EIPA Briefing 2021/2

Health Crises and the Growth of EU Agencies:

The Response to the COVID-19 Pandemic

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Health crises have often triggered the creation of EU agencies. The European Centre for Disease Prevention and Control (ECDC), for instance, was created in 2004 in the wake of a SARS outbreak and the spread of avian flu. The COVID-19 pandemic is no exception. The European Commission has set out to build a European Health Union to strengthen the EU's preparedness for cross-border health threats. The Health Union is also an exercise in 'agencification' as the Commission has proposed to revise the mandates of existing agencies and to create new agencies. This briefing presents the proposals and discusses the challenges of 'agencification' in public health.

Introduction

In her State of the Union address in September 2020, Commission President Ursula von der Leyen stressed the need to build a stronger European Health Union in order to strengthen crisis preparedness and management of cross-border health threats. However, in the EU, public health is an ambiguous policy area (see Art. 168 TFEU). Although health protection is an overarching objective in all policy areas, public health is mainly a supporting competence of the EU. There are some areas, such as setting standards for medicinal products, in which, by way of derogation, EU competences supersede national competences. Regarding serious cross-border threats to health, however, EU action can only complement national policies. The organisation of health services and medical care is the responsibility of the Member States.

The Commission has highlighted several problems. National variance in terms of preparedness means that Member States have different levels of capacities to respond to health crisis. Without coordination, Member States might compete against each other when procuring medical countermeasures. There is currently no common threat assessment which might support joint intervention mechanisms, and the availability of countermeasures and production capacities in the EU is unknown. Existing agencies like the ECDC and the European Medicines Agency (EMA) do not have the mandate to audit national preparedness and to initiate a common response in times of crisis. Finally, developing countermeasures is resource-intensive and entails financial risks for businesses which, in turn, requires public-private partnership for investment and finance.

This briefing presents the most important proposals related to agencies in public health with a focus on crisis preparedness and management. It then discusses the challenges of 'agencification' in relation to agency governance, inter-agency cooperation and funding.

The European Health Union and the existing agencies

In November 2020, the Commission issued two legislative proposals reinforcing the roles of EMA and ECDC respectively.

The **proposal on EMA** aims to establish new organisational structures and working procedures: the Executive Steering Group on Shortages and Safety of Medicinal Products, the Emergency Task Force and the Executive Steering Group on Medical Devices. These bodies are to monitor the availability of critical medicines and devices, and to provide scientific advice and recommendations on measures to mitigate the risk of shortages. In line with these mandates, the proposal entails extensive reporting requirements for Member States and marketing authorisation holders of critical medicinal products. The proposal is currently being discussed in the respective Council working party and two committees in the European Parliament, ENVI (Environment, Public Health and Food Safety) and ITRE (Industry, Research and Energy).

The **proposal on the ECDC** aims not only to reinforce the agency, but also to increase the consistency of its remit with other existing measures relating to cross-border health threats. It includes several provisions to bolster the ECDC's role in epidemiological surveillance and preparedness and response planning, based on monitoring, reporting, guidance and self-assessment by national authorities. Furthermore, the proposal creates a Health Task Force to support Member States in their preparedness, and provides for the agency to make recommendations on strengthening national health systems. The proposal is currently being discussed in the Council and the ENVI committee.

In February 2021, the Commission created the new European Health and Digital Executive Agency (HaDEA) to help implement funding schemes in the context of the EU4Health programme. This complements the Health Union in that it supports actions taken to address serious cross-border threats to health within the remit of ECDC and EMA.

Challenges of creating the new agency HERA

In January 2021, the Commission published the inception impact assessment for the initiative to create a new agency, the **European Health Emergency Preparedness and Response Authority (HERA)**. The assessment was open to initial feedback, which will be followed by more extensive public consultation in the course of drafting. The Commission has also established a High-Level Expert Group of Member States' representatives to discuss the initiative.

The Commission presented a range of options. At one end is a limited option of flexible coordination among the Commission and the Member States for knowledge generation and threat assessment. A more extensive remit requires a permanent agency structure and also entails the development, manufacturing and procurement of medical countermeasures. At the other end of the range is an agency which performs all of these tasks and streamlines all operational and financial measures at the EU level. According to the inception impact assessment, this option creates an agency which is at the centre of all measures related to preparedness and would take the leading role among all actors concerned with cross-border health threats.

Governance

The proposal to create HERA was met with support from Member States and stakeholders. Businesses favour an agency with an extensive remit. So do most Member States, although questions about decision-making procedures and the role of national authorities have been raised. NGOs support the proposal, but many have concerns about public-private partnership for investment and finance. These were echoed in contributions from citizens who reject the proposal due to the involvement of pharmaceutical businesses.

The pandemic has shown that more efficient decision-making procedures are essential for an effective response to cross-border health threats. HERA is supposed to rectify the fragmentation of preparedness and crisis management across the Member States. Here, an important issue is the distinction between non-crisis and crisis operations. In the latter case, efficient decision-making with the agency at the centre of all measures is appropriate, but this is not necessarily the case with non-crisis operations. While Member States generally support creation of an agency, questions about decision-making already cast doubts as to whether HERA will indeed take the 'leading role in the sphere of EU agencies' as envisaged by the Commission.

Inter-agency cooperation

The issue of coordination is critical. This is reflected in the proposals, with several bodies being created as part of the agencies. To implement the extended mandates of both agencies requires, for instance, information sharing with regard to epidemiological data, vaccine effectiveness studies and reports about shortages of medical devices.

In recent years, EU agencies have already built structures for collaboration by creating networks and concluding inter-agency cooperation agreements. Several Member States and stakeholders have pointed to the challenges of coordination in an already 'crowded' policy area involving several agencies, expert groups, one executive agency and various networks of national authorities. The extent to which HERA can provide real added value will depend on its legal mandate as well as its ability to carve out space in the field of cross-border health threats.

Funding

The Commission has repeatedly referred to the example of the US agency BARDA, the Biomedical Advanced Research and Development Authority. BARDA was critical for responding to the COVID-19 crisis, including diagnostics, therapeutics and vaccine development. In total, BARDA made available over USD 60 billion in funding, most of it for the development of vaccines, the build-up of manufacturing capacity and advance purchasing contracts. It is widely accepted that the rapid development of vaccines was due to this immense funding effort.

It is not clear that the Member States are willing to follow this example. Calls to streamline existing instruments already indicate a certain hesitancy, and some Member States have explicitly spoken against increasing the EU budget to this end. Moreover, the public consultation also revealed the concerns of NGOs and citizens with regard to public-private partnerships in the financing of medical countermeasures. These concerns will be even more salient in the legislative process.

Conclusion

The reinforcement of existing agencies and the creation of new agencies is one essential element of the European Health Union. However, creating institutions does not in itself solve the identified problems relating to cross-border health threats. The problems of the current framework for cross-border health threats are well known, but specifying the most appropriate response in the legislative processes will be controversial. The added value of HERA will depend on a coherent legal framework, efficient decision-making procedures and funding appropriate for its mandate and tasks. However, the biggest challenge is perhaps to establish a shared understanding of cross-border threats among the multitude of actors involved at EU and national level. Efficient procedures are a prerequisite for effective crisis management, but in order to overcome the fragmentation of the current framework, these actors will have to establish working relations and build trust in times of non-crisis.