

**Position paper of the German Hospital Federation  
on the European Parliament's term 2019-2024**

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**I. German hospitals' expectations of EU health policy**

German hospitals recognized from an early stage that healthcare and health policy play an increasingly important role in the European Union (EU). They have been constructively involved in health policy debates at EU level for many years and want to play an active role in the future development of EU health policy. An EU health policy can support the health policies of the Member States in a meaningful and unobtrusive way and actively complement them where joint action is more successful than national action. With the following catalogue of requirements and wishes for health policy in the EU, German hospitals would like to provide ideas for a broad debate and thus make an active contribution to the identification of goals that can and should be achieved with a health policy in the EU. The claim and obligation for German hospitals to participate in the European debate on better healthcare result from the following:

The 1,942 hospitals with their approximately 1.2 million employees provide inpatient care for over 19.5 million patients and outpatient care for approximately 20 million patients each year. With an annual turnover of around 97 billion euros, German hospitals are an important economic factor in the growing health market. In many regions, the hospital is the largest employer. Hospitals play a central role in ensuring the sup-

ply security of the population and ensure high-quality health care throughout the country. In order to guarantee a high quality of medical care, within the limited financial resources, hospitals work self-reliantly on the provision of high-quality healthcare at socially acceptable price rates and must also act and think entrepreneurially. For this mission, they are aware of their special responsibility as part of the servicing of general interests.

The principle, that Member States are responsible for the organisation of their social security and healthcare systems, is an important basis of the social peace and cohesion of each of the respective societies. This basic decision was confirmed by the Treaty on the Functioning of the European Union of Lisbon and should remain the basis for discussions on EU health policy. Therefore, an EU health policy must preserve the social consensus of each Member State defining under which financial and organisational conditions healthcare services could and should be accessible to its own citizens. An EU health policy can effectively support and complement national actions. For example, by financing joint research and by organising discussion platforms at EU level, progress could be made that Member States may not be able to achieve to the same extent on their own. This explicitly includes, for example, the cross-border use of Big Data for research purposes. This explicitly includes, for example, the cross-border use of Big Data for research purposes. An effectively supportive but subsidiary EU health policy is therefore a worthwhile challenge, whose construction – taking national structures insofar as is possible into account – meets the greatest acceptance for European complementarity of the national actors.

At the same time, the European Union, gained, in part, extensive competences in other policy areas. Actions on these policy areas can have to some extent, partly significant impact on the structure, on the financial bases or on other organisational aspects of the Member State's healthcare systems. The large number of initiatives requires more sensibility for the – sometimes unintended – consequences of the healthcare service provision. Possible structural and financial consequences for the Member States' healthcare systems should therefore be part of each regulatory impact assessment at EU level. Possible financial consequences of EU legislation for hospitals must be assessed and made transparent by the EU legislator.

## **II. What German hospitals stand for**

### **a) Preservation of the Directorate-General SANTE**

The Directorate-General SANTE of the European Commission offers reliable structures for Member States' stakeholders for approaching – in the spirit of trust – decision makers with expertise and experience in matters of member state organised healthcare systems.

The dissolution of Directorate-General SANTE and a redistribution of the single services would entirely deprive the significant sector of EU healthcare economy of its articulation platform. If the existing health service competences were to be assigned to, for example, the Directorate-General (GROW) responsible for the internal market, health service provider associations and sickness funds associations would have to compete with the automotive and space industry for the attention and influence of the same Directorate-General. Due to the particularities of the European healthcare and social policy, as described above, this would be inappropriate.

### **b) Improvement of healthcare for EU patients**

With the Directive on the application of patients' rights in cross-border healthcare, citizens have greater freedom of choice and possibilities to access healthcare in any EU country. German Hospitals offer a high degree of high-quality medical healthcare and healthcare related services. The expanded range of outpatient services of German hospitals offers additional opportunities. Hospitals are prepared for the European competition for patients and want to provide high-quality medical healthcare and related services for patients from abroad. The Directive, whose effects on cross-border healthcare have fallen far short of expectations, needs to be reviewed and obstacles to the desired mobility of patients removed. In the field of rare diseases, cross-border healthcare can be promoted by further financial support for the European Reference Networks.

### **c) Strengthening of healthcare professions**

The special tasks for hospitals in order to ensure security of supply (provision of healthcare services around-the-clock, varying intensity of use of services) requires flexibility in the organisation of working time in a special manner. Hospitals have to be enabled to manage a financially viable and problem-oriented organisation of working time, for example in the form of on-call duty. Efforts to create patient and employee-friendly organisation of working time in hospitals must be accompanied by a legal framework that permits differentiated forms of organisation of working time as well as of its evaluation. An amendment to the Working Time Directive is urgently needed.

The - also temporary - employment of employees from other Member States can serve to increase the quality of hospital care in Germany and to cover personnel shortages. However, the increased mobility of workers expected from the Directive on the recognition of professional qualifications can be further strengthened.

### **d) Higher quality of services through exchange of information**

The quality of the provision of healthcare services or of medical devices can be increased by sharing experiences and "good practice". The European Union can promote voluntary exchange for all who are interested in it, by providing and supporting exchange platforms. At the same time, it must be recognised that, instead of, for example, binding EU health technology assessments (HTA), added value can also be generated by project based cooperation of HTA authorities/managers. The implementation of possible common objectives must remain the sole competence/ responsibility of the Member States.

### **e) Simplification of EU funding programmes**

All EU funding programmes should be further simplified from the ground up in the next funding period. Experiences with EU project show that the current management is not sustainable for small project partners. The indicators of the programmes should be significantly reduced and national audits should be recognised. Proven simplified cost options should be used to a greater extent.

**f) Promotion of digital transformation**

The digital transformation does not stop at the hospital and healthcare sector. For social service providers in particular, who have no access to the capital market, corresponding investments represent a major hurdle. At the same time, such investments are essential for facing the challenges of the future and to ensure low-thresholds healthcare services for all population groups in the long term. Support programmes for digital transformation should therefore give due consideration to social service providers such as hospitals.

**g) Promotion of joint research with partners in Europe**

German hospitals are innovative and future-oriented. With considerable financial resources and personnel, procedures and products are developed that constantly improve the diagnosis and therapy of patients. This high innovation potential can be even further increased by cooperation between partners in Europe for the benefits of patients. Europe's 500 Million inhabitants provide a large data pool that should be used for cross-border health research. Legal barriers to such cooperation must be removed and cooperation must be given considerable financial support. Promoting research in healthcare means the simultaneous promotion of sustainability and competitiveness of one of the strongest economic sectors in the Member States of the European Union. Research funding in the field of healthcare should therefore be given high priority.

**h) Improvement of drug safety (in particular securPharm)**

The German Hospital Association expressly supports measures for effective protection against counterfeiting of medicines. However, at the hospital sector, the implementation of the measures provided for in the delegated regulation on counterfeit medicines cannot, as a result, contribute to protecting against counterfeit medicines. Rather, the implementation of the Delegated regulation charges hospitals with enormous unilateral challenges without improving protection against counterfeit medicinal products. The Delegated regulation on the safety features appearing on the packaging of medicinal products entered into force in February 2019 despite the problems that are difficult to assess in many countries. The extent to which the EU requirements are implemented in hospitals and public pharmacies must be monitored. A possible threat to the supply of medicines would then have to be resolutely countered.

**i) Supply shortages of medicines**

With regard to the continuing significant problems with supply shortages of medicines, fundamental measures to prevent such bottlenecks are also necessary at the European level. Supply shortages of medicines have become a permanent problem in hospitals in Germany. Though improvements in information about supply shortages of medicines were achieved, hospitals report no change in the extent of the problem. With regards to the accumulation of supply shortages of medicines, even for urgently needed drugs for which no therapeutic alternatives exist, there is a serious danger, from the hospital's point of view, that it will no longer be possible to provide the full range of healthcare services in the future. From the hospital's point of view, it is therefore essential to take measures to contain supply shortages of medicines and to

prevent problems in the provision of healthcare services. Measures have already been initiated in Germany, such as the listing of urgently needed, supply-endangered medicines and the implementation of a “Jour Fixe” on supply shortages of medicines that monitors and evaluates the medicine and healthcare situation. However, these are not sufficient to prevent further supply shortages of medicines, from the German Hospital Federation’s point of view.

#### **j) Encouraging the development of new antibiotics**

At the national and international level, efforts are being made to improve the framework conditions for the development of new antibiotics. These efforts must be further intensified to promote the urgently needed development of new antibiotics. The fundamental problem in the development of new antibiotics is that their development is extremely complex, but their usage is very limited because of the resistance problem. Besides, the prices for antibiotics are comparatively low. Therefore, the economic incentives for pharmaceutical companies to become more involved in the development of new antibiotics under the existing framework conditions are extremely low. Therefore, it is crucial to improve the framework conditions for the development of new antibiotics. At the European level, the European Medicines Agency (EMA) is responsible for the authorisation of new antibiotics. Therefore, supportive measures should be taken especially in the marketing authorisation procedure, as it is already the case for Orphan Drugs. These would significantly improve the framework conditions for the development of new antibiotics and would be, in the long run, an important contribution for the improvement of the availability of antibiotics on reserve.

#### **k) Promotion of tissue supply**

The German Hospital Federation has always welcomed the objectives of the EU Directives on the donation of human tissues and cells. The main problem of the existing European legal framework on the donation of human tissues and cells is the maximum time period for blood samples in the case of a deceased donor as set out in Directive 2006/17/EC. In the case of a deceased donor, blood samples must be obtained in any case within 24 hours after death. If this is not possible, a tissue sample may no longer be taken, even with suitable tissue donors. In many cases compliance with this 24h time limit cannot be achieved due to the processes required prior to tissue donation procedure (for example information and agreement procedure, transfer of the organ donor). As a result, a large number of potential donations could not be realised. Following hospital figures, a modification of the 24h time limit in the 2006/17/EC could raise the donation of human tissues and cells by 25 percent. This could – without any deterioration in quality of human tissue and cell donations – sustainably improve the supply of donations in Germany and Europe. From the German Hospital Federation’s point of view, a modification of this aspect of the Directive 2006/17/EC is therefore urgently required.