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**Attachment to MEMO on HERA/EHSC – MORTAL CHALLENGES AND HOW TO ADDRESS THESE
A PROPOSAL ON STRUCTURE AND ORGANISATION INCLUDING THE COUNCIL and THE
EUROPEAN PARLIAMENT**

Introduction

1. According to Art 168 [TFEU](#), the European Union’s actions concerning Public Health “shall complement national policies”, covering areas such as the “fight against major health scourges, by promoting research into their causes, their transmission and prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health”. As it has been widely acknowledged by the EU Institutions, “a number of developments at Union and international level in the past decade have made a review of [the] legal framework necessary”¹. Indeed, the “current health security arrangements, as established by Decision No 1082/2013/EU on serious cross-border threats to health, provide limited legal framework for EU level coordination [...]. Early lessons learned from COVID-19 have shown that the current system has not ensured an optimal response at EU level to the COVID-19 pandemic”².

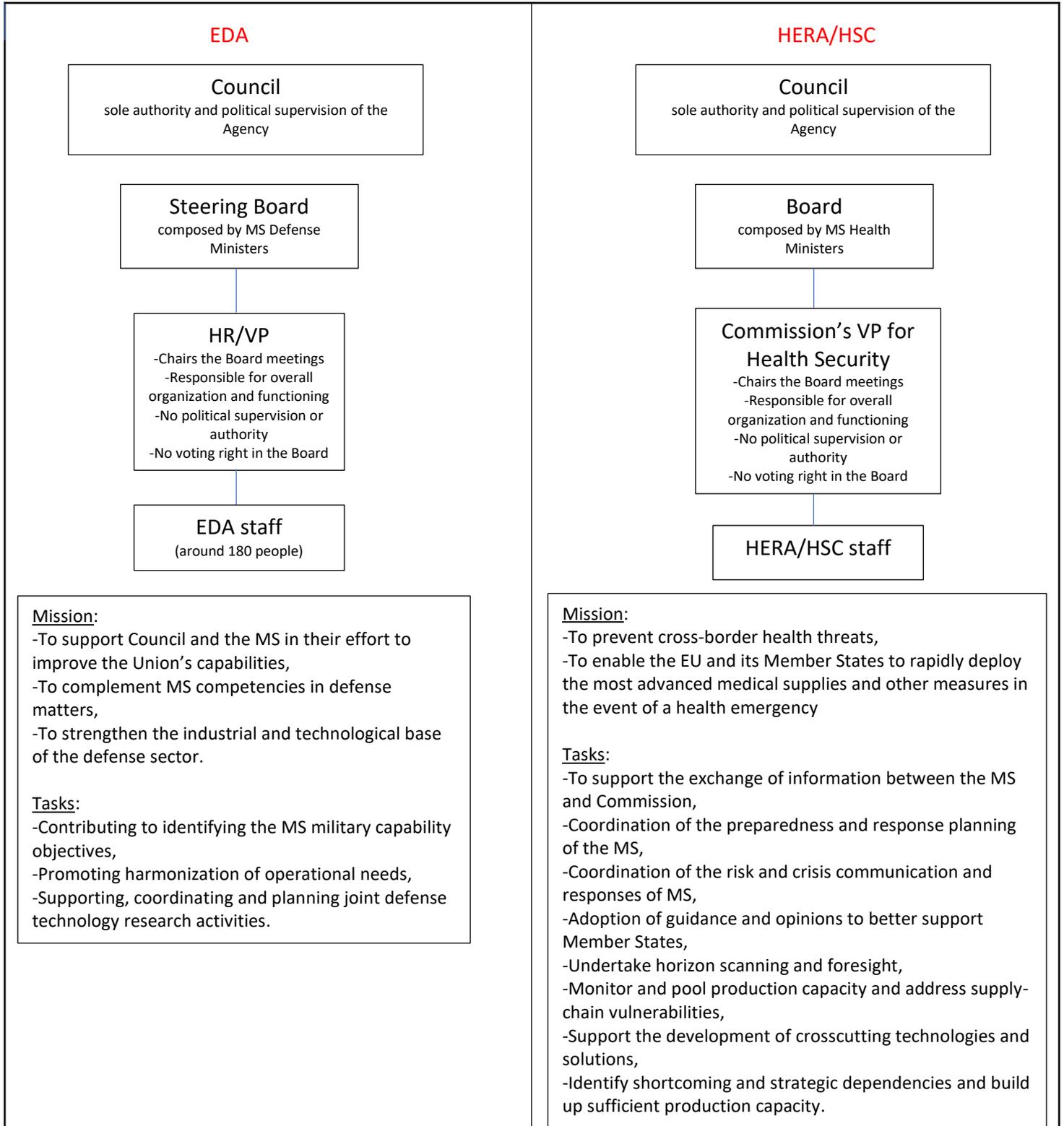
Conclusions

2. One of the current proposals being discussed at EU level to increase the Union’s prevention and preparedness to serious cross-border threats is the establishment of a Health Emergency preparedness and Response Authority (HERA). However, if the new HERA organization as currently planned by the Commission reflects the Commission’s record in dealing with COVID-19 and with AMR (as criticized by the 2019 report of the Court of Auditors), it may never live up to the European citizen’s expectations. In meeting the necessary requirements with regard to democracy, transparency and the Rule of Law, **HERA must include provisions ensuring scrutiny by the European Parliament and supervision by the European Council.**
3. **The solution may well be to place a new HERA/European Health Security Council institution under the authority of the Council rather than the Commission, following the example of the European Defense Agency (EDA) that is now rapidly increasing in attention and importance. Moreover, if HERA is to incorporate the tasks and organization of the current Health Security Committee (HSC), it is clear that such an Agency will holistically integrate all the key aspects of Health Security that should be prioritized at**

¹ Decision No 1082/2013/EU, (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D1082&from=EN>)

² Commission’s Proposal for a Regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU, https://eur-lex.europa.eu/resource.html?uri=cellar:9ac56db8-24e6-11eb-9d7e-01aa75ed71a1.0001.02/DOC_1&format=PDF

EU level. Through this combination, both HERA and the HSC can become *one* Agency (having therefore the necessary legal personality to perform its functions and attain its objectives) under the sole authority of the Council and managed for the overall organization and functioning by a Commission’s Vice-President for Health Security (nominated at the discretion of the Commission’s President); similar as for EDA.



Legislative framework

4. This solution is in line with art. 168(5) TFEU, which states that “the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may [...] adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges [...]”. Therefore, 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.

EDA – an example to follow

5. **The key model** to follow for the establishment of HERA is **the key important European Defense Agency (EDA)**. According to the Council Decision (CFSP) 2015/1835, art. 42 and art. 45 TFEU, EDA is **placed under the Council’s authority and political supervision** within the single institutional framework of the Union, and without prejudice to the responsibilities of the Union institutions and the Council bodies. As a consequence, EDA reports regularly to the Council on its activities. Nonetheless, EDA is managed by the HR/VP, who is responsible for the Agency’s overall organisation and functioning and presents the EDA’s report to the Council. Therefore, the **Commission is represented inside** the EDA organisation. The Commission also receives the Agency’s recommendations and it is a member (without voting rights) of the Agency’s Steering Committee Board (composed of one representative of each participating Member State meeting at the level of Defense Ministers). Moreover, EDA pursues working relations with the Commission, in particular with a view to exchanging expertise and advice. The mission of the Agency is to support the Council and the Member States in their effort to improve the Union’s capabilities, to act without prejudice to the competencies of Member States in defense matters, and to identify operational requirements, promote measures and contribute to identifying and implementing measures needed to strengthen the industrial and technological base of the defense sector. Among its tasks, EDA contributes to identifying the Member States’ military capability objectives, it promotes harmonization of operational needs, and it supports, coordinates and plans joint defense technology research activities, all in an effort to prevent a war or violent confrontation, not to necessarily fight it.
6. Following this example, **the new HERA could incorporate the current tasks and structure of the Health Security Committee** (set up in 2013 with Decision No 1082/2013/EU). The Health Security Committee (HSC) is today an informal advisory group composed of high-level representatives from Member States (from Health Ministries or National Health Centers) and chaired by a representative of the Commission. Through this combination, the HERA/HSC structure will mirror the EDA organization as it will be under the sole authority of the Council and managed for the overall organization and functioning by a Commission’s Vice-President for Health Security (nominated at the discretion of the Commission’s President). As of now, the tasks of the HSC are:
 - To support the exchange of information between the Member States and the Commission (among others on Antimicrobial Resistance);

- Coordination in liaison with the Commission of the preparedness and response planning of the Member States;
- Coordination in liaison with the Commission of the risk and crisis communication and responses of Member States to serious-cross border threats to health.

According to the initial Commission's Proposal for a Regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU, which is now discussed at EU level, the current HSC "should be given additional responsibilities with regards to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health".

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