



Dr. Laura Hering, LL.M. (Bruges); Dr. Pedro Villareal; PD Dr. Katarina Weilert, LL.M. (UCL)

Workshop

The European Health Union

Set up, challenges and global outlook

Time and Place

When?

December 1 (afternoon) and December 2 (morning), 2022

Where?

Max-Planck-Institute for Comparative Public Law and International Law, Im Neuenheimer Feld 535, D-69120 Heidelberg, Room: 038

Outline of the Workshop

The idea of a European Health Union was conceived in November 2020, due to the shortcomings of an effective European Union (EU)-wide preparedness and response system for facing the Covid-19-pandemic. The EU has only limited competences in the policy field of health. While the organisation of medical care is in the exclusive hands of the Member States, there are Union competences for health security and public health. The most far-reaching competence exists in the area of common health security concerns under Article 168 (4) TFEU as part of the shared competences (Article 4 TFEU). This includes, for example, the establishment and operation of the European Medicines Agency (EMA), grounded on the foresaid competence for the policy area of health as on the harmonisation of the internal market under Article 114 (4) TFEU. The European Centre for Disease Control and Prevention (ECDC), on the other hand, operates under the goal of protecting human health in all EU laws and policies according to Article 168 (5) TFEU. For that purpose, the ECDC monitors and issues early warning reports to combat widespread and serious cross-border diseases. These competences are part of the supporting, coordinating and supplementing competences of the EU (Article 2 (5) TFEU). There are, however, advocates of very far-reaching reform proposals. Some even propose an amendment of the European Treaties to extend the EU's competences in the health sector to counter cross border threats to health. Even the then German Chancellor Angela Merkel did not consider an amendment of the European treaties out of the



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question. However, such a reform of the European treaties is not currently being pursued and it also seems unlikely to be implemented in the near future due to the high hurdles.

While pushing forward towards a European Health Union, the EU Commission is promoting its idea with phrases such as “strengthening the EU’s health security framework”, “reinforce the crisis preparedness and response role of key EU agencies” and “stronger preparedness and response during the current and future health crises”. The wording of a “European Health Union” raises multiple questions. It is a political term, and vague from a legal point of view. It suggests that health has an outstanding place in the EU and that the Union might delve more deeply into Health beyond its position in the Single Market. In fact, health has to be considered within all policies and activities (Article 168 (1) TFEU), yet promoting health is not the main goal under which all other purposes are subordinated.

In its different areas, the European Health Union aims at a better coordination between the member states with regard to cross-border health threats, as well as reinforcing the EMA and the ECDC, equipping both with stronger mandates. The European Commission has summarized the enhanced mandates of both agencies as: 1) allowing the ECDC to undertake epidemiological surveillance, preparedness and response planning, reporting and auditing, recommendations for risk assessment and management, deploying the EU Health Task Force, and building a network of reference laboratories; and, 2) the EMA’s mandate will now include monitoring and mitigating the risk of shortages of critical medicines and medical devices, providing scientific advice on medicines for treating, preventing or diagnosing diseases causing those crises, and coordinating clinical trials and pharmacovigilance of vaccines in the market.

In addition to strengthening and revising the EMA and ECDC, a new body, the Health Emergency Preparedness and Response Authority (HERA), was created by the European Commission. The new tasks of HERA are described, in a nutshell, as aiming to “improve EU health security coordination before and during crises; bring together the EU Member States, industry and relevant stakeholders; develop, produce, procure, stockpile and equitably distribute medical countermeasures and reinforce the global health emergency response architecture”. At the moment of writing, the legal competences of this body are the subject of ongoing negotiations, on the basis of two proposed Regulations.



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Research Questions

While the establishment of a European Health Union signals a possible major shift, it also raises many questions:

- 1.) How can the work and influence of the different EU institutions coping with the COVID-19 pandemic be evaluated? What was the particular legal role played by different institutions, organs and agencies?
- 2.) Does the current proposal to build a “European Health Union” constitute a break from the status quo in EU law or is it rather a constrained adjustment?
- 3.) Is Treaty change necessary to build a European Health Union? If so, what could it look like?
- 4.) Which role will different EU institutions, both current and new ones, play? What will be the overlaps with organizations beyond the EU, such as the WHO?
- 5.) What efforts could the declaration of an emergency situation in the EU have? What is its relationship to the WHO’s own international emergency declarations?
- 6.) How can the European Health Emergency Response Authority (HERA) and its mandate be described from a legal and a political perspective? How does HERA interact with the new setup of the ECDC?
- 7.) To what extent would an enlargement of EU activities in health emergencies be capable of improving the EU’s overall performance during a pandemic? Under what conditions?
- 8.) How will European and national law react to the regulatory requirements of a European Health Union? How will the EU’s role in health emergencies relate to multilevel infection control regarding national systems, like Germany, with a high degree of decentralization of infection control?

These research questions are only suggestions. We are open to further ideas in this context.