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HERA (EU BARDA) – MORTAL CHALLENGES AND HOW TO ADDRESS THESE
A PROPOSAL TO PLACE HERA UNDER COUNCIL
AND WITH EUROPEAN PARLIAMENT OVERSIGHT

Introduction

1. **As never before, Covid-19 and a range of other global, regional and 'domestic' current and future public health challenges demonstrate the undeniable need to address these at EU Brussels *Council* level.** This requires a structure that is different from the current and delayed European Commission **Health Emergency preparedness and Response Authority (HERA) initiative that will only become operational in 2023.** Below is established how this can be done without impacting on EU Member States' health policy prerogatives.

2. Today the EU also is faced with incomplete (a not fully equipped European Parliament) and partly less effective EU institutions (for instance DG SANTE – both subjected to Member State prerogatives and less focused management). This does not impress European audiences. They are confronted with both a lack of Commission foresight and of efficient action to prevent human suffering and death. Ever since SARS broke out in China in *2002* and rocked global health and the economy, scientists and politicians warned to be prepared for the outbreak of a next Corona virus. In 2013 the Commission established a European Health Security Committee that could have anticipated Covid-19. But its merely advisory role prevented effective action.

3. Against that background, on 11 November 2020 the European Commission adopted a legislative proposal setting out the main elements of a future **Health Emergency preparedness and Response Authority (HERA), also known as the EU BARDA.** During her State of the Union Address on 16 September 2020, Commission President Ursula von der Leyen proposed the establishment of a biomedical advanced research and development agency for building a stronger European Health Union. Health Commissioner Stella Kyriakides supported this call during a Webinar on the EU Health Policy Package (29 October 2020). The new Authority **would support the EU's capacity and readiness to respond to cross-border threats and emergencies** – whether of natural or deliberate origin. During a press conference on 25 February 2021, German Chancellor Angela Merkel came out in support of the Commission's proposal for a HERA Incubator that will help the Member States tackling COVID mutations. Subsequently virtually all Heads of State and Government supported the proposal. *However, also concerns were raised by Member States. Denmark for instance questioned the practical and bureaucratic obstacles that could delay*

and hinder the establishment and functioning of HERA; obstacles that haunted many Commission initiatives in the area of health policies. Some of these problems may relate to recent appointments in DG SANTE. These reflect a remarkable drive to appoint trade and defense industry-related lawyers in the DG SANTE management. In short: the success of *any* new top pandemic fighter must be able to pre-empt potentially divergent Member State policies and approaches; only the Council may be able to do that. ***At all cost the EU must avoid to land in the same position as before the Covid-19 outbreak. European industry sectors and particularly SMEs will not survive another disaster. And while viruses can be combated within several months costing several hundreds of millions of Euros, the combating of totally or multiple-resistant bacteria will take years and hundreds of billions. Health experts, politicians and indeed the European Parliament conclude: the Commission's current way of dealing with the pharma industry is unsustainable. Because these industries can only be held responsible for their own shareholder value and profit, it is clear that new models for antibiotic development and production must urgently be developed and applied. Otherwise the current problem of a market failure to produce new antibiotics will not be overcome in time.***

What target? What scenario?

4. As in war and peace any prevention and preparedness start with a deep understanding of the 'enemy'. So before deciding on any new institution to resolve past and current shortcomings within the EU's health policy practice, it should be understood *what the next pandemic may be*. On that basis, the track record of the Commission with regards to dealing with that potential pandemic should be highlighted. Next, scenarios should be worked out so as to promote what in military terms is referred to as 'pre-emption', or, in French, 'dissuasion'. It is widely acknowledged by the global scientific community that one of the most likely next pandemics will be an outbreak of totally resistant bacteria, or antimicrobial resistance (**AMR**). The WHO has declared that AMR is **one of the top 10 global public health threats** facing humanity. Faced by this threat, the Commission:

   A. Has requested its own Scientific Steering Committee (SSC) in *1999* to issue an opinion on AMR. In no uncertain terms, the SSC warned the then DG SANCO (now DG SANTE) that the production, distribution and use of antibiotics must immediately be curtailed to prevent increasing levels of antibiotic resistance.
   B. In *2001*, the Commission asked whether the SSC was certain that the animal growth promotion through adding antibiotics to feed for optimal profitability should really be stopped. The SSC confirmed this. It then took the Commission five years (until 2006) to delete the regulation that explicitly allowed the use of antibiotics in husbandry.
   C. In *2017*, the Commission launched the EU One Health Action Plan against AMR, which appears to be less demanding than the 1999 SSC Report.

D. *In the same year (14 July 2017)*, the then European Commissioner for Health Vytenis Andriukaitis – following all kinds of pressures– defended the right of veterinarians in the EU to continue to sell antibiotics.
E. In *2019*, the European Court of Auditors (ECA) concluded that the Commission (with its One Health Action Plan and over 1 billion Euro in expenses) *has not delivered demonstrable results in reducing AMR.*
F. The *2020* Commission's 5th annual Progress Report on the implementation of the One Health Action Plan against AMR depicts that activities of the Commission and agencies have led to some progress, but there is little evidence that antimicrobial-resistant cases have been reduced and that sufficient actions have been taken in regard to the multiple recommendations made by the European Court of Auditors in its 2019 Report.
G. An EP report of *10 July 2018* establishes that the *Commission fails to correctly register annual numbers of AMR victims and annual volumes of antibiotics use*. A strong lobby manages to obstruct requirements for all hospitals throughout the EU to register AMR cases and another lobby appears to prevent that antibiotics sales throughout the EU, particularly to farms, are listed.
H. In response to a question from the European Parliament of *4 November 2019* the Commission states it (still) has no legal means to forbid the massive price dumping practices of major pharmaceutical industries selling large volumes of antibiotics to farmers. To complain about a 'market failure' does not quite cover the causes of the current antibiotics overuse that ***today will lead to a global INCREASE in antibiotics use with 67%*** *(World Bank, 2017)*.
I. Already in 2013, the European Commission established the *EU Health Security Committee (HSC)*. Even though both viral (COVID) and bacterial resistance (AMR) threats are mentioned in its 'statutes', this remains a bureaucratic structure without the required independence and power to effectively act.

5. Does this track record suggest that the European Commission is ready to manage a new body that must save millions of lives and prevent an economic disaster of trillions of euros? *There is no time nor space for failed experiments*.

Potential Solution: HERA transformed into a European Health Security Council

6. *One potential solution is to place the new HERA under the authority of the Council of the European Union, which may well prevent the bureaucratic and slow-motion approaches naturally bred into any civil service structure. Member State Ministers can more directly, swiftly, transparently and responsibly decide on approaches, actions, production and distribution decisions that are required now.* Member States can and should without delay undertake action *to prevent the next outbreak*, whilst a European Health Union will take years to

be established and to function properly. Under the guidance of the Council correct simulations-based decisions and operational flow models can be developed and put into practice without the burden of processes and procedures that arguably the European Commission cannot and should not avoid.

7. *The European Defense Agency (EDA) that rapidly gains political and public attention provides a unique basis for a EUROPEAN HEALTH SECURITY COUNCIL INSTITUTION. This would place the new HERA/EHSC under the sole authority and political scrutiny of the Council, while the Commission (represented by a Vice President for Health Security) manages the overall organization and functioning of the Agency.* This organizational structure would avoid those bureaucratic hurdles previously mentioned that hampered the correct functioning of several Commission's initiatives in the area of EU Health policies. Moreover, if HERA/EHSC is to incorporate the tasks and organization of the 2013 HSC, they would become *one* Agency – with the necessary legal personality to perform its tasks – that will holistically integrate all the key aspects of Health Security that should be prioritized at EU level. *This solution is in line with art. 168 TFEU and with the EU Ordinary Legislative Procedure, since a proposal by the European Commission (at the request of the European Parliament or the Council) may put forward such a legislative framework and place the Agency under the authority of the Council. For an extended explanation of this proposal, please refer to the attached note* (Attachment 1).

Background Information on the Commission HERA proposal

Current status of Commission's HERA proposal

8. The preparatory work is ongoing and the Commission will make a **proposal** for the future agency **in Q4, 2021**. At the same time, the Pharmaceutical Committee working group on Vulnerability of the global supply chain will issue its action plan. **Therefore, HERA will be operational by 2023 at best**.

9. During the EP Plenary debate on the EU vaccine strategy (10 February 2021), Commission President Ursula von der Leyen and Health Commissioner Stella Kyriakides stated that the EU will need to prepare for the COVID variants that have already emerged and for those that might come up in the future; therefore on 17 February 2021 President von der Leyen announced the launch of a preparedness agenda against new variants, or HERA Incubator.

10. Little has been said on how the Agency will be structured or who is going to lead it. As of now, it appears that the newly-appointed Commission's special adviser of vaccines, the Belgian Luc Debruyne, will play a role in it along with his fellow countryman Pierre Delsaux, Deputy Director for Health and Food Safety at the European Commission, who is said to be handling the management of HERA once implemented.

Commission Proposed HERA Goals and actions

11. HERA's **mission will be to enable the EU and its Member States to rapidly deploy the most advanced medical supplies and other measures** in the event of a health emergency, **by covering the whole value chain from conception to distribution and use**.

12. According to the proposal, HERA will undertake **horizon scanning and foresight** to anticipate specific threats, identify promising potential countermeasures and underpinning competencies, and generate and disseminate knowledge on these. **It will monitor and pool production capacity** and development facilities, raw material requirements and availability, it will **ensure that supply chain vulnerabilities are addressed**, and that **more coordination and cooperation in the EU (especially between the public and the private sector) is achieved to address production bottlenecks and to increase manufacturing capacities.** It will **support the development of crosscutting technologies and solutions** sustaining multiple potential future threat responses and the development of specific countermeasures, including through clinical trials and data infrastructure. **It will ensure that sufficient production capacity will be available when necessary,** as well as arrangements for **stockpiling and distribution**. HERA will plan**, coordinate and assemble ecosystems of public and private capabilities** that jointly enable a rapid response when the need arises. **When an EU health emergency is declared, it will acquire specific additional resources required to adequately react** in the interest of all Member States.

13. Within the proposal for the **HERA Incubator**, the latter will work with researchers, biotech companies, manufacturers and public authorities in the EU and globally to **detect and prevent the spread of new COVID variants** and to **provide incentives to develop new and adapted vaccines**, **speed up the approval process** for these vaccines and **ensure scaling up of manufacturing capacities**. In the end, the incubator will serve as a blueprint for the EU's long-term preparedness for health emergencies agency.

Commission proposed Options for a new legislative proposal

14. The Commission considers four 'policy options' for HERA:

a) 'Policy option 0: Baseline scenario': This option assumes the continuation of ad hoc solutions in case of crises.
b) 'Policy option 1: Strengthened coordination for threat assessment and knowledge generation based on joint undertakings and other mechanisms': This option would provide HERA an ability to recognise, prioritise and anticipate threats, analyse corresponding countermeasures, and identify investment gaps and/or market failures.
c) 'Policy option 2: A stand alone authority': Under this option, HERA would have a permanent structure established, with different degrees of operational roles and infrastructure.

a. ‘Sub-option 2.1: Operational Authority’: Under this option, the Authority would have integrated EU stockpiling and distribution mechanisms, as well the development of corresponding technologies and countermeasures addressing market failures and providing support and technical assistance related to regulatory issues concerning the safety and effectiveness of medical countermeasures.
b. ‘Sub-option 2.2: Operational and Infrastructure Authority: This Authority not only provides for the elements of option 2.1, but also establishes – as an end-to-end solution – dedicated EU centralised, flexible and scalable manufacturing and innovation capacities for the development of crisis-relevant countermeasures (including crisis relevant raw materials for medicines and protection gear to ensure stability in times of global supply chain vulnerabilities) adequate to respond to health emergencies and/or address market failures.

d) ‘Policy option 3: Full end-to-end Authority & streamlining of EU level initiatives on medical countermeasures for serious cross-border threats to health’: This Authority not only provides for the elements of option 2.2, but will also serve to streamline existing financial and operational instruments at EU level (e.g. Horizon 2020, Innovative Medicines Initiative, European Innovation Centre, rescEU medical stockpiling) which are active in the area of medial countermeasures under the control of the Authority. To this end, the Authority will act as a single entry point for all initiatives at the EU level concerned with support for, advancing and deploying emergency preparedness and response in terms of medical countermeasures for serious cross-border threats to health.

Initial responses to the Commission proposed HERA initiative

15. During the press conference for the launch of the HERA incubator, several questions were raised as to how the speed up of vaccines approval and the subsequent alteration of the regulatory framework of the European Medicines Agency (EMA) can be achieved without compromising on safety. According to Euractiv, President von der Leyen stressed that “this would not be the case” and that the entire procedure “would involve synchronizing steps in the process rather than losing content”.

16. MEPs: Overall, the HERA project (which is part of the EU4Health programme) has been widely endorsed by the European Parliament, as its members (MEPs) approved it by a large majority in the ENVI Committee. According to POLITICO EU, German MEP Tiemo Wölken (S&D) said he was happy to see plans for better cooperation within the framework of the incubator, especially between the public (EU) and the private (Pharmaceutical companies) sector but surprised some of these proposals “are only being proposed now” given the recent quagmires between the Commission and AstraZeneca on the COVID vaccines. The same opinion was also expressed by MEPs such as Frédérique

Ries (Renew Europe), Christophe Grudler (Renew Europe), and Tilly Metz (Greens).

17. Industry: *The proposal was also welcomed by pharmaceutical manufacturers such as Sanofi, Johnson&Johnson (J&J) and GSK who stress the importance of adequate funding, flexibility, speedy processes, low bureaucracy, a clear definition of role and responsibilities to cooperate with existing European and global bodies, R&D and R&I. According to J&J, "the new agency should be staffed with experts with industry knowledge and experience in drug, vaccine, diagnostics and medical devices development to be able to effectively select, rapidly negotiate, and monitor its projects and to drive product development and licensure". Moreover, "HERA's legal set-up should incorporate a framework to provide adequate indemnification and liability protection to manufacturers who are willing to supply vaccines, drugs, diagnostics and medical devices for use in emergency settings".*

18. Member States: The proposal has been also been welcomes by the EU Member States. In a videoconference meeting of members of the General Affairs Council (23/02/2021), Slovenian State Secretary Gašper Dovžan supported the European Commission's plans to set up a central European Authority for Emergency Preparedness and Response. For the Spanish Ministry of Health, it is essential that the authorities of the Member States participate from the beginning in the different phases of the development of HERA. For the Italian National Institute of Health (ISS), HERA should consider a specific EU training programme on Health Emergency Preparedness and Response to be offered to Public Health Officers or Similar Health Professional, in order to promote and support the overall EU culture on the response to current and future health threats, given in particular by the lessons learned from the ongoing Pandemic. For the French Secretariat-General of European Affairs, in order to promote the production of goods that are essential to the health of European citizens and the long-term European strategic autonomy, mechanisms could be examined to target the manufacture of certain products on European territory. At the same time, each Member State could inform HERA of the projects supported at national level so that HERA can assess the relevance of including them in its roadmap.

19. For the Danish Ministry of Health, the project's focus on highly skilled employees, interfaces with other sectors, global outreach and PPP are highly appreciated; nonetheless, several issues need further clarification. For instance, HERA will have many interfaces with existing agencies such as the EMA and the ECDC, but these interfaces are not fully mapped in the inception impact assessment. Also, Member States have not received a detailed description of the Agency and thus there are still uncertainties with regards to overlapping tasks. Therefore, the Danish Health Minister Magnus Heunicke urges the Commission to put forward a more detailed outline of HERA's

proposed tasks and interfaces with other agencies as soon as possible. The same worries have been also expressed by the Czech Ministry of Health. The Belgian Federal Public Health Service is generally supportive of the Commission's proposal, but it also raised questions concerning, for instance, how to establish the right scope and priorities, the relation between HERA and other EU bodies, fairness and equity in financing, and how to avoid dependency on companies.

20. Institutes: Also EIT Health welcomes the European Commission's ambition to create the HERA, and it emphasizes the importance of a strong partnership mindset and collaborative culture. For EIT Health, "to enhance the attractiveness and overall performance of the authority, HERA should aim to integrate with the existing preparedness and response ecosystem, and to work closely with key partners. EIT Health would like to be closely aligned with agency objectives and priorities, and is ready to contribute to the development and realisation of the HERA objectives as soon as is practical. EIT Health foresees several opportunities to contribute to projects under HERA's mandate".

21. Patients: For the European Public Health Alliance (EPHA), HERA is a "great opportunity to build on the excellent European science" and it "should be a purely public organisation with a clear public health mission, not to be conflated with areas of industrial policy." According to EPHA, HERA should also have a transparent and balanced governance structure, it should be independent, sustainable and protected from political pressure, it should address the current lack of coherence between EU and national funding schemes, and it should have enforceable rules on Open Access and reasonable pricing clauses. Also the BEAM Alliance welcomes the HERA initiative, highlighting that it must include AMR in its scope of action.

Attachment: A Proposal on Structure and Organisation including the Council and the European Parliament

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