



Spitzenverband



Europe: Acting together, mastering challenges.

GKV-Spitzenverband's Position Paper

Resolved by the Administrative Council on 20 March 2024



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The National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) is the central association of the health insurance funds at federal level in accordance with section 217a of Book V of the German Social Code (SGB V). It also acts as the central association of the long-term care insurance funds in accordance with section 53 of Book XI of the Social Code (SGB XI). The National Association of Statutory Health Insurance Funds is a public-law corporation with self-government.

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Foreword by the Chairpersons of the Administrative Council

Dear Reader,

European unification has long been part of everyday life for many people: they study, work or live temporarily or permanently in other EU countries and can rely on good social security and healthcare. The digital exchange of treatment data, prescriptions and invoices will make cross-border treatment and aftercare even easier and safer for mobile insured persons.

In the face of major common challenges such as demographic and technological change, the impact of climate change and the management of unforeseen crises, health and care systems also benefit from cooperation at European level. Important foundations are being laid, for example, to ensure high-quality, affordable medicines and medical devices and their reliable availability by strengthening production and supply chains. The same applies to tackling cross-border health threats such as the coronavirus pandemic. Joint action based on the diversity of health and social systems and a sensible division of labour thus promotes social cohesion and the future of a Union based on solidarity.

For more than 30 years, statutory health and long-term care insurance has therefore been involved in the joint shaping of Europe's social and health dimension and has contributed its expertise. With the positions adopted by the Administrative Council of the GKV-Spitzenverband (National Association of Statutory Health Insurance Funds), we are once again making a contribution to the further development of health and social policy in Europe.

Social self-government, with its elected representatives of employers and insured persons, stands for the realisation of the principle of democracy in the statutory health and long-term care insurance. Europe as an area of freedom, security and social progress is also based on full respect for democracy, human rights and the rule of law. We stand together and firmly for these values - especially against populist, nationalist or anti-democratic tendencies.

In the face of many crises and challenges, we are convinced that only together can we secure a peaceful and worthwhile future for Europe. We look forward to engaging in a dialogue with you.

Warmest regards,

Dr Susanne Wagenmann
Uwe Klemens

1 The insured benefit from Europe

European integration is creating an area of individual freedoms, social rights and joint economic activity and work. In times of multiple crises, a peaceful and worthwhile future can only be secured together. Europe is based on full respect for democracy, human rights and the rule of law.

European integration brings concrete benefits to citizens. The open borders between Member States make it possible to live, study or work abroad temporarily or permanently. Thanks to European law, citizens can also rely on good social protection in the event of illness or need for long-term care.

European integration also has many advantages for health and social systems. In the European single market, they benefit from mobile professionals from abroad, from common rules on quality, safety and, increasingly, joint assessment of new medicines and medical devices, and from ongoing exchanges between health and long-term care systems to address challenges that Member States face together. Dealing with new technologies, ensuring healthcare in ageing societies and the consequences of climate change are challenges that affect all EU Member States and require learning from good examples and joint action.

The statutory health and long-term care insurance recognises the role of the EU in health and social policy and has been involved in the joint shaping of Europe's social dimension for more than 30 years. Joint action based on the diversity of health and social systems and a sensible division of tasks between the European and national levels, as well as self-government, promotes social cohesion and the future of solidarity-based social systems in Europe.

Joint action promotes social cohesion and the future of solidarity-based social systems in Europe.

2 Europe benefits from self-government

The health and social systems in Europe are diverse. The German social insurance provides effective protection against the consequences of major life risks such as illness and the need for long-term care. At the same time, it contributes to social cohesion in society and to security and stability in times of crisis. It has proven its efficiency and flexibility, not least during the coronavirus pandemic. The strengths of a self-governed healthcare system were once again demonstrated, not only by making a significant contribution to coping with the coronavirus pandemic in Germany, but also by showing solidarity with the healthcare systems of other countries.

The statutory health and long-term care insurance ensures needs-based and economical care for over 74 million insured persons in Germany and is based on the principles of benefits in kind, solidarity and self-government. Social self-government as the elected representation of employers and insured persons as well as joint self-government consisting of representatives of the medical professions, hospitals and statutory health insurance are

The statutory health and long-term care insurance contributes its expertise and experience to the committees and legislative processes at European level.

subsidiarity in practice, as they fulfil sovereign tasks by way of indirect state administration. Control through self-government

and division of tasks at all levels of government are different manifestations of the same principle: tasks should be solved in a self-determined and autonomous manner where they arise.

The EU benefits directly from self-government: The statutory health and long-term care insurance contributes its expertise and experience to the committees and legislative processes at European level. In this way, it helps to shape European health and social policy as it is being developed, so that implementation in the Member States, the healthcare systems and the responsible institutions on the ground can be as effective as possible.

The European institutions have the entire Union in their sights. For the details of the multi-layered and highly complex health and care systems, they depend on the stakeholders in the Member States. It is therefore essential to involve self-government in the planning of reforms, in determining the details of their implementation and in the application of common law in day-to-day operations, and to take their experience into account. This ranges from the financial viability of pharmaceutical care to the safety of medical devices and the further development of digital cross-border administrative systems.

3 Facilitating mobility through digitalisation

Living, studying or working abroad has become commonplace for many insured persons. Thanks to the coordination of social security systems, they can rest assured that they have social protection within the EU, the European Economic Area, Switzerland or the United Kingdom and have access to the healthcare systems of their place of residence. Social protection for mobility within Europe is not only an example of meaningful cooperation at European level in the interests of patients and contributors, but also one of the oldest achievements of the European project. In order to make it future-proof, it must be constantly adapted to new challenges.

From the perspective of the GKV-Spitzenverband, it is therefore essential to swiftly finalise the revision of the regulations on the coordination of social security systems, which began in 2016. In particular, the provisions on long-term care benefits created by the case law of the European Court of Justice and already implemented in practice must be included in the regulations and regulated together with sickness benefits. This will contribute to transparent and policyholder-friendly coordination without any undesirable deviations from previous practice, loss of entitlements or other disadvantages for the insured.

The future-proof coordination of social security systems in Europe also involves their digitalisation. Social security institutions have already digitalised their communication with each other. Many settlement and administrative processes within the EU are carried out quickly and reliably by electronic means, without any inconvenience to the insured. Further European initiatives to digitalise the coordination of social systems - such as the electronic European Health Insurance Card - will only be successful if they meet the operational requirements of social security institutions, simplify administrative procedures, increase the efficiency of processes, reduce the susceptibility to fraud and errors, support service providers in providing care and facilitate citizens' access to benefits. From the point of view of the

GKV-Spitzenverband, these goals should be given priority and the statutory health and long-term care insurance should be involved in the design and planning of digitalisation processes as early as possible.

Shared digital solutions at EU level also require the allocation of EU funds to strengthen the digital literacy of socially disadvantaged and vulnerable groups and to ensure that digital solutions are user-friendly and tailored to the needs of citizens.

Social protection for mobility within Europe is one of the oldest achievements of the European project.

4 Ensuring the sustainable provision of medicines

Healthcare systems in the EU face the common challenge of ensuring an innovative, affordable and safe provision of high-quality medicines to patients.

The EU bears part of the responsibility for the safe, high-quality and innovative provision of medicines. Across Europe, there are harmonised rules for the authorisation of medicines and common incentive schemes for certain groups of medicines. Considering rising pharmaceutical prices, healthcare systems in the EU face the common challenge of ensuring an innovative, affordable and safe provision of high-quality medicines to patients.

The GKV-Spitzenverband welcomes the objective of the EU to secure and improve access to medicines as well as their affordability and availability. Existing incentive systems within the framework of European pharmaceutical legislation, which often reward the development of new medicines with additional protection periods, should be designed in such a way that they demonstrably lead to better affordability and availability. Overall, an adjustment of the protection periods should help to strengthen competition from generic and biosimilar medicines and ensure the financial sustainability of healthcare systems.

The EU should promote better foresight of new therapeutics in the development pipeline to ensure that regulatory and evaluation authorities are better prepared to assess new products and their financial impact. As many medicines are protected from competition mainly by patent law and supplementary protection certificates, the objectives of access, affordability and availability should also be taken into account in the reform of intellectual property rights.

In particular, incentives for the development of new antibiotics must be targeted to avoid expensive sham solutions. The EU should provide targeted research funding at critical stages in the development of new antibiotics and develop volume-independent reimbursement models as part of the joint procurement of reserve antibiotics. In

addition, the “silent pandemic” of antimicrobial resistance needs to be addressed through prudent prescribing and monitoring of antibiotic use.

The reliable availability of medicines is essential for the supply of medicines to patients. As medicine shortages are a Europe-wide challenge, a joint European response is essential. The EU should put the sustainability of healthcare systems at the heart of its efforts to diversify, strengthen resilience and ensure transparency in supply chains. Supply and reporting obligations for pharmaceutical manufacturers must be made mandatory throughout Europe so that they live up to their responsibility for quality and availability in all EU countries. It must be possible to enforce the Europe-wide supply obligations of the pharmaceutical companies concerned by means of specific sanctions. Effective sanctions are also needed for breaches of obligations due to production-related bottlenecks.

In order to prevent and detect supply bottlenecks, there is a need for better networking and cooperation between the relevant authorities at European level. The causes of bottlenecks and weaknesses in supply chains should be jointly analysed. Where shortages are expected or have already occurred, authorities should be able to take concrete steps to prevent or eliminate them. As part of the revision of European pharmaceutical legislation, the reporting process needs to be harmonised, digitalised and effectively applied across Europe. Voluntary measures taken by industry to create transparency in supply chains are not always sufficient. Mandatory and sanctionable requirements should therefore be considered.

5 Improving care through data

Europe is playing an increasingly important role in the digitalisation of healthcare. The European Health Data Space aims to make electronic treatment data and prescriptions available to insured persons across borders in the electronic patient record. The Health Data Space is intended to help improve cross-border healthcare and make it significantly easier for mobile insured persons in the EU. It will also provide the basis for using health data available in Member States for research, improving care and optimising health systems. Moreover, it will help enhance the ability to respond to cross-border health threats.

The GKV-Spitzenverband supports this central EU health policy project as well as the development of the necessary digital infrastructure and contributes its expertise, especially for the future implementation in the German healthcare system. It is crucial that the exchange of treatment data is organised in the interests of the insured. Sensitive health data must be treated securely and confidentially at all times. Insured persons must also be able to control and understand who is authorised to access their data in a cross-border context. It is important that national systems are interconnected in a way that avoids unnecessary interference with national telematics infrastructures. The expertise of the Member States and their healthcare systems must be taken into account, in particular in the technical specifications, to ensure smooth implementation and application.

There is great potential in the Europe-wide use of pseudonymised health data. In the view of the GKV-Spitzenverband, the use of health data must be oriented towards the common good. Projects that generate and demonstrate added value for the insured, their care or health systems should be approved for use of data. Research results must also be published promptly. The use of data must also be guaranteed primarily for the fulfilment of statutory and regulatory tasks, e.g. for the safety and quality-related tasks of the European Medicines Agency or for the tasks of social

insurance institutions to ensure high-quality and affordable care and advice for insured persons.

In addition to research funding, there is a need for increased European exchange on process innovation and best practice in health and care management. There is also a need to ensure that the use of data from the solidarity community for the development of products and services is made transparent and can be taken into account, particularly in pricing.

The European Health Data Space is intended to help improve cross-border healthcare and make it significantly easier for mobile insured persons in the EU.

6 Bringing climate and health protection together

According to the World Health Organisation, climate change is the greatest global health threat of the 21st century. Its effects are already being felt in Europe: severe weather events such as storms, heavy rainfall, droughts and heat waves, the increase in allergies and the spread of some new infectious diseases not only threaten individual health, especially that of vulnerable groups. They can also have an impact on healthcare infrastructure and place unanticipated additional burdens on health and social systems. The spread of new pathogens, including antibiotic-resistant bacteria, is also a challenge for Europe as a whole.

With the Green Deal, the EU has set itself the goal of making Europe the first carbon-neutral continent by 2050. To achieve this, the EU and its Member States must work together to drive the transition to a decarbonised economy. In addition to opportunities, the transition to a sustainable and climate-friendly economy also entails structural changes in the labour market, which may affect the financial stability of contribution-based systems. In implementing policies for a green transition, the EU should seek to minimise the social and financial impact on society and social security systems. For example, the EU Social Climate Fund must ensure that socially disad-

The EU should assess the impact of the expected burdens of climate and environmental change and promote the sustainable transformation of social and health systems.

vantaged and vulnerable groups are not left behind. With a view to the financial stability and sustainability of health and social systems, the EU should also assess the impact of




the expected burdens of climate and environmental change and promote the sustainable transformation of social and health systems by helping them to reduce their own environmental and climate impact, facilitating the exchange of best practices to this end and providing EU funding to finance such initiatives.

Climate, environmental and health protection go hand in hand: the EU must also pursue these goals in other policy areas. For example, environmental aspects must be taken into account in European pharmaceutical legislation. Environmental risk assessments should be available for all authorised medicines and should be taken into account when authorising them. Therapy-appropriate pack sizes and comprehensive usability data, particularly for custom-made medicines, should help to reduce the need to dispose of medicines. Careful handling of antibiotics is essential to ensure that no residues are released into the environment and that no further resistance develops. Overall, the EU should promote disease prevention as part of the One Health approach and support preventive care through targeted education programmes.

7 Well represented together

In accordance with its statutory mandate, the GKV-Spitzenverband represents all statutory health and long-term care insurance funds in Germany and thus the interests of more than 74 million insured persons vis-à-vis policymakers and service providers, including supranational and intergovernmental organisations and institutions.

The GKV-Spitzenverband works closely with the associations of health and long-term care insurance funds at federal level and contributes to the international exchange through the following organisations with statements, contributions to consultations and dialogue with politicians and stakeholders.

| Organisation | DSV German Social Insurance - European Representation | ESIP European Social Insurance Platform | MEDEV Medicine Evaluation Committee |
|--------------|---|---|--|
| |  Deutsche Sozialversicherung Europavertretung DSV |  |  |
| Members | <ul style="list-style-type: none"> ▪ GKV-Spitzenverband ▪ AOK Federal Association ▪ BKK Association ▪ IKK e. V. ▪ KNAPPSCHAFT ▪ Association of Substitute Health Insurance Funds ▪ Social Insurance for Agriculture, Forestry and Horticulture ▪ German Social Accident Insurance ▪ German Federal Pension Insurance | 50 national social insurance organisations from across Europe | National social health insurers and institutions responsible for evaluating medicines |
| Tasks | Representing common interests in EU opinion-forming and legislative processes | Promoting the exchange of information and experience as well as joint positioning | Exchanging information and experience on therapeutic added value and reimbursement systems for medicines |

The German Liaison Agency Health Insurance - International (DVKA) in the GKV-Spitzenverband supports health and long-term care insurance funds and their insured persons in interpreting and processing national and international health insurance law. This includes the settlement of health insurance benefits provided abroad and the conclusion of exemption agreements with foreign organisations for employees who wish to

remain insured in the German social insurance during temporary employment abroad. In addition, the DVKA acts as the national contact point under the Directive on the application of patients' rights in cross-border healthcare. With this pooling of European policy and operational expertise in the interests of the insured and contributors, the statutory health and long-term care insurance is well positioned in Europe.

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