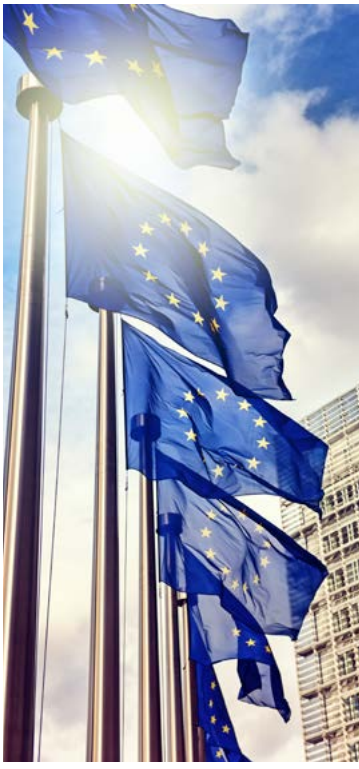
Spitzenverband



Europe:
Pooling Strengths, Utilising Potentials

GKV-Spitzenverband's Position Statement
of 19 March 2019

Imprint

Published by:
GKV-Spitzenverband
Reinhardtstraße 28
10117 Berlin

Responsible:
Michael Weller, Johannes Eisenbarth, Policy Department
Communications Staff Department

Design:
BBGK Berliner Botschaft
Gesellschaft für Kommunikation mbH

Photographs:
Cover le.: Medizinfotografie Hamburg, Sebastian Schupfner, www.schupfner.com; ri.: Grecaud Paul – stock.adobe.com; Tom Maelsa/tommaelsa.com (p. 7); lenets_tan – stock.adobe.com (p. 11); Syda Productions/Fotolia.com (p. 14); Marko – stock.adobe.com (p. 16); Georg Lopata/axentis.de (p. 19)

Order code: 2019-004

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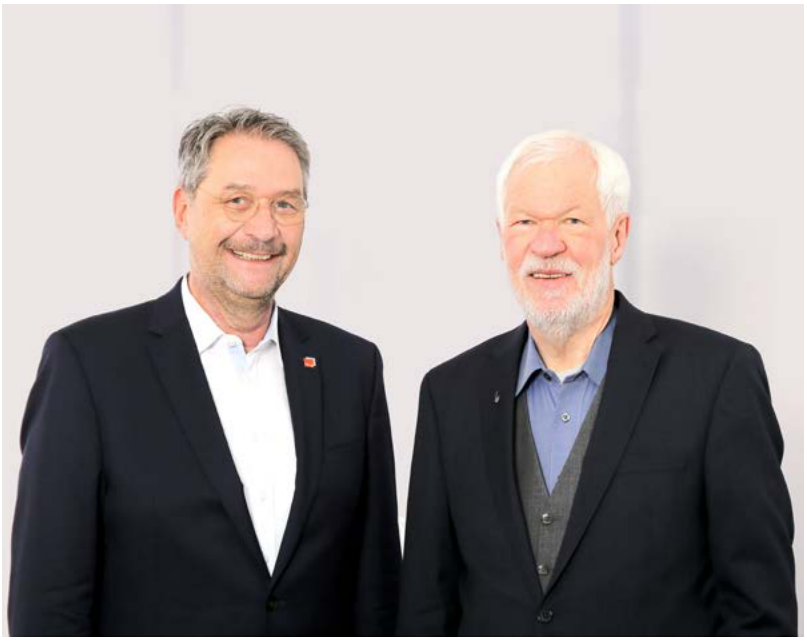
I. Foreword

Dear Reader,

It is regrettable that the United Kingdom is withdrawing from the EU; however, this makes us even more aware of what we have achieved together. Our citizens benefit greatly from European unification, whether directly through a well-functioning health insurance system when abroad in another EU country or indirectly through fruitful cooperation between Member States; for example, the authorisation of medicinal products.

The GKV-Spitzenverband (National Association of Statutory Health Insurance Funds) emphasises the importance of a clear division of competences between the EU and the Member States when it comes to European cooperation. In terms of future issues, it is vital to work together to make full use of the potential of important future developments in order to make health systems fit for the future. This applies to areas such as evaluating medicinal products and medical devices to ensure the best possible care for patients, making use of digitalisation and artificial intelligence, or joint research efforts.

Germany's statutory health and long-term care insurance system wants to both utilise and shape the opportunities and potential offered by European integration. In Germany, there are already 73 million people with statutory health insurance who can be confident that they will receive high-quality, cost-effective care in the event of an illness or the need for long-term care. Regardless of their financial means, they benefit from medical advancements in both Germany and beyond, ultimately thanks to common European regulations.



A great deal has also been achieved for insured persons in recent years. The Medical Devices Directive was adopted as an important step towards patient safety; extending VAT to public services of general interest was averted; and further improvements regarding social security and the free movement of citizens are well on their way.

The GKV-Spitzenverband wishes to make a positive contribution to further developing health and care policy in Europe with this Position Statement. We hope that you enjoy reading our comments and look forward to entering into a dialogue with you on the future design of health and long-term care policy in Europe.

Warmest regards,

Uwe Klemens Dr. Volker Hansen

II. In brief

1. European cooperation offers huge potential. This must be harnessed in order to better face challenges, tackle future issues together, and thus support health and long-term care policy in the Member States. It is important to take into consideration the unique characteristics and requirements of Germany's self-governing health and long-term care insurance system.

2. Across Europe, it is necessary to pool strengths with regards to research in the fields of healthcare and long-term care, as well as research into health systems. Digitalisation in particular is opening up new opportunities for cooperation. Health and long-term care insurance funds must be more actively involved in the setting of the research agenda at EU level.

3. A European network for sharing and using data has the potential to help improve treatment strategies; for example, for rare diseases. Using large amounts of data to take a systematic digital approach to tackling corruption and fraud in the health and care sectors can also be done in cross-border cooperation.

4. The aim of a Europe-wide infrastructure for exchanging health data is to enable access to electronic patient summaries and prescriptions when receiving treatment abroad. National systems must be networked in such a way that there is no interference with national telematics infrastructures.

5. Benefit assessments have proven to be an important pillar for ensuring high-quality health care. Future cooperation in the field of Health Technology Assessment (HTA) requires national assessment bodies to have sufficient flexibility when it comes to making meaningful use of evaluation results in the context of different health systems. Decisions on reimbursements and pricing remain the responsibility of each Member State. Medical devices must also be assessed.

6. The debate initiated by the Council of EU Health Ministers on strengthening the balance of pharmaceutical systems in the EU and its Member States must be brought to a conclusion. Given the high cost of medicinal products, it is a Europe-wide challenge to guarantee affordable, high-quality medicines for patients. The common European rules on marketing authorisation of medicinal products and the common incentive system for certain groups of medicinal products mean that the EU shares responsibility for the safe, innovative and high-quality supply of medicinal products.

7. The provisions of the Medical Devices Regulation must be implemented as soon as possible. The European Database on Medical Devices (EUDAMED) must be made publicly available, and be transparent and easy to search. Health apps should be listed as medical devices in public databases with information regarding their purpose, risks and benefits. There should be a Europe-wide exchange of knowledge and experiences together with a joint HTA.

8. The coordination of social security systems is a good example of where it makes sense to have European cooperation in the interests of patients. In order to ensure the effectiveness of the coordination mechanisms, these need to be continuously developed; for example in the area of long-term care.

9. As part of implementing the European Pillar of Social Rights, systematic comparisons and the voluntary exchange of experiences between the Member States can help them to learn from one another and help modernise health and long-term care systems in Europe.

10. The Treaties oblige the European Union to take into consideration social and health aspects in all policy areas. As such, prior to new legislation being proposed by the European Commission, the impact of this legislation on public healthcare and health policy must be investigated as part of a social and health impact assessment.

III. Pooling strengths

European cooperation has great potential, including for statutory health and long-term care insurance. The GKV-Spitzenverband is of the opinion that this cooperation must be used to better overcome challenges, to tackle future issues together, and thus support health and long-term care policy in the Member States.

The health systems and the challenges in the Member States of the European Union are diverse and wide-ranging. However, there are also urgent issues that affect not only Germany. How can medical and long-term care and prevention be organised in a world of work that is changing and becoming more mobile? How can innovations be identified and utilised in the interests of patients and contribution payers? How can health and long-term care systems be designed in a way that they are financially sustainable?

In many areas, it makes sense to pool strengths at European level. Greater European cooperation when evaluating medical devices and medicinal products must help ensure high-quality healthcare for patients when using new products. It also makes sense to work together when it comes to digitalisation. It must be possible to exchange electronic medical records and prescriptions for cross-border healthcare. Shared use of big-data applications and artificial intelligence can also improve patient healthcare and optimise the structures that underpin it. In doing so, national health systems will benefit if research priorities are set jointly and available data is collected from various sources.

The role of the EU is to provide support to the Member States with shaping their health systems. However, primary responsibility for this lies with the Member States. In the German healthcare system, there are some 73 million people with statutory health insurance who can be confident that they will receive high-quality healthcare in the event that they need treatment and who benefit from medical advancements regardless of their financial situation. However, it is also clear that, given Europe's open borders and integrated labour markets, good health and long-term care insurance for all EU citizens is also in the interests of patients and contribution payers in Germany.

IV. Shaping digitalisation

Digitalising data exchange

In order to make communication between social security institutions across Europe more efficient and reliable, the Electronic Exchange of Social Security Information (EESSI) system is currently being put in place. Germany's statutory health and long-term care insurance funds are working hard to make sure that they can exchange standardised, electronic social security data with other EU countries by mid-2019.

Germany's statutory health insurance funds are also involved in establishing the European eHealth Digital Service Infrastructure (eHDSI). The aim is to have cross-border access to electronic patient summaries and prescriptions for treatment abroad. The GKV-Spitzenverband believes that the main challenges associated with networking Europe are: clearly identifying and reliably authenticating those accessing data; authorising service providers in another EU country; and guaranteeing the confidentiality of health data. National systems must be networked in such a way that this does not interfere with national telematics infrastructures.

Fostering research

The GKV-Spitzenverband supports the European Union's goal of jointly tackling European health challenges and pooling efforts at European level by conducting joint research in the fields of health and long-term care. New opportunities for cooperation are opening up as a result of the digitalisation of the healthcare sector. Joint research projects within the framework of Horizon Europe that make use of synergies and the sharing of databases or infrastructures across Europe could generate significant added value.

In terms of rare diseases, common diseases (such as cancer and dementia) and infectious diseases, the GKV-Spitzenverband believes that there is significant potential for European cooperation with regards to generating, using and assessing data.

It would also be worthwhile to clarify any legal and technical issues regarding the cross-border exchange or joint use of treatment data, billing data and any other data in healthcare systems within the framework of research data infrastructures. When setting the research agenda at EU level, health insurance funds should be more actively involved. In addition to funding research, the European Union should continue to expand the exchange of innovations in processes and good practices in health and long-term care management. The EU should also encourage and support the dissemination of research findings.

Utilising artificial intelligence

The German Federal Government has its own strategy for promoting the use of artificial intelligence (AI). The European dimension of this topic becomes clear when looking at initiatives such as the Franco-German Research and Innovation Network, a European AI innovation cluster and an Important Project of Common European Interest (IPCEI). The goal in the medium term is to have an integrated, pan-European network made up of the sciences and industry.

The GKV-Spitzenverband believes that a European network with infrastructures for data exchange has the potential to help develop treatment strategies for rare diseases. It is important to ensure that data security, patient data sovereignty, and the control and transparency of AI-supported procedures are in line with the EU General Data Protection Regulation.

Tackling fraud and misconduct

Cross-border cooperation in digital approaches involving the systematic use and evaluation of big data can also be used to combat and prevent corruption and fraud in the health and long-term care sectors. Other sectors already have years of experience in this area. Given the increase in cross-border health and long-term care relationships, the Europe-wide use and analysis of data should also help assess the extent of cross-border fraud and combat misconduct. This would benefit from encouraging cooperation and possibly one of the EU's own initiatives.

V. Boosting patient benefits

European Union initiatives for technologies and products are very important for the healthcare of European citizens and the economic sustainability of health and long-term care systems. The GKV-Spitzenverband observes, assesses and advises on these initiatives with the aim of strengthening the benefits for patients and contribution payers.

Health Technology Assessment

Health Technology Assessment (HTA) has established itself internationally as an important pillar for ensuring high-quality healthcare. All patients in the European Union should be able to benefit from independent, scientifically sound information on the benefits of medicines and medical devices and to rely on the safe and cost-effective supply of these products. The GKV-Spitzenverband therefore welcomes the goal of consolidating and progressively expanding cooperation in the evaluation of health technologies within the European Union. In doing so, it is imperative that medical devices be assessed in order to do justice to their importance for the care of patients.

Cooperation in the future should see national HTA bodies taking a leading role and should be characterised by high levels of consensus and transparency. A vital step towards enhanced EU cooperation is to reach consensus on the process of conducting an assessment. The underlying methodology must be based on international standards of evidence-based medicine and must not fall short of what has already been achieved in the Member States.

National assessment bodies need sufficient flexibility in order to make the best use of the assessment results in the context of divergent health systems. It must also be made clear that decisions regarding reimbursements and pricing must remain the responsibility of the individual Member States. Health insurance funds must be involved in joint horizon scanning.

Regulating the pharmaceuticals market

Given the high cost of medicines, ensuring the supply of affordable, high-quality medicines for patients is a Europe-wide challenge. The centralised marketing authorisation procedure for medicinal products and joint incentive schemes for certain groups of medicines mean that the EU shares responsibility for ensuring the supply of safe, innovative and high-quality medicines.

The debate started by the Council of EU Health Ministers on strengthening the balance in the pharmaceutical systems in the EU and its Member States must not be allowed to lose momentum. The EU needs to systematically review existing incentives for the pharmaceutical industry to develop medicines.

It is concerning that new medicines with extremely high prices are being authorised for increasingly smaller patient groups, even when additional benefits have not been clearly demonstrated. Incentives for developing medicines for truly rare diseases must provide real added value for patients. Experience with accelerated marketing authorisation has shown that the data on safety and benefits that manufacturers promise to provide is often provided late or is incomplete. Accelerated authorisation procedures must not compromise patient safety and the accelerated marketing authorisation of medicinal products must focus on filling genuine gaps in healthcare. These special arrangements must not result in prices that jeopardise the sustainable financing of health systems.

Research and development at European level also play an important role in providing patients with innovative medicines. In order to maximise the benefits for patients and ensure they have access to innovative and affordable medicines, public investment in research and development must be channelled into areas which have the most urgent medical needs. Health insurance funds from the Member States must be involved in setting priorities for the European research

agenda. In addition, public investment in the research and development of medicines must be reflected in their pricing.

Throughout Europe, supply bottlenecks and contamination of active ingredients have negatively affected patients' confidence in the supply of medicines. The main reason for supply bottlenecks is that production has been reduced to just a few locations. The GKV-Spitzenverband is of the opinion that supply bottlenecks are unacceptable. The supply chain must be organised in such a way that it guarantees the supply of medicines to patients.

When a pharmaceutical company places a medicinal product on the European market, it must be responsible for the quality of the medicine and check this in conjunction with the manufacturer of the active ingredients. The responsible authorities should be provided with greater access rights and the ability to impose tougher sanctions in order to ensure that patients are supplied with quality medicinal products.

Implementing the Medical Devices Regulation

After years of political debate, the European Medical Devices Regulation entered into force at the end of May 2017. Greater levels of transparency and safety when placing medical devices on the market, together with stricter quality requirements for the clinical assessment of medical devices are an important step towards improving patient safety and the quality of healthcare. From 26 May 2020, all medical devices placed on the market must comply with the new regulation.

Implementation by the Member States and the European Commission is proceeding according to plan. The vast majority of notified bodies have already applied for designation under the new law. The GKV-Spitzenverband believes that the transition periods are adequate and should be used by all stakeholders to ensure a smooth transition from previous regulations to the new Medical Devices Regulation. Industry associations are being called on to support this process by providing information to their members. This is in the interest of patient protection and would strengthen Germany's standing as an innovation location.

It is currently impossible to gain an overview of medical devices on the European market. There is also no way to view data from a central location on the safety and efficacy of individual

medical devices. According to the provisions of the new Medical Devices Regulation, the European database on medical devices (EUDAMED) will be established and go into operation in March 2020. Its contents will be publicly accessible in part.

The GKV-Spitzenverband calls for the requirements of the Medical Devices Directive regarding the public availability of data to be implemented to the letter and that all content, such as information on conformity assessments, scrutiny procedure results, intended purpose, safety and performance data for high-risk products and clinical trial reports, to be made available to the public in a way that is transparent and easy to search.

Assessing health apps

The number of health apps is on the rise and they are of great interest to insured persons. They help people to take responsibility for their own health. The benefits to insured persons, as well as the quality and safety of these products, must be given priority when assessing medical device apps. The thoroughness of the assessment must be based on the risk class of the product according to the Medical Devices Directive. Medical device apps should be listed in public databases with information regarding their intended purpose, risk class and proof of their benefits. It would also be beneficial to have a Europe-wide exchange of insights into and experience with health apps that goes beyond the joint benefit assessment.

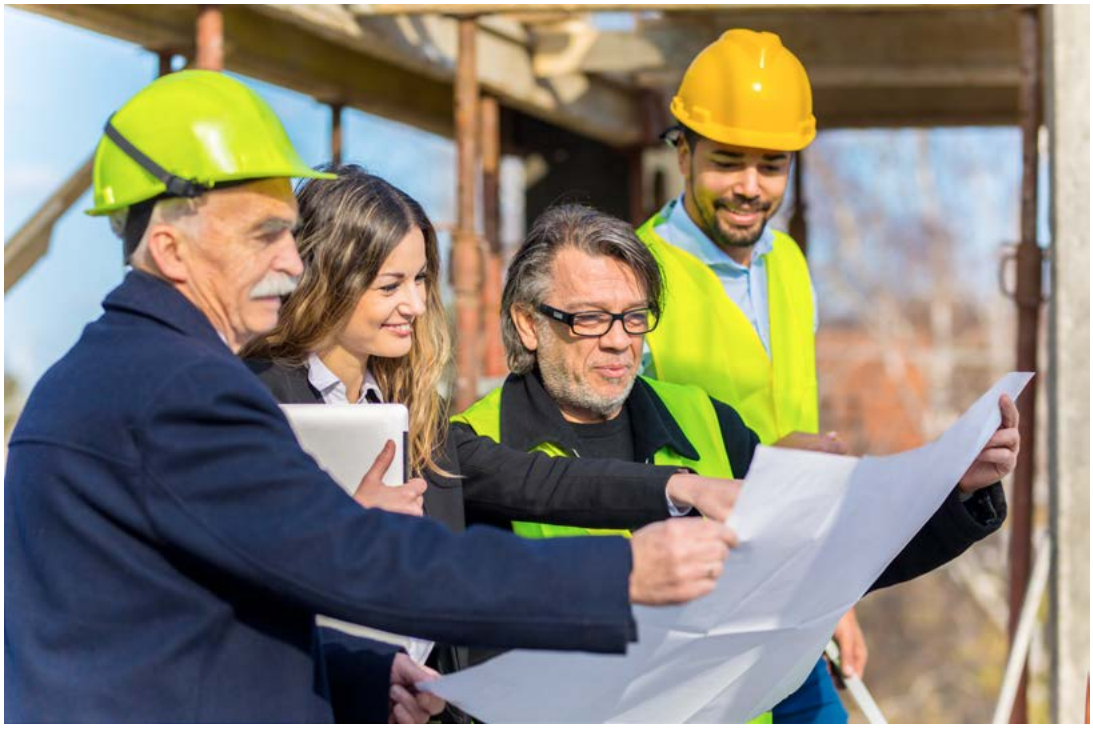
VI. Safeguarding mobility

Persons insured by Germany's statutory health and long-term care insurance funds are also protected beyond Germany's borders. The regulations on the coordination of social security systems provides them with access to the health systems of the host country when they are in any of the EU countries, the European Economic Area or Switzerland. Coordination of the social security systems is a good example of where it makes sense to have European cooperation in the interest of patients and contribution payers. In order to ensure the effectiveness of the coordination mechanisms, they must be continually developed. The GKV-Spitzenverband works toward breaking down borders and supporting the mobility of insured persons.

Expanding the European Health Insurance Card

When temporarily staying in another EU country, the European Health Insurance Card (EHIC) makes it possible for persons with statutory health insurance to access all benefits in kind which are considered medically necessary, taking into account the nature of the benefits and the expected length of stay. Persons covered by Germany's statutory health insurance who are in another EU country are treated as if they were covered by the insurance system of that country. In the opinion of the GKV-Spitzenverband, the card must be developed more in order to further improve the card's acceptance. The EHIC should be issued to all insured persons in Europe to ensure that benefits in kind can be accessed as easily as possible. Service providers themselves must also be encouraged to do more in terms of accepting the EHIC. Furthermore, other identifying features, such as a photograph, could be included on the card to improve its use as a means of visual identification.

Settling treatment costs incurred abroad with the institution where the person is insured must be become more effective. The European Union must safeguard the financial interests of contribution payers and include additional tools in the regulations to control compliance with deadlines, billing and enforcement of claims.



The GKV-Spitzenverband views the European Commission's intention to introduce a European Social Security Number as generally positive. If properly designed and organised, an additional European Social Security Number as a single identifier across systems in all Member States can reduce the administrative burden on social security institutions and improve the exchange of electronic data. The GKV-Spitzenverband believes that all EU citizens and insured persons from third countries should, in principle, be given a European Social Security Number.

Protecting people in need of long-term care

Long-term care benefits are also covered by the EU regulations on the coordination of social security systems. As a result of case law in the European Court of Justice, long-term care benefits are treated the same as sickness benefits. People in need of long-term care can receive a care allowance while staying abroad or receive benefits in kind.

The European Commission has proposed reforms designed to increase transparency. The Commission has proposed adding a separate chapter on long-term care benefits and a common definition of these benefits to the coordination regulation. Although at first glance this would appear to be an insurance-friendly amendment, it could actually make things more difficult for insured persons and even result in a loss of entitlements. The GKV-Spitzenverband is therefore in favour of the joint regulation of sickness and long-term care benefits. By adjusting the existing rules for sickness benefits, long-term care benefits can be coordinated in a more transparent manner without any undesirable deviations from the existing system of coordination or disadvantages for insured persons.

European Labour Authority: preserving expertise

The European Commission has proposed establishing a European Labour Authority to ensure that legal acts in the area of labour mobility are implemented in a fair, simple and effective manner. The proposal also covers some tasks which are currently assigned to the Administrative Commission for the coordination of social security systems and which are carried out by experts from the Member States and the social security institutions.

From the point of view of the GKV-Spitzenverband, it must be made clear that the tasks currently assigned to well-established bodies continue to be performed by them and that the Member States and social security institutions are able to continue contributing their expertise in this area. Competences should not be moved from Member State to EU level without objective reasons.

Brexit: cushioning the negative effects

Insured persons and patients have nothing to gain from the United Kingdom leaving the European Union. When the UK ends its membership of the European Union, the arrangements with respect to the UK and European coordination of social security systems, which insured persons have been able to rely on in the past, also cease to apply.

In the future, there will have to be arrangements between the UK and the EU or individual Member States in order to ensure the social protection of citizens in cross-border situations. For the GKV-Spitzenverband it is important to avoid disadvantaging those affected and to provide legal certainty with regard to insurance status and entitlements and benefits of statutory health and long-term care insurance.

VII. Acting jointly

Member States are responsible for designing, organising and financing their own healthcare and medical services. The European Union has clearly defined competences; for example, in areas such as medicinal products and medical devices or providing support to the Member States. This is done via joint learning and coordination processes such as the European Semester and the European Pillar of Social Rights.

The Treaties also oblige the European Union to take into consideration social and health aspects in all policy areas. This also applies to initiatives for the internal market and competition policy. As such, a social and health impact assessment on the effects of any new legislation on public healthcare and health policy must be conducted prior to the proposal being put forward by the European Commission.

In order to strengthen not only economic integration in the European Union but also the social dimension, the EU and the Member States have agreed on a set of common principles included in the European Pillar of Social Rights. The Member States have primary responsibility for their social policy. All Member States must ensure that their health systems function well and that there is efficient healthcare and long-term care. In a Europe without internal borders, this is also in the interest of insured persons and contribution payers in Germany. A high degree of social protection and a reduction in social and health inequalities in all Member States is the basis for the long-term economic and political cohesion of the European Union.

European Semester

As part of the European Semester, the European Commission conducts an annual review of the Member States' draft budgets and reforms in order to ensure national budgetary discipline and competitiveness. The reports and recommendations of the European Union also address aspects of health and long-term care policy. In recent years, Germany has repeatedly been recommended to pursue a growth-friendly fiscal policy by improving the cost-effectiveness of public expenditure on healthcare and long-term care.

However, the GKV-Spitzenverband is of the opinion that fiscal aspects and economic growth should not be at the forefront of health policy, but rather access to health services, their quality and efficiency, and thus the benefits to patients and contribution payers.

European Pillar of Social Rights

With the proclamation of the European Pillar of Social Rights in 2017, the European Commission, the European Parliament and the Member States committed themselves to common, key principles in twenty areas of social and health policy. All people should have the right to timely, affordable access to good quality prevention and health services. The same applies to long-term care. In terms of access to social protection, workers, and under comparable conditions the self-employed, should have the right to adequate social protection, regardless of the type and duration of their employment relationship.

In order to encourage commitment to the principles, the European Commission has established a social scoreboard to monitor social trends over the long term using certain indicators. The GKV-Spitzenverband believes that systematic comparisons and the voluntary exchange of experiences between the Member States can help them to learn from each other and to modernise the healthcare and long-term care systems in Europe.

VIII. Utilising strengths

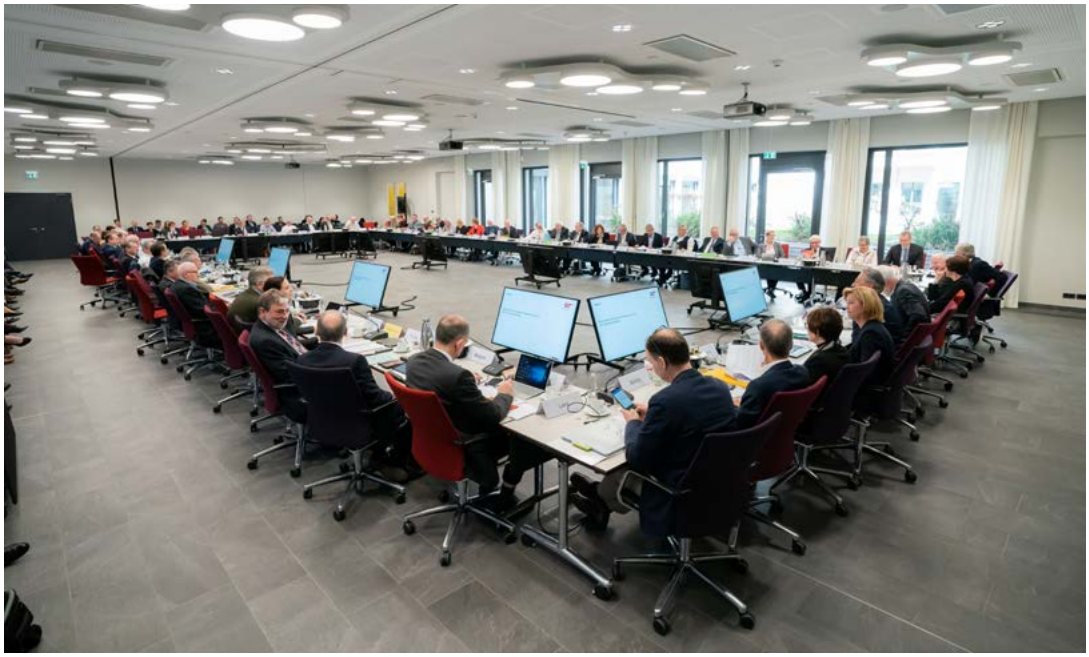
When it comes to healthcare and long-term care, Europe is united in its diversity. Germany's statutory health insurance system is characterised by its structural principles: healthcare geared towards medical needs; the principle of benefits in kind; the solidarity principle; financing through contributions; and the principle of self-governance. These principles ensure a high standard of healthcare and are the foundation for important coordination and reform processes that are needed in Europe.

Representatives of insured persons and employers are directly involved in the self-governing committees of the German statutory health and long-term care insurance funds and their umbrella associations. This is a strong, efficient system which differs from a system that is purely controlled by the state or by the private sector. The system of self-governance combines self-regulation, that is mostly independent of government influence, with affordable, needs-based care for all. As the system is financed through contributions payments, this means that there is a large degree of independence from government budgets.

An important prerequisite for the efficiency and performance of the statutory health insurance funds, which unlike private companies are not-for-profit, is a competition framework based on solidarity and which is tailored to the specific features of the German social insurance healthcare market. These include the statutory catalogue of benefits, the statutory healthcare mandate of the health insurance funds, and their obligation to provide insurance coverage to people without a health check. European internal market and competition law must also take into consideration these special requirements.

Social dialogue

The significance of steering social policy through social self-governance in Germany's social insurance system finds its counterpart at European level in social dialogue. In terms of social policy, the European Treaties place particular worth on cooperation between trade unions and employers. They must have their voices heard before any initiatives in social policy and labour market policy are submitted. Social dialogue may also result in agreements which become legally binding upon a resolution of the Council.



IX. Pooling competences

The GKV-Spitzenverband represents all statutory health and long-term care insurance funds in Germany, and thus the interests of approximately 73 million insured persons and contribution payers in its dealings with policy makers and service providers. Its work also includes advising the German parliaments and ministries with regard to current legislative procedures.

The GKV-Spitzenverband is also actively involved in observing and helping shape important processes at EU level by submitting statements and providing advice, as well as via international exchange. The legislature has mandated the GKV-Spitzenverband with representing the interests of the statutory health insurance funds vis-à-vis supranational and international organisations and institutions. It works in close cooperation with the various health insurance and long-term care insurance associations at federal level.

In order to effectively represent the interests of the German statutory health insurance system, the GKV-Spitzenverband is a member of the following organisations:

	DSV **German Social Insurance – European Representation, Brussels** Deutsche Sozialversicherung Europavertretung	**ESIP** **European Social Insurance Platform, Brussels** esip EUROPEAN SOCIAL INSURANCE PLATFORM	**MEDEV** **Medicine Evaluation Committee, Brussels** MEDEV Medicine Evaluation Committee
Members	GKV-Spitzenverband AOK Federal Association BKK Association IKK e.V., KNAPPSCHAFT Association of Substitute Health Funds The Social Insurance for Agriculture, Forestry and Horticulture The German Social Accident Insurance The German Federal Pension Insurance	40 national social insurance organisations from across Europe	National social health insurance organisations and the national authorities responsible for the evaluation of medicines
Tasks	Influence opinions and the legislative process at EU level	Promote the exchange of information and experiences, as well as joint positions.	Exchange information and experiences on the therapeutic added value and reimbursement systems for medicines

In addition, the GKV-Spitzenverband networks with numerous stakeholders at European level, such as the Association Internationale de la Mutualité (AIM).

The GKV-Spitzenverband's German Liaison Agency Health Insurance – International (DVKA) provides support to the statutory health insurance funds and their members with interpreting and administering national and international health insurance law. Health insurance benefits provided abroad are settled via the Liaison Agency. The same applies to costs incurred by German health insurance funds for the treatment of persons insured abroad who temporarily reside in Germany. The total amount of settlements is approximately €1.2 billion annually.

In all areas of social security, the DVKA enters into special agreements with foreign bodies for employees who are temporarily employed abroad and wish to remain covered by German social insurance during this period. In addition, the DVKA acts as the National Contact Point as provided for in the Directive on the application of patients' rights in cross-border healthcare. A target group-oriented information platform has been set up at www.eu-patienten.de; there are also options for telephone and one-on-one consultations for patients and healthcare service providers.

Thus, the GKV-Spitzenverband pools European policy and operational competences in the interest of insured persons and contribution payers.

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