BRIEFING

European Parliament

European Health Emergency Preparedness and Response Authority (HERA)

Pre-legislative synthesis of national, regional and local positions on the European Commission's initiative

This Briefing forms part of an EPRS series which offers a synthesis of the pre-legislative state-of-play and advance consultation on a range of key European Commission priorities during the latter's five-year term in office. It seeks to summarise the state of affairs in the relevant policy field, examine how existing policy is working on the ground, and identify best practice and ideas for the future on the part of governmental organisations at all levels of European system of multilevel governance.

Summary of findings

This analysis of the positions of partner organisations at EU, national, regional and local levels suggests that they would like the following main considerations to be reflected in discussion of the legislative proposal to establish an emergency framework for a European Health Emergency Preparedness and Response Authority (HERA):

- Governmental organisations at all levels advocate a **robust operational and infrastructural framework**, with a long-term vision, a coherent legal structure and efficient decision-making procedures. They generally favour a **comprehensive impact assessment** in advance of the establishment of HERA.
- Public authorities at national, regional and local levels suggest that the HERA should develop a strong relationship with the **World Health Organization** (WHO). Some governmental organisations especially stress the need for robust links with **developing countries**.
- Public authorities agree on the need for a clear interface between HERA, the European Centre for Disease Prevention and Control (**ECDC**) and the European Medicines Agency (**EMA**). A further issue is the relationship between HERA and existing EU operational **crisis management** mechanisms, where national authorities recommend **avoiding duplication of work**. They also suggest taking into account **regional and local circumstances** in a coordinated crisis response.
- Many governmental organisations hold a rather positive view of the interaction between the EU and the national levels, where HERA could have a beneficial **coordinating role**, although some public authorities have expressed concern about **possible conflicts of competence** between national and EU levels in the health sector.

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1. Current state of play

Background

The Member States of the European Union (EU) and their regional and local authorities are the main actors responsible for health policies and the operation and management of health systems. The EU level has only a complementary role in relation to national public health policies.[1] The coronavirus pandemic revealed critical weaknesses in the ability of the EU and its Member States to face cross-border health emergencies. Neither individual Member States nor the EU were able to effectively anticipate threats and monitor needs. They lacked coordination and a systematic approach to support development, production and procurement of necessary medical countermeasures.[2] They also demonstrated an imperfect overview of the supply chain of medical countermeasures and manufacturing capacities. Overall, the pandemic has underlined the value of cooperation between all levels of governance – global, EU, national, regional and local – and demonstrated that there is a need for the EU to build up its capacity to respond to crises and ensure better resilience to future shocks.

Figure 1 – Greek goddess Hera

Source: © zwiebackesser / Adobe Stock.

To address these challenges, the European Parliament and EU Member States called for proactive action at the EU level to ensure preparedness, as well as the ability to pre-empt and respond jointly to crises. As a result of these calls, the European Commission published on 11 November 2020 its communication 'Building a European health union: reinforcing the EU's resilience for cross-border health threats'. This communication sets out proposals to strengthen the EU's health security framework, with a particular emphasis on the role of EU agencies such as the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). It further proposes the creation of a new authority, the Health Emergency Preparedness and Response Authority (HERA). According to the Commission's description in the subsequent pharmaceutical strategy for Europe, 'HERA will ... develop strategic investments for research, development, manufacturing, deployment, distribution and use of medical countermeasures. This will require the assembly of ecosystems of public and private capabilities that jointly enable a rapid response when the need arises.'

On 27 January 2021, the European Commission published its inception impact assessment on the proposed creation of the HERA and received feedback from stakeholders. It then launched a public consultation, which ran from 31 March to 12 May 2021. The Commission subsequently published a factual summary of this public consultation exercise and uploaded public contributions to it. In February 2021, the Commission set up a HERA Incubator – a new bio-defence preparedness plan, operated by the Commission on behalf of the EU, to prevent, mitigate and respond to coronavirus variants, which served as a vanguard for the proposed HERA.

On 16 September 2021, the Commission adopted: the Commission decision establishing the Health Emergency Preparedness and Response Authority (HERA), as a Directorate-General of the Commission, which entered into force on the same day; and the proposal for a Council regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in

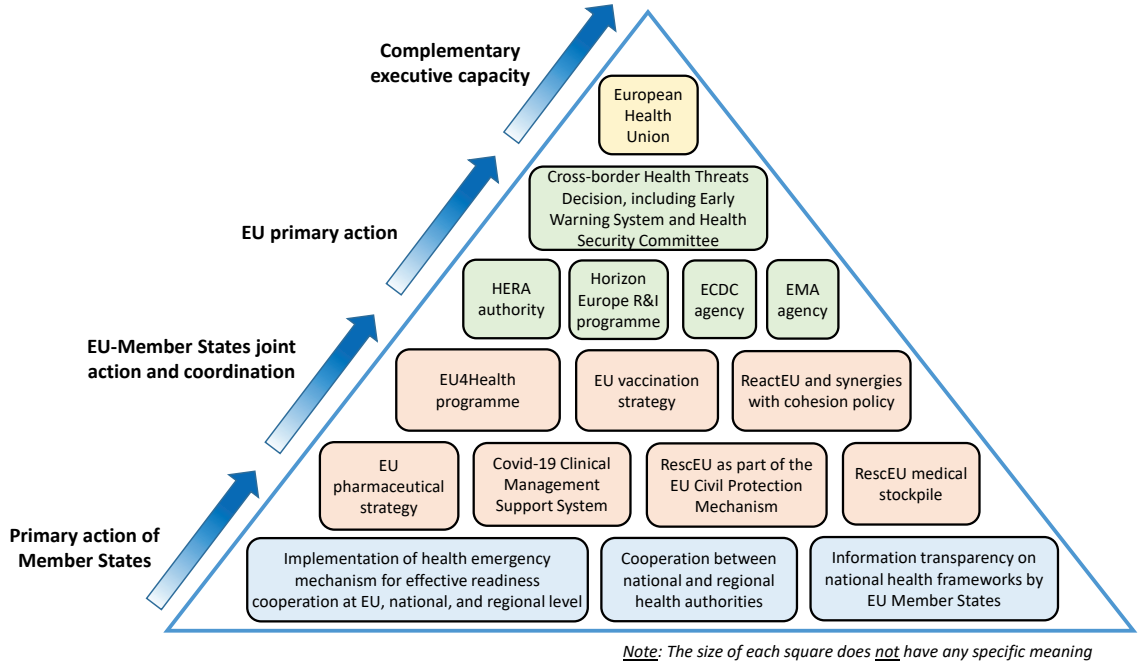
the event of a public health emergency at Union level. The proposal establishing the emergency framework was not accompanied by an impact assessment, according to the Commission, 'due to the urgency of the matter'. The proposal is not based on the health or internal market legal basis, as initially announced in the inception impact assessment, but on Article 122(1) TFEU, which states:

> *Without prejudice to any other procedures provided for in the Treaties, the Council, on a proposal from the Commission, may decide, in a spirit of solidarity between Member States, upon the measures appropriate to the economic situation, in particular if severe difficulties arise in the supply of certain products, notably in the area of energy.*

This legal basis implies that the European Parliament is not formally involved in this legislative process[3]. According to Article 6(3) of the Commission decision, a 'representative of the European Parliament may participate as an observer in the meetings of the HERA Board'. According to article 5(2) of the proposed regulation, 'the Commission shall invite a representative of the European Parliament... to the Health Crisis Board', proposed to be established during a public health emergency[4].

The HERA initiative fits within a broader set of measures in the field of health, outlined in Figure 2.

Figure 2 – Multi-level governance in the field of health



Source: EPRS.

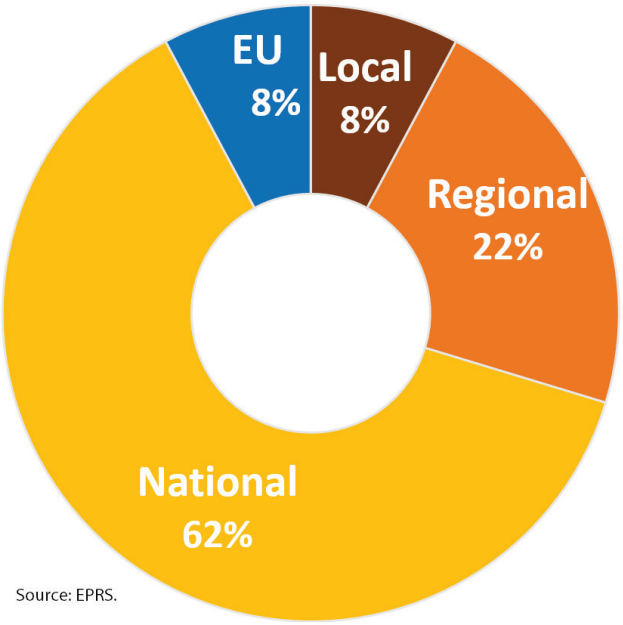
On the basis of the public information available to date, this briefing focuses on:

1. The HERA's level of ambition and mandate;
2. The global dimension of public health;
3. Competences in the health sector at EU level;
4. Cooperation between Member States and the EU;
5. Financing issues and public-private relationships.

Methodology

The data sources for this briefing were obtained through: 1) **requests** for input from governmental organisations at all levels of government; and 2) **desk research**, aimed at obtaining additional relevant input.

Figure 3 – Level of governmental organisations which contributed input analysed in this briefing



Source: EPRS.

First, requests for input on key Commission priorities were sent to all the governmental organisations in the Linking the Levels Unit network. These organisations are active in a broad range of policies. This was done by means of the monthly newsletter *The Link*,[5] with calls sent each month between February and May 2021, to an expanding network, reaching 711 contacts by the end of that period. Second, desk research was carried out to gather further information from other governmental organisations, as well as to cover the relevant literature, including European Parliament Library knowledge resources. This process took place from April to September 2021.

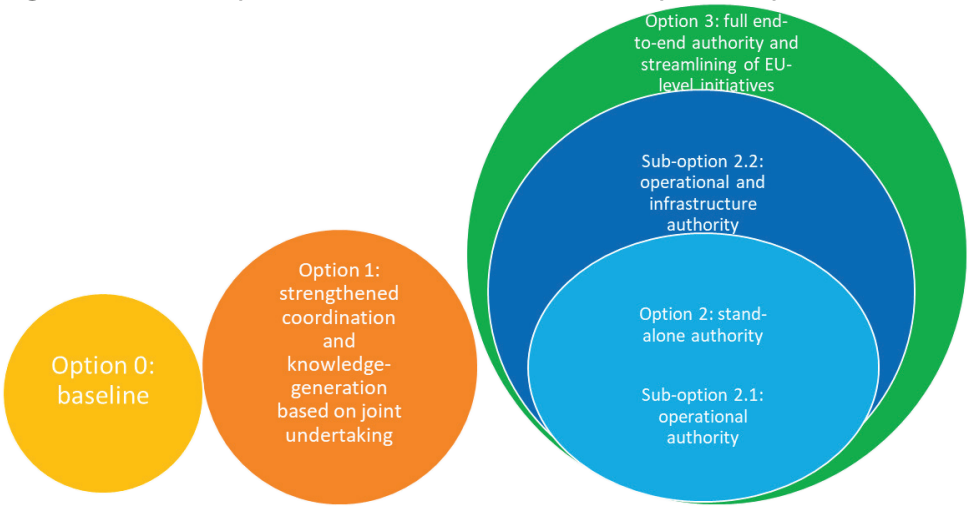
This strategy garnered 110 documents, which are analysed in this briefing. The main sources analysed as part of the desk research include: the feedback sent to the Commission on the above-mentioned inception impact assessment by 15 respondents who declared themselves to be public authorities; and 4 documents from governmental organisations annexed to the contributions on the public consultation. Finally, they also included responses from two EU-wide umbrella public authority organisations, Council of European Municipalities and Regions (CEMR) and Eurocities. Figure 3 shows the levels of governmental organisation that published input documents analysed in this briefing. While the majority are national governmental organisations, regional and local governmental organisation represent a sizeable 30 % share.

2. Governmental organisation positions to date

The HERA's ambition and mandate

The European Commission's inception impact assessment presents four policy options and two sub-options in detail. As Figure 3 shows, the options have an increasing level of ambition. Options 2 and 3 are incremental.

Figure 4 – HERA options in the Commission's inception impact assessment



Source: EPRS, based on European Commission.

Only a limited number of governmental organisations take a position on these policy options. Among those who do, the Spanish Ministry of Health proposes to develop the HERA as a centralised authority at EU level along the lines of sub-option 2.2. This authority would have the power to provide public health alerts, estimate necessary resources, mobilise research funds, and introduce the regulatory flexibility needed to speed up the availability and distribution of medical items across Member States.

The Belgian Federal Public Health Service would favour an outcome around sub-option 2.2 or option 3. It would like to see the HERA having the power to develop long-term strategies and responsive capabilities to address emerging threats, including basic explorative research. It believes that the HERA should be structured on the US model of the Biomedical Advanced Research and Development Authority (BARDA), with the mission to address previously undefined threats (e.g. bio-terror attacks or chemical, biological, radiological and nuclear hazards) as well as existing and well-known risks (e.g. viruses, multi-drug resistant bacteria). It would like to see a broad focus on medical countermeasures, not simply vaccines, but also medical devices and other tools such as regulations, guidelines, and obligations on manufacturers.

The Danish Ministry of Health has opted to refrain from pointing to a preferred policy option at this stage, arguing that it would need more detailed information. It has observed that in the planning for the HERA, tasking it with pandemic coordination would leave the other relevant agencies to concentrate on regulatory tasks, which would be beneficial. It further noted that the EU's overall preparedness and response abilities would be strengthened by a common EU overview of the overall supply of medical countermeasures, including manufacturing and development capacities and demand/supply monitoring of raw materials in particular.

Additional governmental organisations raised relevant points related to the HERA's level of ambition and mandate. In a non-paper devoted to HERA, **the Netherlands** stresses the need to have a full and thorough impact assessment which analyses all of the policy options presented by the Commission. This assessment should focus on identifying the gaps that this future authority should fill, as well as mapping overlaps between the HERA and existing agencies, mechanisms, and instruments. The government envisions the authority as focusing on antimicrobial resistance, rapid deployment of medical countermeasures in case of a crisis, stimulating innovation, and boosting crisis preparedness. To this end, the HERA should enable innovative pilot approaches to research and development and public procurement in this field, as well as promote investments and coordinate research, manufacturing and deployment of novel antibiotics. In this context, synergies with the EU's pharmaceutical strategy are key and should be leveraged to ensure the success of this objective. According to the Dutch government, the authority should further concentrate its activities on horizon-scanning programmes for vaccines, medical products and technologies, and on strengthening the supply chain for medical products and devices. In this context, the Dutch government is keen to ensure the single market also functions correctly in times of crisis, guaranteeing free movement and avoiding intra-EU export restrictions. Based on its potentially very expansive mandate, the Dutch government advocates for a stepwise approach, where the allocation of any additional tasks should be preceded by an independent evaluation at specific milestones, making sure to involve Member States.

Figure 5 – Preparing for the next threats

Source: © karrastock / Adobe Stock.

The French General Secretariat for European Affairs sees the understanding, prevention and response to health threats at the heart of the ambitions for the HERA. Moreover, the HERA should be

equipped with a long-term strategic vision, as well as adapted and adjustable means across the full spectrum of financial, regulatory, technical and organisational tools. The core aim of the HERA should include strengthening industrial autonomy in the field of health, research and development, and acquiring and distributing medical countermeasures.

The Italian National Institute of Health believes that the HERA should offer a specific EU training programme on health emergency preparedness and response for public health officers and similar health professionals, to promote and support the general EU culture on the response to current and future health threats.

The Swedish government considers it important to strike a balance between strengthening crisis preparedness and dealing with cross-border threats, on the one hand, and improving public health for citizens on the other. The government argues that health promotion and disease prevention measures should not have a lower priority, especially since good public health contributes to resilient societies.

Addressing the scope of the HERA, the Swedish innovation agency Vinnova believes that the HERA should deal both with viral threats and with the lack of effective therapies against resistant bacteria and other pathogens. It should focus not only on infectious diseases, but, in the long-term, also on other pharmaceuticals and medical equipment. This would require increased funding of basic and clinical research. Mechanisms and incentives would then be needed to translate targeted programmes for basic research into concrete innovation.

The Italian health network, PRO.M.IS, which brings together Italian regions, the Italian Agency for Regional Health Services and the Ministry of Health, has also underlined that the HERA should strengthen the implementation of practical tools, initiatives and studies that can be used by everyone, avoiding duplication of effort at different governance levels.

Along the same lines, the Italian region of Veneto believes that policy option 3 of the Commission's inception impact assessment would be the most appropriate to achieve the objectives on which the HERA should work as a matter of priority. These include improving anticipatory capacity and exploitation of public-private ecosystems, counteracting market and supply-chain failures, and improving the process of financing, developing and deploying new countermeasures in times of crisis. The Veneto region argues that the HERA should have a strong legal framework in the area of access to national health data and preparedness plans in order to implement anticipatory risk assessment and modelling.

The Catanzaro local health authority, in the south of Italy, considers the HERA indispensable, in light of what it considers EU Member States' health organisations' inadequate response to the coronavirus crisis. Catanzaro suggests that centralising the crisis management 'control room' at EU level is vital to achieving a rapid response strategy, and to solving critical issues related to logistics, such as the procurement of equipment, medical devices, drugs, and vaccines. Furthermore, it stresses that promoting the integration of information systems and ensuring an effective use of health databases is fundamental.

Finally, at the EU level, the European Committee of the Regions suggests that, in order to respond to citizens' expectations and improve the efficacy of healthcare systems, the evolution of the EU's role in health – including crisis preparedness – should also be discussed in the framework of the Conference on the Future of Europe.

Global dimension of public health

Looking at the interactions between the HERA and global health governmental organisations, the Danish Ministry of Health has stressed that interfaces with international actors and third countries should be further explored, mentioning particularly the WHO and the US BARDA.

Belgium's Federal Public Health Service would further like to see the WHO and other international health authorities playing a key role as a source of inspiration for the HERA's priorities, citing as an

example the WHO priorities on antimicrobial resistance. The Belgian Federal Public Health Service has moreover focused on the importance of solidarity between EU and non-EU countries and the need to build the European HERA 'together and in parallel with an African HERA'.

Figure 6 – Global health

Source: © Lightfield Studios / Adobe Stock.

At the local and regional level, the Council of European Municipalities and Regions (CEMR) has noted that the coronavirus crisis required a global response and joint actions. When facing cross-border health threats, CEMR identifies that cooperation between the EU and non-EU countries is key, as well as with international bodies such as the UN agencies, the Organisation for Economic Co-operation and Development (OECD). Third countries and regions identified include the Western Balkans and the wider EU neighbourhood, as well as partner countries in Africa, Asia and Latin America. To achieve effective global action, the CEMR suggests a decentralised model focusing on local-to-local and region-to-region cooperation, including exchanges between local and regional elected representatives and national associations. The role of the PLATFORMA coalition and of the umbrella organisation United cities and local governments is considered a good way to address joint challenges in a decentralised way. CEMR further recommends adequate financial support for decentralised cooperation between the EU and partner countries' municipalities and regions.

Competences in the health sector at EU level

Synergies and possible conflicts of competences at EU level are a recurrent theme when analysing the division of tasks between different EU health-related agencies and instruments. In addition, competences in the health sector at EU level and responding to health crises can be seen within the broader backdrop of crisis management.

When it comes to synergies, the HERA proposal is strictly linked with the other building blocks of the European health union, currently under the scrutiny of the Parliament and Council: the proposals on extending the mandates of the ECDC and of the EMA, as well as the ongoing proposal on an upgraded framework for cross-border health threats.

At the national level, the Belgian Federal Public Health Service considers that the HERA may overlap with the proposals for a regulation on cross-border health threats and on the extension of the ECDC's mandate, for example concerning risk assessments. According to the Belgian Health Service, it would be better for the ECDC to continue performing the risk assessments, while the HERA could allocate funds based on these assessments.

Another Belgian public organisation, the Belgian Federal Agency for Medicines and Health Products considers that the EMA's mandate and structure should be further enlarged to cover the complete field of medical devices, which should be taken into consideration when designing the HERA's architecture.

Denmark's Ministry of Health would also like to see clarification of the interface between the HERA's mandate and the proposed regulation on the strengthening of the EMA's mandate.

The Swedish innovation agency Vinnova expresses its support for the role of the ECDC as the coordinating agency for matters concerning the standardisation of data, while also supporting the 'EU FAB' project[6] – which will set up a network of production capacities for vaccines and medicine manufacturing – within the context of the future HERA.

According to the government in the Netherlands, it is also crucial to create several procurement options following an assessment of their effectiveness. These should be tailored to various threat levels. In this context, HERA could be the single point of contact for EU procurement, bringing existing instruments together, such as the joint procurement initiative, the Emergency Support Instrument, and the rescEU mechanism.

As mentioned above, responding to health crises can be seen within the broader backdrop of crisis management. The French General Secretariat for European Affairs argues that the HERA and other competent EU agencies should work together to support crisis preparedness. Within this context, key tasks would include identifying serious threats and risks that could cause a major crisis and defining a common strategic direction, taking different sectors into account (e.g. health, defence).

In the non-paper 'The future of crisis management in the EU', adopted by **the Netherlands**, **Sweden** and **Romania** in November 2020, the three EU countries consider that the basis for further development of crisis management in the EU should be an extensive evaluation of the response to the coronavirus pandemic. They consider that Member States should be responsible for their own domestic policies on prevention and resilience. However, they identify the need for enhanced cooperation and communication, especially for crises that require cross-sectoral coordination, where local and regional circumstances should be taken into account. They argue that to achieve these synergies, the correct level of action is within the Council. A permanent Council crisis coordination structure should be established (e.g. a 'crisis management working party'). This would work together with the Council presidency, strengthening the EU integrated political crisis response (IPCR) mechanism, which currently coordinates EU crisis management at the Council level. This strategic agenda-setting forum would avoid 'parallel tracks' when it comes to exchanging information and decision-making.

The Swedish Civil Contingencies Agency also highlighted the existing operational crisis management mechanisms in place at EU level and that initiatives within different fields of EU policy should complement and strengthen each other. From its perspective, the links between the legislative proposal at hand and the rescEU mechanism gives rise to a possible duplication of efforts at EU level, which goes against the stated goal of the Commission to reduce fragmentation. Hence, according to the Swedish agency, when considering the establishment of HERA, what could be achieved within the framework of already existing structures, and what the added value of this authority could be, should be analysed carefully.

At the EU level, in a 2020 European Committee of the Regions (CoR) opinion on future perspectives for cross-border healthcare, the CoR recommends that the future EU health emergency mechanism be closely integrated into existing structures for crisis management, such as the ECDC and the EU Solidarity Fund. For information, the EU Solidarity Fund enables the EU to provide financial support to a Member State in the event of major natural disasters, including major public health emergencies.[7]

Cooperation between Member States and the EU

Some governmental organisations have expressed their position on the cooperation, synergies and possible conflicts of competences between the national and the EU level in the health sector.

The French General Secretariat for European Affairs has a rather positive view, and sees the HERA as having a coordinating role in joint EU-Member State action. For example, it has proposed that the HERA could coordinate EU funding allocation and provide guidance to Member States in defining the priorities of EU-level programmes, via their programme committees. The instruments quoted by France are the Union Civil Protection Mechanism (UCPM), Horizon Europe, InvestEU, EU4Health and the Emergency Support Instrument. Member States could further inform the HERA about national-level projects supported in the specific area of health preparedness and response, so that the HERA may assess their relevance and incorporate them in its strategic roadmaps and plans.

The Department for emergency situations, within the Romania Ministry of Internal Affairs, has drawn attention to the need for detailed discussions to ensure synergies with the UCPM, noting two areas of activity that would fall under the responsibility of both instruments. The first is the deployment of medical teams and experts to support states with prevention, preparedness and response actions. Romania argues that HERA should complement the UCPM by focusing on intra-EU preparedness measures, enabling the creation of centralised and scalable manufacturing and innovation capacities for the development of medical countermeasures. The second is EU stockpiling under the rescEU reserve (which was established in March 2020 and was used several times during the coronavirus crisis to respond to request for assistance from participating Member States). According to the Romanian department, it is important to have a clear delineation of responsibilities between the existing rescEU stockpiling mechanism and that planned by HERA, to ensure complementarity. The Romanian department would like to maintain rescEU as the main emergency response stockpiling system, given that it is operated by civil protection authorities across Member States, with integrated logistics and coordination. HERA should instead play a complementary role, by phasing in after rescEU and triggering the EU development and production capacity to ensure a sustained response over longer periods of time. HERA stockpiling should feature both physical and virtual stocks, aggregating service contracts with production capabilities and industrial reconversion arrangements for the creation of new medical countermeasures.

Similarly, for the Danish Ministry of Health, the main concerns about the division of competences are about joint EU-Member State actions, especially the interface between the rescEU instrument for strategic medical stockpiling and the HERA's tasks. Finally, the Czech Ministry of Health stressed the importance of respecting the division of competences between EU Member States and EU institutions in the field of health.

Financing issues and public-private relationship

How to finance the new authority and, relatedly, the level of funding that the EU should allocate to the HERA is another recurrent theme in the input analysed. One complementary area was the relationship between different public and private health actors, such as universities and private companies, including small and medium-sized enterprises (SMEs). Strengthening the public-private ecosystem was a repeated requirement.

The French General Secretariat for European Affairs believes that the HERA should coordinate the allocation of funds from all relevant EU programmes (see previous section for their list). After an evaluation process, the HERA could then be given more resources of its own and become directly responsible for certain funds from these programmes, or even have its own dedicated budget in a future multiannual financial framework.

The Belgian Federal Public Health Service believes that the relationship between public/private investment and return-on-investment in health-related research and development should be at the centre of the discussion around the future HERA. In the HERA, public interests should prevail over private interests, possibly guaranteed through ethical committees. This means that the HERA should avoid creating even more dependency on private companies for agreements, production, pricing, discussion about patents, and other similar matters. According to the Belgian Federal Service, new governance models are needed and the HERA should play a role in developing them. Especially in times of pandemic, a specific legal status for vaccines, medicines and personal protective equipment should be considered, and the EU should consider how to guarantee the affordability of such products. Public investment in private health activities should be conditional and based on the principle that citizens 'should only pay once'. Under this principle, public financing of early-stage development of medical countermeasures should be reflected in the final cost of the product, under the consideration that citizens have already paid through the public financing for earlier phases. Additionally, Belgium notes a strong link with the EU's pharmaceutical strategy, with many developments already being financed by public funds and later privatised. Public-private partnerships, in this context, are a possible way forward. Support for initiatives, such as Civica Rx, a

US non-profit pharmaceutical company founded in 2018, which produces generic drugs, could also be promising for producing off-patent drugs, reducing shortages and preventing price fluctuations. Another option could be to offer support to universities to allow them to bring their innovations to the market in a 'not for profit' manner.

The Dutch National Health Care Institute comments on the European partnership for innovative health (part of the Horizon Europe programme) and believes that it is crucial to engage in a multi-stakeholder, cross-sectoral innovation partnerships to relieve the financial and organisational pressures faced by EU healthcare systems. According to the Dutch institute, adequate participation of SMEs within relevant EU programmes, such as Horizon Europe, should be ensured. As a best practice example, the institute refers to the recently launched public-private partnership Health Innovation Initiative Holland. By creating a new platform which includes all stakeholders involved in the process of medical device development, it aims to reduce the length of the supply chain and ensure that innovative medical countermeasures can reach healthcare systems as soon as possible.

The Danish Ministry of Health also highlights the need for public-private partnerships, which would be especially important to taking vaccines from research and development to production. It is also important that these partnerships focus not only on a few technologies, but on a wide range of tools that would be able to face future threats. The HERA should increase incentives for the private industry to invest in unmet public health needs, with the caveat that these incentives should not come at the expense of existing general incentives for innovation in other parts of the industry. Denmark also touches upon SMEs and the academic ecosystems. On the former, it advocates its support for a strengthened and sound business environment for SMEs, including start-ups, within the EU single market, so that these businesses and their knowledge remain in the EU. The Danish Ministry of Health also stresses that the HERA should pro-actively interact with academia, particularly due to the need for highly skilled employees, specialised in science, technology, engineering and mathematics.

On the regional level, Veneto's Health territorial assistance units consider it advisable to develop mixed public-private research centres on a territorial basis. These should then be integrated at the national and EU levels to work on pharmacological and non-pharmacological research projects directly sponsored by the HERA.

3. Analysis of governmental organisations' positions

The documents analysed in this briefing discuss the implementation of the new HERA authority, as well as tackling the future of health in the EU. All acknowledge the EU vulnerabilities revealed by the coronavirus pandemic and highlight the need for action to be taken at EU level to coordinate crisis response and enhance preparedness. Most welcome the HERA as a positive development in this direction, viewing it as an important element to support EU-level action and reduce fragmentation. There is broad consensus that all levels of governance should learn from the coronavirus experience and take action to improve preparedness planning for future health emergencies such as epidemics. Against this backdrop, the reinforcement of the mandate of existing EU health agencies and the creation of a new HERA authority are seen as essential elements towards the European health union.

Regarding HERA's mission and mandate, the comments collected demonstrate the existence of different positions and opinions. However, most of them, at all levels of governance, suggest providing the new authority with a robust operational and infrastructural framework, with a long-term vision, a coherent legal framework and efficient decision-making procedures. A call for a strong impact assessment underpinning these choices has also been made.

The question of HERA's mandate and mission is intertwined with other issues analysed in this briefing, related to multi-level governance at global, EU and national level, as well as with financing issues and the relationship with the private sector.

Public authorities at national, regional and local levels suggest that the HERA should develop a strong relationship with the World Health Organization (WHO) and other international health organisations. According to several commentators, the EU was not a sufficiently strong supporter of global health policy and of the WHO before the coronavirus pandemic. Some governmental organisations recommend creating strong links with developing countries, for instance in Africa.

The need for better synergies and possible conflicts of competences at EU level are a recurrent theme when analysing the division of tasks among EU health-related agencies and instruments. The HERA proposal confirms this trend. The HERA proposal will interact with other pending Commission legislative proposals in the health sector that make up the European health union, namely on extending the mandates of the ECDC and of the EMA, as well as the ongoing proposal on an upgraded framework for cross-border health threats. Governmental organisations agreed on the need to clarify the interface between these proposals and the HERA. An additional element is the interplay with existing operational crisis management mechanisms at EU level: here, national authorities recommend avoiding any duplication of effort, but see the potential for increased coordination, including with the Union civil protection mechanism. There is also a call to strengthen structures within the Council and to take account of regional and local specificities.

Some governmental organisations have a rather positive view of the interaction between the EU and the national level, arguing that HERA would have a beneficial coordinating role. Other governmental organisations have expressed concern regarding such cooperation and possible conflicts of health sector competences between the national and EU levels. These positions and the related national approaches to handling the pandemic reflect the differing ways Member States structure and organise their own health systems, as well as their independence in defining their own national health policies. However, it should be observed that, during this pandemic, Member States have increasingly shown more predisposition to work collectively than in the past. Despite initial difficulties and more recent criticism aimed at the EU's vaccination strategy, the benefits of collective action have become more evident to Member States, and, in response to crises, the EU seems more adaptable and resilient than before. One of the major obstacles revealed is the need to have a common understanding of cross-border threats among the actors involved at EU and national level. To overcome the fragmentation of the current situation, these actors could establish more structured working relations in the future. In this context, the input of individual Member States remains crucial.

Governmental organisations agreed on the need to provide HERA with a level of funds in line with the tasks conferred upon the new authority. Strengthening the ecosystem between public organisations and the private sector was also a repeated demand, notably related to universities and innovative SMEs. Governmental organisations stressed that public interests should prevail over private interests, possibly guaranteed through ethical committees. Relatedly, one national organisation expressed the concept that citizens 'should only pay once', meaning that public financing to early-stage development of medical countermeasures should be reflected in a lower cost of the product to the end-user.

To conclude, previous infectious disease crises have triggered the expansion of EU powers and structures related to health. In 1999, following the bovine spongiform encephalopathy (BSE) outbreak, the European Commission established its Directorate-General for Health. In 2004, in the wake of several epidemics, the ECDC was created. In other words, previous crises prompted the creation of EU bodies and mechanisms in public health which, although limited in power, worked actively in the response to the coronavirus crisis. This seems also to be the case for the HERA authority following this pandemic.

EXPERT READING ON THE TOPIC

Scholz, N. Boosting the European Union's defences against cross-border health threats, European Parliamentary Research Service, September 2021.

Scholz, N. Strengthening the European Centre for Disease Prevention and Control, European Parliamentary Research Service, September 2021.

Quaglio, GL. EU public health policy, European Parliamentary Research Service, July 2020.

Scholz, N. Building up resilience to cross-border health threats: Moving towards a European health union, European Parliamentary Research Service, April 2021.

Quaglio, GL. Forestalling future health crises. In: Towards a more resilient Europe post-coronavirus. Options to enhance the EU's resilience to structural risks. European Parliamentary Research Service, April 2021.

Parker, C.F., Persson, T., Widmalm, S., The effectiveness of national and EU-level civil protection systems: evidence from 17 member states, *Journal of European Public Policy*, September 2019, Vol. 26 (9), pp. 1312-1334.

ENDNOTES

[1] Article 168(1) of the Treaty on the Functioning of the European Union (TFEU) gives the EU a complementary role to national policies to improve public health and combat serious cross-border threats to health. Article 168(7) further stipulates that Union action must respect the responsibilities of Member States to define their health policy and the organisation and delivery of health services and medical care, including their management and the allocation of resources assigned to them. See also, Quaglio, G., EU public health policy, European Parliamentary Research Service, July 2020.

[2] 'Medical countermeasure' means medicinal products for human use, medical devices or other goods or services for the purpose of preparedness and response to a serious cross-border threat to health (according to the European Commission proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health, proposed article 3).

[3] In December 2020, a Joint declaration of the European Parliament, the Council and the Commission established a procedure of budgetary scrutiny for Commission proposals based on Article 122 TFEU with potential appreciable implications for the Union budget.

[4] Progress of the HERA legislative file may be monitored in the relevant carriage of the legislative train schedule.

[5] Governmental organisations wishing to subscribe to *'The LINK'* newsletter can write to EPRS-LinkingLevels@europarl.europa.eu.

[6] On the 'EU Fab' flexible manufacturing capacity reserve, see the Commission's questions and answers of 17 February 2021.

[7] On the EU Solidarity Fund, and the European Parliament's May 2021 resolution, see the EU Fact sheets. See also the studies commissioned by the CoR, Implementation of the Cross-border healthcare directive in the European regions, 2020 and Regional health policy responses to the COVID crisis, 2020.

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