

German Social Insurance
European mission
Rue d'Arlon 50
1000 Brussels
Belgium

Tel.: +32 2 282 05-50
info@dsv-europa.de
www.dsv-europa.de
Transparency register no.:
917393784-81



Deutsche Sozialversicherung
Europavertretung | DSV

Feedback from German Social Insurance dated 6 February 2024

European Health Emergency Preparedness and Response
Authority (HERA) - Review

I. Preliminary remarks

As part of the creation of a European Health Union, the European Commission established the Health Emergency Preparedness and Response Authority (HERA) as a Directorate-General within the European Commission on 16 September 2021. Being a crisis authority, it is responsible for preparing for and responding to serious cross-border threats in the medical countermeasures sector. Its mandate includes the EU-wide coordination of health safety, controlling strategic dependencies within the European Union (EU) with regard to developing, producing and procuring medical countermeasures as well as strengthening global crisis preparedness and response structures in the event of health emergencies.

The European Commission's evaluation provides an opportunity to expand HERA's mandate, improve its transparency and accountability, obtain adequate funding, and define its role more clearly in relation to other EU organisations.

DSV believes that the HERA mandate should be further developed with appropriate financial resources and improved transparency in its governance. HERA can only be further developed into an efficient and transparent EU organisation in close cooperation with the member states in order to strengthen the EU's health preparedness and response capabilities over the long term. This would be in line with the lessons learnt from the COVID-19 pandemic. HERA's work must always focus on supporting member states in providing healthcare to patients in the EU, both in times of preparedness and in times of crisis.

II. Opinion

1 _ HERA mandate and tasks

HERA has so far been able to make good use of its important latitude for action, for example, in procuring vaccines against monkeypox, in creating its priority list of health risks, in its medical countermeasures inventory and in preparing studies about financing and procuring crisis-relevant medicines.

However, DSV's view is that HERA's role needs to be more clearly defined, especially when it comes to "preparedness".

DSV's opinion is that in the future HERA should play a **stronger role** in the challenges posed by drug shortages and, especially, in **combating antimicrobial resistance**. This health threat posed by resistant pathogens represents a potential emergency with implications for all EU member states. In order to create incentives for developing medicinal products against resistant microbes, practicable instruments should be developed at EU level, also through HERA, as part of a "push-and-pull scheme".¹ This can be realised if the sales volume and the price of medicines are no longer linked at the level of reimbursement. The foundations for the joint, coordinated implementation of this model must be laid at EU level.

HERA could also be utilised to support the early phases of research and development of antimicrobial drugs. The current major obstacle to developing these products is procuring sufficient risk capital for investing in early clinical trials. Effective public research funding that builds on existing European initiatives such as HERA INVEST is needed; in order to bring more developments up to market maturity. Intensive research and promotion of infection prevention strategies also remains a key element in holding-back the development of antimicrobial resistance.

2 _ HERA governance

In its endeavours to achieve a more effective and coordinated approach to tackling health threats of all kinds, it makes sense for HERA **to support the work carried out by Member States**. The European institutions have the entire Union in mind. They are dependent on the stakeholders in the member states for the details from the multi-layered and highly complex health and care systems. Therefore, it must also be ensured that the member states' health policy competencies are not violated. HERA's ability to react quickly in times of crisis, even across borders when necessary, must be embedded in political governance structures that ensure close coordination with the member states.

Using public funds for developing medical countermeasures will also require further measures such as the creation of transparent structures and the introduction of accountability. DSV agrees that public investment in developing medical countermeasures by private companies should be taken into consideration with regard to reimbursement of the resulting products, such as medicines, medical equipment, diagnostic tests or personal protective equipment such as gloves or masks, by member states or national funding agencies. Reimbursement for the costs incurred must reflect the fact that these medical countermeasures were developed

¹ "Pull" incentives are used to promote the development of antimicrobials and to support commercialisation and market access. Conversely, "push" incentives are upstream measures that promote and support antimicrobial research and development.

using public funds. The crisis and readiness capacities for research, development, production, storage and distribution of crisis-relevant products must be fully available at all times.

Currently there is only limited **transparency** with regard to the governance of HERA, as there is a lack of information about the composition and work of HERA Advisory and the HERA Civil Society Advisory Forum. More transparency is needed here.

About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations of statutory health and longterm care insurance funds as well as the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance – Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e.V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union and other European institutions and advises the relevant players in the context of current legislative projects and initiatives. As part of a statutory insurance system, health and long-term care insurance with 74 million insured people, pension insurance with 57 million insured people and accident insurance with more than 70 million insured people in 5.2 million member companies, citizens in Germany are provided with effective protection against the consequences of major life risks.