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Transparency Register
No. 917393784-31

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The "European Health Union"

Opinion by the German Social Insurance dated 16th December 2020

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the national associations for statutory health and long-term care insurance have come together because of their common European policy interests to form the "German Social Insurance - Working Group Europe".

The association represents the interests of its members vis-à-vis the EU organs as well as other European institutions and advises the relevant players within the context of current legislative projects and initiatives.

As part of Germany's statutory security system, health and long-term care insurance, pension insurance and accident insurance offer effective protection against the consequences of major life risks.

I. Preliminary remark

On 11 November 2020, the European Commission presented its outline for a European Health Union. The current pandemic has particularly highlighted deficits in pan-EU crisis management. Therefore, intensified and coordinated cooperation between Member States will be of huge importance in dealing with such health crises and future ones. In its "Building a European Health Union: Strengthening EU's resilience to cross-border health threats"[1] communication, the European Commission proposes additional, primarily coordinating tasks in the public health sector at EU level.

The European Commission's communication is accompanied by three draft regulations. In this respect, it sets out the initial priorities of the envisaged European Health Union: On one hand, the focus is on the legislative strengthening of the EU's framework covering serious cross-border health threats, and on the other, it is on building up the competences of key agencies through the strengthening of

[1] COM(2020) 724 final

the EMA (European Medicines Agency)[2] and the ECDC (European Centre for Disease Prevention and Control)[3].

This opinion comments on the European Health Union package. The draft extension of the EMA mandate is assessed in detail in a supplementary opinion by the German Social Insurance.

II. Comments

1. Basic principles of the European Health Union

In its communication, the European Commission calls for lessons to be learned from the COVID-19 crisis. Probable future outbreaks of communicable diseases will increase the urgency for forward-thinking planning, good coordination and the strengthening of preparedness and response capacities. Antimicrobial resistance, pressures on biodiversity and climate change would increase and demographic change will result in new health vulnerabilities. All of this requires a holistic approach, on which the European Health Union should be built.

The first proposals refer, in particular to Article 168(5) of the Treaty on the Functioning of the European Union (TFEU). According to the European Commission, the competences of the Member States in the health sector will be "fully preserved"[4]. The memorandum mainly focuses on measures:

- for improving coordination and communication,
- for monitoring and crisis reporting,
- for responding and preparing for health crises and
- international cooperation.

Evaluation by the German Social Insurance:

The proposals are designed within the framework of the current treaties. The German Social Insurance welcomes the fact that no discussion is being held on extending competences, but that constructive answers are being sought to the COVID-19 pandemic and future crisis situations through fact-based, further development of structures and cooperation between European and national institutions. Member States should be open to this.

[2] COM(2020) 725 final
[3] COM(2020) 726 final
[4] Memorandum released by the Commission on 11/11/2020 COM(2020)724 final, Page 4

The European Commission also wants to place more binding obligations on the Member States. This intention is reflected, on the one hand, in the upgrading of Decision No. 1082/2013/EU to a regulation in its own right, and on the other, in the cooperation obligations that are to be imposed on the Member States. The agreement process between the Council and the European Parliament will show how far the opportunities to create European added value will be utilised.

Significant parts of the intended measures are to be financed through the "EU4Health" programme. In this context, the German Social Insurance welcomes the compromise reached between the Council and the European Parliament on the 10th of November to increase the funding for this purpose to a total of EUR 5.1 billion.

2. Coordination and communication

Pan-European coordination of health measures has proved to be of limited effectiveness during this coronavirus crisis. In particular, the initial phase of the COVID-19 pandemic was characterised by national unilateral action. Therefore, coordination mechanisms at EU level must be improved.

For example, the HSC (Health Security Committee), which comprises representatives from the Member States, will be given a stronger mandate to initiate and implement a coordinated response through official guidelines and opinions, which will also be supplemented by Commission recommendations. Practical support will be provided by specific recommendations from the ECDC and appropriate decentralised EU agencies.

In coordination with the WHO (World Health Organisation) and with the support of an independent advisory committee, the European Commission will in future also be able to identify a public health emergency of pan-European concern. As a result, it will be easier to develop, produce, store and procure essential products and to adopt measures to protect health and ensure that the single market functions correctly.

Evaluation by the German Social Insurance:

By declaring a public health emergency of pan-European concern, the European Commission has provided itself with a tool for legitimising decisive and specific cri-

sis measures, thus strengthening the Union's resilience mechanisms. Coordinating the measures will be undertaken by the HSC, which comprises representatives from the Member States. This is imperative because the Member States are responsible for organising their own health systems and for implementing the measures in a national context.

3. Monitoring, early warning system and crisis reporting

The proposal for a European Health Union aims to establish a new risk assessment framework, which will include rapid and appropriate recommendations for the implementation of counter-measures by the Member States. An EU preparedness and response plan will also be developed in this context. This should form the basis for the pandemic plans to be drawn up in the Member States in accordance with the uniform guidelines. The ECDC supports the development of national plans through recommendations, including the provision of medical personnel and targeted training. Regular exercises should ensure that the plans are feasible in times of crisis. An audit procedure will also verify the national plans. The conclusions should describe the deficits and provide information about funding options through EU programmes.

The ECDC should collect, analyse and distribute all relevant medical and epidemiological data, thus establishing a robust surveillance and monitoring system as part of European health data governance. The EMA is also associated with this. Modern technology and the use of artificial intelligence are expected to bring the surveillance system up-to-date, enable real-time monitoring, help identify health hazards at an early stage and provide risk assessments. New digital platforms should also be established, e.g. for automated, cross-border contact tracing.

The Member States will be obliged to transfer the data digitally in accordance with the uniform specifications and indicators so that comparable analyses can be obtained. They will also be obliged to report any serious cross-border health threat through the EWRS (Early Warning and Response System), which will be expanded to cover the need or lack of medical countermeasures or immediate assistance. The States should also provide information about medical and intensive care capacities as part of their reporting obligations. Communications are to be implemented through competent bodies to be specified by the Member States.

The establishment of networks - including reference laboratories - is intended to improve international cooperation with regard to uniform evaluating of test alternatives and harmonising diagnostics, test methods as well as how the tests are used.

Evaluation by the German Social Insurance:

It is right that Member States should be better prepared in the future for health crises and coordinate with one another. The interdependence of national health systems, in particular makes coordinated action necessary in the event of health emergencies with pan-European impacts. It is important to the German Social Insurance that the entry into a system of coordinated crisis response succeeds and it should be consistently developed in the future without interfering with the competence of the Member States in organising their own health care systems. The coordination of joint and national crisis response plans is an essential module with regard to preparedness. It makes sense to support the relevant capacity building through EU programmes as well. A robust database is essential for risk assessment and joint responses during crisis situations. In principle, the provision of data by Member States according to common rules is to be welcomed, but it must be subject to the applicable data protection rules. However, it is questionable whether targeted debt measures should be organised at an EU level or whether the Member States, possibly through mutual exchange, are better placed to undertake such measures.

4. Response and preparation for health crises

An essential building block of the European Health Union's basic framework is the developing, manufacturing, purchasing and procuring of crisis-related products such as vaccines, diagnostics, therapeutics, medical devices as well as personal protection and laboratory equipment.

Building on the experience gained from the strategic RescEU reserve, which enables crisis-related products to be provided when national capacities are exhausted, long-term measures should now be established. On the one hand, the legal framework for joint procurement should also reduce the risk of internal competition.

On the other hand, the EMA’s structures should be used to monitor the availability of essential medicinal products and medical devices in the event of a public health

emergency of pan-European significance or in the event of special incidents. Manufacturers and Member States will be obliged to collect data about shortages and the inventory levels of these products and to make them available through the use of harmonised IT tools. In order to better assess potential shortage situations and develop appropriate measures and guidelines, the EMA is working closely with the ECDC to use epidemiological information to assess the expected demand for essential products.

The EMA and ECDC should also cooperate closely, especially in evaluating vaccination strategies, coordinating studies and monitoring the efficacy and safety of the vaccines. A separate IT platform should be created for this. In the event of a crisis, the EMA should also be able to advise and coordinate the approach to clinical trials.

An EMA emergency task force should provide scientific support for clinical trials on medicinal products and their safety. A health task force, which can be dispatched by the ECDC, should be able to support Member States on the ground in the event of a crisis.

The European Commission also plans to fill a structural gap by establishing another Health Emergency Preparedness And Response Authority (HERA) before the end of next year. In order to be better prepared for future crises and health threats, all tasks related to the responses to operational crisis will be handled by the new authority. Therefore, an infrastructure should be created in which public and private capacities can be planned and coordinated and it should have the ability to respond operationally when a public health emergency is declared.

Evaluation by the German Social Insurance:

The EU wants to be able to respond quickly and appropriately in the future. Therefore, in addition to transparency covering pan-EU market availability of essential medicinal products and medical devices, opportunities to accelerate clinical trials should also be exploited. The German Social Insurance expressly welcomes the approach of creating comprehensive transparency covering the availability of crisis-relevant medicinal and medical products and of consistently holding the Member States accountable for avoiding bottlenecks. We also suggest that similar procedures should not only be set up in the event of a crisis, but that they should also

be basically studied with regard to medicinal products and medical devices relevant to the provision of health care.

5. International cooperation and outlook

The COVID-19 pandemic has shown that serious health threats cannot be stopped at the borders. Consequently, the EU wants to strengthen international cooperation, such as that with the WHO, and position the issue of public health centrally at international level. The ECDC should also intensify networking at the global level. The health task force should also be able to participate in international crisis teams and be deployed in third-world countries. The EU pharmaceutical strategy[5] explicitly takes the international interdependencies in the production and distribution of medicines into its outlook and it suggests further measures for further developing the European Health Union.

Evaluation by the German Social Insurance:

German Social Insurance has already spoken out several times[6] in favour of taking a look at global production conditions, product and production standards, supply chains and distribution conditions in order to secure supplies for people in Europe, but also to guarantee fair competitive conditions for industry. The European Commission's efforts in this regard are warmly welcomed.

[5] A pharmaceutical strategy for Europe, COM(2020) 761 final
[6] See statement about the Roadmap to the Pharmaceutical Strategy, p. 11, et seqq.