies in the Member States, in particular on the planning and implementation of HERA's scientific, health and industrial activities.

Mission

HERA's mission is to improve preparedness for and response to serious cross-border health threats in the area of medical counter-measures (such as vaccines, medicines, medical equipment and diagnostics) through three main complementary channels:

1. strengthening health security coordination within the EU during preparedness and crisis response times, and bringing together Member States, industry and relevant stakeholders in a common effort;
2. addressing vulnerabilities and strategic dependencies within the EU related to the development, production, procurement, stockpiling and distribution of medical counter-measures;
3. contributing to reinforcing the global health emergency preparedness and response architecture.

HERA's activities follow two different types of impact logic, corresponding to a preparedness and a crisis phase, respectively. In the **preparedness phase**, HERA will steer investment and action towards strengthening prevention, preparedness and readiness for new public health emergencies. In the **crisis phase**, HERA will draw on stronger powers for swift decision-making and implementation of emergency measures. HERA activities in the preparedness and crisis phases call for smooth interaction with other EU institutions and agencies (such as the EMA and the ECDC), Member States and stakeholders.

Preparedness phase

In the preparedness phase, HERA will support activities to strengthen the EU's capacity to identify new health threats, design science-based counter-measures through research and innovation, and ensure the existence of appropriate counter-measure manufacturing capabilities.

This includes, for instance, support for research targeted at key and emerging pathogens (micro-organism that can cause disease), and at the development of relevant technologies and counter-measures including diagnostics, therapeutics and vaccines. Key assets put in place during the coronavirus pandemic will be utilised in this process, such as the EU's Horizon 2020 programme for

research and innovation, which allocated €469 million in funding to Covid-19 in 2020, corresponding to a portfolio of 105 research projects. Preparedness efforts also include support to clinical trial networks, aimed at making them easily adjustable to a broad range of potential threats, and reduce current lead times. An early milestone of this cooperation is VACCELERATE, the first EU-wide network for Covid-19 vaccine trials, launched as part of the HERA incubator.

Preparedness efforts also include forming resilient industrial capacities to ensure timely and commensurate supply of counter-measures. To support large-scale production of medical counter-measures and maintain these facilities, HERA will build on EU FAB, a network of 'ever-ready' multi-technology production capacities for vaccine and therapeutics manufacturing in the EU. The objective is to unlock a production capacity of 700 million doses of vaccine, of which 50 % within the first six months. This would be ensured by the selection of a production capacity reserve to be activated in case of crisis. In order to be operational at all times, and to be able to act promptly, the participating production sites are expected to ensure availability of qualified staff, clear operational processes, and quality controls. This objective is commensurate with relevant approaches of the EU vaccines strategy, such as the advance purchase agreements. EU FAB is also expected to contribute to the objective of reaching an annual EU production of two to three billion doses of Covid-19 vaccine.

Crisis phase

The HERA crisis management phase can be triggered by a declaration of a public emergency by the European Commission as defined in article 23 of the proposal for a regulation on serious cross-border threats to health.[9] Based on this declaration, article 3(1) of the proposal for a Council regulation on the emergency framework of measures for ensuring the supply of crisis-relevant medical counter-measures in the event of a public health emergency at Union level enables the Council to adopt a regulation activating the emergency framework.

The **emergency framework** entails the activation of emergency research and innovation plans, including the use of EU-wide clinical trial networks and data-sharing platforms, and the procurement, purchase and manufacturing of crisis-relevant medical counter-measures and raw materials. In particular, article 7 of the proposal for a Council regulation provides a scheme to procure, purchase and manufacture crisis-relevant medical counter-measures and raw materials.

Budget

The budget framework outlined in the Commission communication of 16 September 2021 reflects both activity streams, i.e. preparedness and crisis. The indicative budget allocations available cover only the preparedness phase. The HERA 2022 work plan, published on 10 February 2022, provides a total contribution of €1.3 billion from the EU budget for preparedness activities. At least €100 million are included to launch an additional crisis activity (production and deployment of medical counter-measures beyond Europe).

Funding during the preparedness phase

HERA will draw on existing structures, programmes and activities at the EU and national levels. As mentioned before, its activities will rely on an indicative budget (2022-2027) of €6 billion from the current MFF, part of which will come from the Next Generation EU top-up.

Several EU initiatives already have a scope and objectives corresponding to HERA's. The EU4Health programme allows for major support to health security preparedness; research and innovation in health is a key work stream of Horizon Europe; and the Union civil protection mechanism (UCPM) has considerable experience in areas such as building stockpiles. The legal instruments governing these programmes allow for expenditure of this kind, in accordance with their respective rules and implementing structures.

Other EU instruments could also contribute directly and indirectly to health emergency preparedness, both inside and outside the EU. For instance, investment to build resilient health systems through the Recovery and Resilience Facility and REACT-EU, and investments in the EU's neighbourhood countries through the Neighbourhood, Development and International Cooperation Instrument, are expected to contribute to health systems' resilience.

Moreover, HERA operations will rely on national budgets allocated to activities aimed at supporting national plans for preparedness and response to health threats. As stressed by the Commission, HERA could also benefit from the mobilisation of private funding (in the form of loans, guarantees, equity or quasi-equity), supported by budgetary guarantees under InvestEU and possibly the European Fund for Sustainable Development for external actions, in cooperation with the European Investment Bank Group and other financial actors.

Funding during the crisis phase

In the event of a public health emergency at EU level, the Council of the EU could trigger financing through the Emergency Support Instrument (ESI) in order to ensure the necessary flexibility and rapidity in implementation; this has previously proved both flexible and fast. As envisaged by the ESI founding regulation, contributions could also come from EU Member States (and from other public or private donors as external assigned revenue) in accordance with the EU Financial Regulation.

Evaluation

As of January 2022, the ex-post evaluation of HERA is only mentioned once in the European health union legislative proposals, namely in article 13 of the proposal for a Council regulation (in the version of the December 2021 political agreement).[10]

Main implementation challenges

HERA's launch comes with various immediate challenges, such as budget absorption and governance. It has a significant impact on the 2021-2027 MFF, with €5.3 billion funding throughout this period. The EU4Health programme thus sees a more than ten-fold increase compared with the €450 million the EU spent on health priorities in the previous seven-year MFF period. HERA missions entail a range of activities for which it is necessary to bring different stakeholder communities together (including research, industry, healthcare professionals and patients), and to provide for the institutional expertise needed to ensure preparedness in a multi-level governance scheme.

Budget absorption

In 2021, HERA-relevant calls for funding were published across EU programmes directly contributing to HERA, i.e. EU4Health, Horizon Europe and rescEU. The **EU4Health** 2021 work programme includes three calls for proposals (to prepare HERA in the field of antimicrobial resistance, mapping of medical counter-measures, and intelligence gathering) for a total of €20 million. The 2022 work programme dedicates €274.8 million to activities contributing to HERA missions. The 2021/2022 work programme for **Horizon Europe** includes three calls for funding relevant to HERA operations (on building a European partnership for pandemic preparedness; on research and innovation in pandemic preparedness; and on a contribution to the Coalition for Epidemics Preparedness initiative) for a total of €47 million. As for **rescEU**, the call on stockpiling of medical counter-measures and/or personal protective equipment aimed at combating serious cross-border threats to health, has a total available budget of €150 million. A €160 million call to establish **EU FAB**, the network for vaccines and therapeutics manufacturing, was to be published at the end of January 2022. It is included in the HERA 2022 work plan mentioned above.

While the 2021 funding of **€337 million** represents an opportunity, it is important to mention the organisational challenges related to following these activities, which correspond to a portfolio with

different timeframes, beneficiaries, outcomes and policy streams. This implies the need for a wide range of expertise in different fields, including research and innovation, procurement, healthcare and the medical industries. This is all the more important as HERA's establishment calls for the recruitment of qualified staff in different sectors, such as clinical research, healthcare and logistics. An October 2021 study for the European Parliament on the cost of non-EU agencies focusing on the health and safety cluster of the EU decentralised agencies highlights the challenge faced by the Commission of finding and attracting these specialised profiles among EU civil servants.

In 2022, the HERA work plan contains contributions from EU4Health (€275 million), Horizon Europe (€395 million) and UCPM/rescEU (€630 million), corresponding to a total of €1.3 billion for preparedness activities. These activities will be implemented and monitored in addition to the investments mentioned above.

Coordination

Another immediate challenge for HERA is the need to establish the appropriate strategy for coordination with EU agencies, Member States and stakeholders.[11]

- **ECDC** and **EMA**: the reinforced roles of the ECDC and EMA qualify them as key partners for HERA. For instance, the ECDC mandate is extended to antimicrobial resistance, while EMA has a remit to monitor medicines shortages. An annex to the communication on HERA shows a systematic mapping of the possible cooperation of HERA with the ECDC and EMA under the preparedness and crisis phases.
- **EU Member States**: HERA activities fall under a significant number of comitology procedures. The proposal for a regulation on serious cross-border threats to health establishes a Health Security Committee (article 4), whereas the proposal for a regulation on a framework of measures for ensuring the supply of crisis-relevant medical counter-measures sets up a Health Crisis Board (article 5). In addition, HERA will need to follow the relevant programme committees in charge of the funding allocated to the activities (EU4Health, Horizon, rescEU).
- **Stakeholders**: HERA has yet to establish its advisory forum. However, in addition to the above-mentioned VACCELERATE project – a consortium of 29 national partners in 18 EU Member States and five third countries associated with Horizon 2020 – national initiatives to explore a possible important project of common European interest (IPCEI) on health are supporting the actors in the research and healthcare industries value chain.

Opportunities

Both HERA's launch and the outcome of the ramp-up of production capacity for Covid-19 vaccines and therapeutics present significant opportunities for the EU, not least in ensuring its industrial and scientific preparedness; this will then facilitate the international dimension of the authority's mission.

An important opportunity for HERA is to ensure the EU's vaccine manufacturing preparedness by 2022 through the establishment of **EU FAB**, the network of 'ever-warm' production capacities for vaccines and medicines manufacturing, which will be launched to make reserve surge manufacturing capacities available. From the establishment of the Commission Task Force for Industrial Scale-up of Covid-19 vaccines, in February 2021, to mid-July 2021, the EU produced over 1 billion doses of vaccines. This is the result of EU investments, in particular through MFF programmes such as Horizon 2020, but also through advance purchase agreements with pharmaceutical companies. Thanks to these agreements, the Commission secured the right to buy a specific number of vaccine doses in a given timeframe at a given price. In return, the Commission financed a part of the vaccine developers' upfront costs. With the EU FAB initiative, the EU is expected to support the formation, resilience and networking of EU ecosystems of vaccine

development, production and distribution. The EU FAB initiative could also contribute to de-risk vaccine production while ensuring a better return for tax payers.

Beyond vaccine manufacturing, in 2022, HERA will have the opportunity to interact with **research and innovation** actors and expertise. As mentioned by several respondents to the public consultation organised in 2021, with the establishment of a Partnership for Pandemic Preparedness under Horizon Europe's 'health' cluster, HERA will have access to a pan-European network of research and innovation actors, geared around four priorities: 1) new scientific knowledge and innovation; 2) development of counter-measures; 3) improved evidence for policy-making; 4) enabling EU-wide infrastructure. Concretely, this initiative will be included in the Horizon Europe 2023-2024 work programme, to be prepared and adopted by the end of 2022. This partnership will rely on collaboration, including in transnational projects, among national research-performing organisations, funding organisations and end users. It will thus provide HERA not only with expertise, but also with the relevant researchers' and practitioners' contacts across the EU, thereby facilitating the authority's coordination and driving role.

HERA will be deployed in an international context characterised by the importance of **global cooperation**. During its second special session (from 29 November 2021 to 1 December 2021), the World Health Assembly agreed to launch a process to draft and negotiate an international instrument under the World Health Organization's constitution to strengthen pandemic prevention, preparedness and response. This step echoes the Parliament's above-mentioned July 2021 resolution, which 'urges the Commission to pursue an effective vaccine and medical supply diplomacy'. As the Commission communication notes, HERA will help ensure close collaboration with global partners to address international supply chain bottlenecks, remove unnecessary restrictions, and expand global production capacity. In particular, HERA will facilitate cooperation to ensure availability of and access to needed medical counter-measures, both for the EU and third countries. This includes developing local manufacturing and distribution capacities. As for research and innovation activities, HERA will support the efforts of the Coalition for Epidemic Preparedness Innovations (CEPI), ensuring the right interface between Horizon investments on the one hand and the relevant global agenda and research funders on the other.

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ENDNOTES

1 See also the four-column table (version of 4 January 2022) on the proposal, following the political agreement reached in the Council on 20 December 2021. The table includes the EU preparedness and response plan.

2 See the latest version of the text following the December 2021 political agreement in the Council. It includes the procurement and purchase of crisis-relevant medical counter-measures and raw materials, and the activation of reserved industrial facilities for flexible manufacturing of vaccines and therapeutics.

3 According to the Commission communication, medical counter-measures relevant for public health response include pharmaceutical and non-pharmaceutical products, such as medical devices, personal protective equipment, vaccination supplies, testing material and kits, and laboratory equipment.

4 See '60. Reiterates its position that the Commission should consider the creation of a European version of the US Biomedical Advanced Research and Development Authority; welcomes the fact that the Commission has made a proposal for a European HERA but expresses its disappointment that Parliament has not been involved in its proper role as co-legislator;'.

5 See, for instance, new articles 6.1, 10.1 and 11.1.

6 See, for instance, new articles 4.7 and 24.2.

7 Global Health Advocates; European Public Health Alliance; Treatment Action Group; Asociación por un Acceso Justo al Medicamento; Health Action International (HAI); Access to Medicines Ireland; SOMO-Centre for Research on Multinational Corporations; Prescrire; Wemos Foundation; Consilium Scientific; Salud por Derecho; Consumer Association the Quality of Life-EKPIZO; Plataforma NoGracias; Universities Allied for Essential Medicines (UAEM Europe); AIDES; Médecins du Monde International Network (MdM International); Pharmaceutical Accountability Foundation; France Assos Santé; Ligue contre le cancer.

8 See the composition of the 2019-2024 College of Commissioners.

9 Article 23 – Recognition of emergency situation: '1. The Commission may, based on the expert opinion of the Advisory Committee referred to in Article 24, formally recognise a public health emergency at Union level; including pandemic situations where the serious cross-border threat to health in question endangers public health at the Union level. [….]. 4. […] On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread among Member States, the Commission may recognise situations of public health emergency pursuant to paragraph 1 through immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3).'

10 Article 13 - Review: 'By 2024 at the latest, the Commission shall carry out a review of this Regulation and present a report on the main findings of that review to the European Parliament and the Council. This review shall include an evaluation of the work of HERA under the emergency framework established by this Regulation, and their relation to the preparedness activities of HERA [, taking account of the evaluation referred to in Article 29(1) of the SCBTH [Serious Cross-border Threats to Health] Regulation] and shall include an assessment of the need to establish HERA as a distinct entity considering relevant agencies or authorities active in the field of health crisis. Member States shall be consulted and their views and recommendations on the implementation of the emergency framework reflected in the final report. The Commission shall, if appropriate, present proposals based on that report in order to amend this Regulation or make further proposals.'

11 Article 2(1) of the Commission decision establishing HERA: '(a) strengthening health security coordination within the Union during preparedness and crisis response times, and bringing together Member States, the industry and the relevant stakeholders in a common effort'.

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