Deutsche Sozialversicherung
Europavertretung

Feedback on the Inception Impact Assessment on HERA

The German Social Insurance supports the initiative of the European Union to review the existing legal framework, instruments and options for coordinated actions and measures in times of cross-border health emergencies such as the COVID-19 pandemic. This might include the creation of new permanent structures. EU action, which shall complement national policies, shall be directed towards improving public health and combating serious cross-border threats to health, excluding any harmonisation of laws and regulations of the Member States. The COVID-19 crisis has highlighted that there is room for improved preparedness and response capacity in terms of medical countermeasures for serious cross-border threats to health. A review of the existing instruments and EU level initiatives on medical countermeasures, how to streamline or harmonise them in a more effective way, should be part of any policy approach.

Policy option No. 1 (Strengthened coordination) would be an improvement compared to the status quo. It would also align with the intention to create a European Health Data Space (EHDS). This option could be implemented as a segment of the EHDS and would be in accordance with the principle of subsidiary.

Effectively facilitating the development, production, procurement and purchase of vaccines, therapeutics, diagnostics or personal protective equipment (PPE) and medical devices with public funds is equivalent to the core idea of the US BARDA. This approach needs to be thoroughly considered in terms of its effects on both the public and private sectors and in its adequacy for the different kinds of possible threats as identified in the inception impact assessment. Health threats caused by communicable diseases, biological or chemical agents, environmental and climate events, and threats of unknown origin should be considered, as different risk scenarios need tailored answers.

Policy options 2 (A stand-alone authority) and 3 (Full end-to-end Authority) envision a public engagement in the development of medical countermeasures. We fully agree that public returns on medical countermeasures, which have been developed by private entities by means of public funds, must be ensured. Reimbursement by health insurance funds or the Member States must clearly reflect that these medical countermeasures have been developed with public funds in the first place. In addition, the relationship between public, semi-public, semi-private and private sectors need to be defined with regard to granting and use of patents. The same applies to reimbursement for such publicly funded countermeasures. This includes tripartite arrangements for partnerships between the public sector, universities and businesses.

Crisis and preparedness capacities for research, development, production, stockpiling and distribution must be fully employed at all times to ensure personnel are well trained, equipment is up to date and operations are economical even outside times of crisis. In addition, advantages and disadvantages should be discussed as to whether all the tasks acknowledged in the Inception Impact Assessment necessarily need to be centralized in one body. In the United States, BARDA and the Strategic National Stockpile are separate agencies.

In pursuit of a more effective and coordinated approach to countering health threats of all kinds, the scope of tasks, competencies and funds of a future public body should fully comply with the subsidiary principle. Especially when considering policy option No. 3 it must be ensured that Member States' health competences are not being violated. HERA capacity to react swiftly and potentially cross-border in times of crisis must be anchored in governance structures that ensure involvement of Member States. Governance structures must furthermore reflect the role of Member States' competent authorities and the multi-level division of tasks when it comes to combating serious cross-border threats to health.