

AIM FEEDBACK TO THE EUROPEAN HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (HERA)

I. Introduction

The pandemic has shown that “more Europe” is an opportunity. However, the prerequisite is that real solidarity between the states and their people is actually put into practice and not only vocalized. The EU with its institutions must succeed in communicating real joint action and its benefits to all European citizens. The EU should become proactive regarding the management of European global public health risks. Protecting citizens, including preparedness for epidemics is one of the major objectives of the current EU health policy and should be read in conjunction with other health-related legal basis, such as disaster protection (Article 195 TFEU). Health crises like Covid-19 are global in nature and require collaboration. This has been proven by various examples such as the help provided by the German state of Baden-Wuerttemberg to patients from Alsace in France. Such a collaboration and collective action can only work if certain powers are transferred to European level while respecting national competences. At the same time, it should be accompanied with local knowledge related to the management of health systems. There is a clear case for a stronger EU health policy that can ensure cooperative policy solutions across Member States.

II. Proposals

1. **A stronger EU health policy with regards to preparedness for epidemics is necessary in collaboration with the EU Member States**

Whether a stronger EU global public health policy with regards to preparedness for epidemics should be tackled by an “end-to-end-authority”, which takes a leading role among the EU agencies and acts as a unique principal coordinator and unique decision maker as suggested in policy option number 3 is questionable. For the moment, there is still not much hindsight on how the EU coped with the COVID-19 pandemic and it is still not possible to draw all the knowledge and experience from the pandemic. Even though a stronger cooperation at EU level is necessary, Member States have knowledge about their regions and their health system. Europe should especially act as a power, where the various member states are “powerless” compared to other major powers, such as multinationals. But it should also be possible that the outbreak of pandemics can be dealt with very quickly at local level, if necessary. It is therefore important to find a good balance between a European and a local approach. Therefore, an operational authority (and infrastructural authority) with participation of European Commission, industry-led associations and Member States as well as small and medium-sized enterprises, research organizations, academic and corporate members seems to be more worth a discussion (policy option 2, notably option 2.2). A strengthened coordination for threat assessment and knowledge generation based on joint undertakings and other mechanisms as pointed out in policy option 1 might also be a possibility and should be discussed. However, it seems to be too weak of an institution to tackle an epidemic crisis.

2. The relationship to existing authorities and other EU mechanisms should be clarified

With regards to already existing institutions like the European Centre for Disease Prevention and Control (ECDC), which plays a crucial role in identifying, assessing, and communicating threats to health from communicable diseases and the WHO, which coordinates the implementation, the relationship and tasks should be clarified. The collaboration with the World Health Organization and the research of synergies with the World Health Organization could feature more highly in the plan. The document aims to address global threats to health, so some sort of coordination with the global health organization is also needed. They have developed an R&D Blueprint for Action to Prevent Epidemics back in May 2016. The Blueprint is probably outdated but it shows that reflection needs to be taken, at some point, at international level. Other coordination mechanisms coming from Decision 1082/2013/EU on serious cross-border threats to health, e.g. the Early Warning and Response System (EWRS) or the coordination of responses of the Health Security Committee didn't seem to be sufficient to tackle the COVID-19 crisis. When establishing a HERA, the missing parts should have been analysed and understood before creating a new authority. The relation to the above-mentioned mechanisms should be made clear to avoid legal uncertainties and to ensure a clear distribution of competences and tasks.

3. For a better stronger EU health policy with regards to pandemics, the EU should develop

a) EU scenario book for pandemics should be developed describing competences and tasks of European/International institutions

Independently from the question, whether there will be an independent new authority called HERA or not, the EU should in any case develop a European preparedness plan for pandemics with clear competences of the European and International institutions including a clear governance description. This European preparedness plan should include:

- The measures, which have to be taken at European level
- The measures, which have to be taken at national level
- Tasks of the main institutions such as European Commission, European Parliament and Council should describe:
 - clear competences of the institutions
 - clear governance description
 - permanent cooperation between institutions and Member States
 - cooperation with the WHO/WHO Europe
 - cooperation between task forces, which include specialists from certain areas.

b) A mapping of national pandemic measures is necessary

To make informed recommendations for more effective pandemic governance in the EU, a mapping of national legislation regarding the pandemic management should be undertaken. Time and expenditure that have already been taken into account to make use of what is already in place and to communicate if planning was not included in legislation. The pandemic plans of the Member States should be shared between the countries. In this connection, the improvement of digitalization of the surveillance systems could help. Member States should conduct stress tests, which focus on hypothetical scenarios, during which it would be difficult for the health system to maintain its essential function of providing services

to protect population health. The stress test explores approaches to effectively manage acute and chronic climate-related events and conditions that could directly impact health systems, and climate-related events in non-health sectors that can indirectly impact health outcomes and/or health system function.

c) Affordability and availability of medicinal products

The Commission rightly pointed out that the planned HERA should help ensure the affordability of medicinal products that were brought to the market thanks to its mechanisms. We call on the European Commission to ensure transparency on the underlying elements of the product's cost. The debate is very important at EU level and the European Commission should support transparency, when it has a significant input into products' development. Such steps could also help increase transparency of other products' underlying costs.

COVID vaccines were developed by public-private initiatives. This implicates a return of investment for the public sector as well by affordable medicines. However, that this is not the case for all vaccines. Huge profits are being made. In any case, there should be stronger clauses and a call for solidarity with other countries outside the EU. There is no room for IP's in times of crises.

During the current coronavirus crisis, the European Commission took a leading role in putting together mechanisms to make sure that Member States would have access to needed medical countermeasures and vaccines. The current difficulties with regards to securing the availability of doses shows that there is still room for improvement for action at EU level. The European Commission's role is currently focusing on coordination and facilitation. The new HERA should help the European be not only a procurer, but also a stronger, proactive technology researcher and developer, as well as coordinator of the European industrial network in times of crises.

d) A new tertium genus: Guidelines between existing recommendations and binding acts

Guidelines of the new authority could serve as a new tertium genus being more than the mere coordination public health measures and less than the harmonization of public health measures. Not following these guidelines would lead to a justification of the Member State, they would be asked to comply or explain. As mentioned above: In the beginning of the pandemic, Member States failed to come together and it was too late, when they finally started acting jointly together. The ineffectiveness of the EU Cross-border Health Threats mechanism is based on one major structural cause: Healthcare falls within the competence of the Member States including common methods for data collection on the spread of the virus, the characteristics of infected and recovered persons and their potential direct contacts as well as a EU-wide common testing strategy to cross-border cooperation in healthcare emergency assistance. The new role for the EU must be in designing and enforcing an EU-wide coordinated approach for a better preparedness in the future. The proposed "Joint European Roadmap towards lifting COVID-19" of the European Commission together with European Council is such an approach, balancing the need for EU-wide coordination and Member States' different country-specific needs and cost-benefit calculus.¹⁰ The guidelines of the ECDC could follow the same path. Still the legal implications of these guidelines remain unclear. They do not constitute legal acts at EU level, what is more, they should be more than simple recommendations, that can be followed or not. These guidelines could go through the legislative process and become 'soft' legislative acts. They could serve as a new tertium genus being more than the coordination public health measures and less than the harmonization of public health measures. Not following these guidelines should only be exceptionally allowed.

4. Role of Member States: Resilience of healthcare systems as a political priority in the European Semester

As mentioned above, the national competence for public health policy remains with the Member States. National policies matter for convergence, but their coordination is essential to maximize their effectiveness. Member States should commit to common rules and recommendations adopted at European level, may it be a stand-alone authority or coordination.

The resilience of healthcare systems was one of the major issues during the COVID-19 crisis and the reason for the lock down in Member States. The European Semester for economic policy coordination can help facilitate to ensure better resilience of these systems and to reach a better preparedness of Member States during pandemics. Through the Semester a solid economic and fiscal coordination system has been put in place, in which Member States commit to common rules for economic policies adopted by the Council of the European Union under the surveillance of the European Commission. Health, notably the improvement of resilience of healthcare systems and a better preparedness for health emergencies, should be given the same weight, especially with regards to the current COVID-19 crisis. However, the recommendations need to be correctly targeted to ensure sustainability in and adequacy of healthcare and to improve their resilience. It must be made a political priority at national level and aligned with political ambitions. Social aspects such as the Pillar of Social Rights should be even more integrated into the process. Countries need to pledge themselves to commonly agreed goals to prevent the collapse of health systems. If Member States do not implement an agreed goal, pressure should be put on their justification for not following the agreed goals.

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AIM Healthcare and social benefits for all

The International Association of Mutual Benefit Societies (AIM) is an international umbrella organisation of federations of health mutuals and other not-for-profit healthcare payers. It has 57 members from 30 countries in Europe, Latin America and Africa and the Middle East. 33 of its members, from 20 countries, are based in the European

Union. AIM members provide compulsory and/or supplementary health coverage to around 240 million people around the world, including close to 200 million people in Europe, on a not-for-profit basis. Some AIM members also manage health and social services. Collectively, they have a turnover of almost €300 billion.

AIM members are either mutual or health insurance fund.

They are: private or public legal entities; solidarity based; not-for-profit oriented organisations: surpluses are used to benefit the members; democratically-elected members play a role in the governance of the organisation.

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