THE HEALTHCARE LAW REVIEW

Seventh Edition

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URÍA MENÉNDEZ

PREFACE

The seventh edition of *The Healthcare Law Review* covers three new jurisdictions (India, Mexico and Nigeria), summing up to a total of fifteen jurisdictions from countries in Europe, North and South America Asia and – for the first time – Africa. All reports have been provided by leading experts in the field of healthcare law in their countries. The reviews have been prepared by the authors as a practical, business-focused analysis of recent changes and developments, their effects, and a look forward at expected trends. The reviews are intended to provide an overview of legal issues which are of interest for healthcare providers and related businesses.

The global covid-19 pandemic has come to an end this spring. The WHO chief Tedros Ghebreyesus declared the end to covid-19 as a global health emergency on 5 May 2023. According to the reviews from the individual countries, most of the exceptional measures, which had been implemented by the countries to fight the pandemic, have largely been scaled back or totally withdrawn. Therefore, the authors report back to normal in their reviews.

As a major result of the pandemic, many countries have geared their healthcare systems to ensure safe access to healthcare for citizens, even in extraordinary situations, through more digitisation and telemedicine. This is not just about supplementing or replacing face-to-face doctor visits with communication options via telephone or video consultation. Many countries, not only in Europe, have also introduced electronic patient files, regulations for the exchange of health data and other digital communication channels. It seems that it is still a long way to go to implement these innovations successfully in a healthcare reality that is no longer solely determined by a pandemic. A particular challenge in the future will also be to utilise the new digital tools not only within a national healthcare system in a single country, but also across borders.

The European Union is already well on the way with the implementation of a European Health Data Space. Furthermore, the European Commission has published a proposal of a new pharma package, which may have major impact on the healthcare systems in the member states of the European Union in particular.

Germany however, the largest healthcare system in the European Union, still faces many hurdles before implementing electronic prescriptions, electronic patient records or statutes for the secondary use of health data. The authors report from South Korea that the strict measures for telemedicine services are back in force. These examples show that healthcare systems in the individual countries tend to defend the status quo rather than to implement digital and electronic tools with fast speed.

Even if the individual countries solve the problems differently, we all can only benefit from knowing the different approaches to solving the problems and how successful

the respective countries have been with their solutions in each case. I truly hope that the publication of the new edition of *The Healthcare Law Review* will particularly be helpful in that respect.

Like in past years, it has been an extraordinary pleasure to work with this group of exceptional authors of *The Healthcare Law Review* in this edition and in the years to come to provide a practical overview of the healthcare systems of the countries covered. We will continue our efforts to include more countries to be able to give a comprehensive worldwide approach to health issues by each country.

Ulrich Grau
D+B Rechtsanwälte Partnerschaft mbB
Berlin
July 2023

Chapter 4

GERMANY

Tobias Volkwein[1]

I OVERVIEW

For more than 100 years, Germany's healthcare system has been characterised by the statutory health insurance. Nowadays, approximately 73 out of 83 million inhabitants are covered by statutory health insurance whereas only 10 million patients are privately insured. Germany's yearly expenditures on health amount to €390 billion. This corresponds to around 11 per cent of GDP. The statutory health insurance funds spend approximately €220 billion a year on services for their insured. Hence, the statutory health insurance funds (SHI) have an important impact on all stakeholders in the German life sciences business. This leads to a highly regulated life sciences industry with a major emphasis on the cost-benefit ratio of services provided.

II THE HEALTHCARE ECONOMY

i General

In the centre of the German healthcare system stands the principle of self-administration. Whereas the framework for medical care and its responsibilities are defined by the state through legislation and regulations, the details of medical care, particularly the extent of its reimbursement by the SHI, are decided by the administrative bodies themselves. The four leading umbrella organisations of the self-governing German healthcare system are the National Association of Statutory Health Insurance Physicians and the National Association of Statutory Health Insurance Dentists, the German Hospital Federation and the Central Federal Association of Health Insurance Funds (GKV-Spitzenverband), all members of the Federal Joint Committee (see Section IV.i).

ii The role of health insurance

As of 1 January 2009, health insurance was made mandatory for everyone registered or usually resident in Germany, depending on further conditions either within the SHI or a private health insurance (PHI). Almost all employees (self-employed and some other groups such as civil servants are exempt) are required to get join a SHI if their income is below a certain level (in 2023 the threshold was €66,600 per year[2]). Above this level, someone can

1 Tobias Volkwein is a partner at D+B Rechtsanwälte Partnerschaft mbB.

2 https://www.bundesregierung.de/breg-de/suche/beitragsbemessungsgrenzen-2023-2133570.

decide to become a member of a PHI, or to anyhow take out voluntarily a SHI. In Germany, there is a wide range of options between different SHI: statutory health insurance is currently made up of 93 insurance funds.[3]

All SHIs are members of the GKV-Spitzenverband, who represents the interests of statutory health insurance at federal and European/ international level, founded on Section 217a of the main regulation relating to the SHI, the Social Code Book 5 (SGB V).

iii Funding and payment for specific services

Both SHI and PHI are funded by contributions or premiums from their members. Whereas contributions to PHI depend on a person's health, the age at which they take out the insurance, their individual risk, the type of coverage and any excess, contributions to the SHI are based on a person's salary. With the SHI, all the insured receive the same level of services. Those who earn more pay higher contributions. This is what is meant by solidarity in the statutory health insurance system. The general contribution rate in the SHI is 14.6 per cent of salary, of which the employer pays half. Each insurance fund can also charge an additional premium, which currently averages around 1 per cent and of which the employer also pays half.[4] The premiums only scale up to a certain income level, above which the premium does not further rise.

Most of the general medical services are covered by the SHI. Besides special requests – such as a private hospital room, treatment by a senior consultant or certain dental treatments – that must be paid by the patient, benefits that have been legally excluded from SHI health insurance coverage include eyeglasses, lifestyle medications, and all over the counter (OTC) medications with a few exceptions, which are defined by the Federal Joint Committee. There are certain co-payments a SHI insured person has to bear (e.g., 10 per cent of the price with a minimum co-payment of €5 and a maximum of €10 per product).[5] Reimbursement in PHI essentially depends on the assumption of a medical need and the concrete contract conditions.

III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

The German healthcare system is divided into inpatient and outpatient treatment. Both medical and nursing care are provided on an inpatient and outpatient basis. All treatments, rehabilitation activities and therapies provided outside hospitals belong to the category of outpatient care. Hospitals can also provide outpatient care; however, for example, this is in specialist outpatient departments.[6] Germany's healthcare system leans towards sectoral integration.

3 https://www.vdek.com/presse/daten/b_versicherte.html.

4 Federal Ministry of Health. The German healthcare system, 2020, page 9.

5 Blümel/Spranger/Achstetter/Maresso/Busse, Germany: health system review 2020, *Health Systems in Transition*, Vol. 22 No. 6, pages 91, 93.

6 Federal Ministry of Health. The German healthcare system, 2020, page 30.

SHI-insured patients have in principle free choice of physicians, psychotherapists, dentists, pharmacists and urgent/out-of-hour care services. About 42 per cent of all SHI-affiliated physicians work as family physicians and in primary care. Although GPs are usually the patient's first point of contact with the health system, they are not official gatekeepers.[7]

In addition, SHI also covers a wide range of inpatient and outpatient medical rehabilitation (largely covered by the Social Code Book IX). Rehabilitation facilities provide treatments that help people to regain independence and improve their fitness after getting over a serious illness and recovering from intensive treatment. These treatments include physiotherapy, psychological care and help learning how to use medical aids and appliances. This is often done immediately after a hospital stay, for instance following surgery.[8]

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

According to Germany's general legal framework, the legislature and state health policy define the framework in which the various partners in the healthcare sector can make their decisions. The aim is to align the priorities of health policy with the effective use of available funding. The Federal Ministry of Health (BMG) supervises a number of institutions, particularly the following three very important ones: (1) the Federal Institute for Drugs and Medical Devices (BfArM); (2) the Paul-Ehrlich-Institut (PEI), Federal Institute for Vaccines and Biomedicines, responsible for the research, assessment, and marketing authorisation of biomedicines for human use and immunological veterinary medicinal products; and (3) the Robert Koch Institute (RKI), the government's central scientific institution in the field of biomedicine, including the Standing Committee on Vaccination (STIKO) that develops national recommendations for the use of licensed vaccine. PEI and RKI/STIKO have played decisive roles during the covid-19 pandemic.

The Federal Joint Committee, which is also supervised by the BMG, determines the services to be covered by sickness funds. To the extent possible, coverage decisions are based on evidence from comparative-effectiveness reviews and health technology (benefit-risk) assessments. The Federal Joint Committee also sets quality measures for providers and regulates ambulatory care capacity (the number of SHI-contracted physicians practicing), using needs-based population–physician ratios.[9]

In its bylaws and rules of procedure – both of which must be approved by the BMG – the G-BA defines the details of these statutory regulations. Resolutions and directives passed by the G-BA are audited by the BMG in accordance with the requirements set forth in SGB V, and then published in the Federal Gazette if no objections are found.[10]

7 Blümel/Spranger/Achstetter/Maresso/Busse, Germany: health system review 2020, *Health Systems in Transition*, Vol. 22 No. 6, page 150.

8 https://www.ncbi.nlm.nih.gov/books/NBK298834/.

9 https://www.commonwealthfund.org/international-health-policy-center/countries/germany.

10 https://www.g-ba.de/english/structure/.

The Federal Joint Committee also compiles the evidence base necessary for decisions and is supported by The Institute for Quality and Efficiency in Healthcare (IQWiG) on the one hand, that examines the benefits and harms of medical interventions (e.g., pharmaceuticals) for patients. It provides information about the advantages and disadvantages of examination and treatment methods in the form of scientific reports and easily understandable health information for the general public. Further, the Institute for Quality Assurance and Transparency in Healthcare (IQTIG) is responsible for developing tools and indicators to secure quality across hospital and outpatient care.[11]

ii Institutional healthcare providers and healthcare professionals

Under Germany's federal structure, the states are responsible for regulating and financing education, as well as for registering and supervising health professions. The state health authorities of the respective federal state are, among other things, responsible for issuing full and temporary licences to practise for physicians, psychotherapists, pharmacists and dentists.

To practise medicine or carry out speciality training in Germany, all physicians must be in possession of a valid full or temporary licence to practise. The full licence to practise is valid across the country for an unlimited period. The temporary licence to practise is limited to a certain time and is valid only within the federal state in which it was issued.[12]

With regard to pharmacists in Germany, it is similar: you will either need a governmental approval, which also can be an 'approbation' or a permit to practice the pharmacist profession, which are both made by the competent authorities in each of the individual German states.[13] Since 2004, the German Pharmaceuticals Act and the German Pharmacy Act allow mail order sales (i.e., including online sales, of both prescription-only and OTC medications, subject to receipt of specific regulatory permissions). Online pharmacies located in the EU and EEA can sell medications cross-border via online sales to customers located in Germany without having a physical establishment in Germany and, consequently, without holding a German licence to operate a physical pharmacy, if they comply with some further regulatory requirements.

According to Section 108 SGB V, licensed hospitals in Germany are differentiated between university hospitals, hospitals listed in state hospital requirement plans and hospitals contracted by sickness funds, but there are also licensed hospitals without contracts operating on a private basis.

V OWNERSHIP OF HEALTHCARE BUSINESSES

Even though the direct ownership for non-physicians of a physician's practice is almost impossible in Germany (irrespective of the concrete organisational form of the physician's practice), the German healthcare industry offers interesting investment opportunities. The main targets for financial and strategic investors are inpatient medical care centres and nursing homes. For instance, medical care centres can be founded by a hospital whose ownership is relatively free. Investors' activities increased even in the pandemic situation. After a market

11 Blümel/Spranger/Achstetter/Maresso/Busse, Germany: health system review 2020, *Health Systems in Transition*, Vol. 22 No. 6, page 25.

12 https://www.bundesaerztekammer.de/en/work-training/work-and-training-in-germany.

13 https://www.abda.de/en/working-in-germany/recognition-of-degrees-in-pharmacy/working-as-a-foreign-pharmacist-in-germany.

consolidation in the areas of radiology, laboratory medicine and dialysis services, the focus shifted to investment opportunities in orthopaedic service providers. The legislator still assesses this development closely because there are concerns that the prospect of profits might outweigh the quality of the provision of care. Hence, legislative impediments have constantly to be foreseen and considered, in particular since minister of health Professor Lauterbach has several times announced restrictive measures to come.

German pharmacies need to comply with the ban on corporate ownership stipulated in particular to Section 7 Sentence 1 of the German Pharmacy Act, according to which the licence shall oblige the holder to manage the pharmacy personally on their own responsibility. Therefore, an investor cannot purchase a German pharmacy, but is dependent on the pharmacist holding the pharmacy licence. As a result, pharmacies based in Germany can only sell medications via mail order only if they operate a brick-and-mortar pharmacy. A possible way of investment can be the purchase of co-operators, for example, a manufacturing site, combined with a cooperation agreement with the pharmacy, in line with the pharmacy regulations.

VI MARKETING AND PROMOTION OF SERVICES

The marketing and promotion of services in the healthcare sector in Germany are mainly regulated by the German Advertising of Healthcare Products Act (HWG) and the German Act on Unfair Competition (UWG), as well as in the professional codes of the different healthcare providers. The UWG was reformed in 2022, in particular strengthening the consumer rights in online marketplaces, but also introducing a legal basis for consumers to claim damages due to unfair competition acts.

An important and widely discussed decision in that area is the judgment of the German Federal Court of Justice (BGH) from 9 December 2021 (I ZR 146/20) on the interpretation and scope of the ban on advertising remote treatments in Section 9 HWG. In its judgment, the BGH ruled that the advertising of a private health insurance for the 'digital physician visit' via app (remote treatment by physicians from Switzerland) violates Section 9 HWG, since it advertises comprehensive primary medical care (i.e., diagnosis, therapy recommendation or sick leave), but failed to prove that the comprehensive remote treatment complied with the recognised German medical standard. The decision was heavily criticised in the industry, particularly because the required proof is almost not possible to provide.

Anti-bribery regulations were essentially restricted in 2016 by the Act to combat Corruption in the Healthcare Sector, introducing some anti-bribery offences into the Criminal Code (Sections 299a and b StGB). The former design of the criminal law provisions had prevented the recognition of certain behaviours as relevant under criminal law in connection with the provision of healthcare services before, but only under the respective professional codes and laws. The apparently small number of criminal procedures in the meantime do, however, not seem to fit to the enormous discussions and consultations about this reform in 2016.

VII PROCUREMENT OF SERVICES AND GOODS

The German system of provision of care services for SHI insured persons is mainly based on collective (supply) agreements between associations of SHIs and the respective associations of health care providers; see, for instance, Section 82 SGB V for physicians and Section 129 Paragraph 2 SGB V for pharmacies.

Single SHIs can conclude selective contracts for special goods or services with single or several health care providers. Rebate contracts for generic medicinal products according to Section 130 Paragraph 8 SGB V are the most famous and probably most frequently used example. Selective contracts about 'special care provisions' according to Section 140a SGB V increased in the past few years, probably due to their ability to bring innovative care concepts into the SHI system. Innovative services are also promoted by the Innovation Committee at the Federal Joint Committee set forth in Sections 92a and b SGB V that established a special grant programme for innovative concepts in 2016.

When procuring through selective contracts, SHIs need to observe the EU-wide harmonised rules for public procurement. For example, the conclusion of such contracts requires regularly a prior public tender. In the medicinal products sector, at the latest after the decision C-148/15 of the European Court of Justice in 2016, the procurement by 'open-house' contracts has become more and more attractive for SHIs, since in accordance with certain requirements, SHIs can conclude those without a formal public procurement procedure. In particular when it comes to a loss of exclusivity of certain medicinal products or patents, SHIs have to consider all exigences that a remaining exclusivity of such products still can oppose such open-house procedures. For instance, on 21 April 2021, the Higher Regional Court of Düsseldorf, competent for all public procurement revisions, ruled that a German SHI, when awarding a rebate contract for a second medical use patent-protected medicinal product, is obliged to at least provide an invoice procedure ensuring that the rebates they demand are invoiced in a manner that is appropriate to the patent protected indication (VII-Verg 1/20).

Some hospitals, particularly the ones that are mostly government-funded, frequently need to observe public procurement rules when providing services and goods. In 2021, to their surprise, privately-owned hospitals, among others, were partially and indirectly (via the grant conditions) obliged by the Hospital Future Act to follow public procurement law when applying for grants.

Outside the SHI system, the procurement of services and goods is particularly regulated with regard to pricing: for instance, the German Drug Price Ordinance provides, with only a few exceptions, for determined price margins in the whole distribution channel of medicinal products supply (pharmaceutical companies, wholesalers and pharmacies).

In 2016, the ECJ decided that the fixed prices set out in the German Drug Price Ordinance in its current version were not applicable to (mail order) pharmacies from other EU countries. The ECJ held that Article 34 TFEU must be interpreted as meaning that national legislation, such as that at issue in the main proceedings, which provides for a system of fixed prices for the sale by pharmacies of prescription-only medicinal products for human use, constitutes a measure having equivalent effect to a quantitative restriction on imports. In reaction to this, the German legislator passed the Law to Strengthen Local Pharmacies (VOASG) at the end of 2020, maintaining uniform prices for the sale of prescription-only medicines and transferring the provision into the SGB V. This legislation is heavily criticised as not compliant with European law.

VIII REIMBURSEMENT OF SERVICES AND GOODS

The collective and selective contracts system described under Section VII also mainly provides for the reimbursement of the respective services and goods.

With regard to hospitals, the reimbursement by SHI is based on the G-DRG system (German Diagnosis Related Groups). According to the G-DRG system, the hospital only gets one flat fee for the whole treatment of the patient from the admission till the discharge, covering all costs of the hospital. Some 1,200 different diagnosis groups with up to five complication levels allow much defined invoicing, which is prepared by specialists in the hospitals who use 'OPS codes' and special grouper software. The institute for reimbursement in hospital recalculates the relative weights and further develops the number of groups on a permanent basis while the base rates are renegotiated annually, including the introducing of new treatment methods.[14]

The new approach to reimbursement of medicinal products of 2010, the Act on the Reform of the Market for Medicinal Product is still noteworthy, and also noteworthy because of its continued development. AMNOG completely revised pricing regulations for newly authorised medicinal products and their reimbursement by statutory health insurance providers, which depends on the result of a benefit assessment by the Federal Joint Committee. The reimbursement price of a newly authorised medicinal product needs to correspond to its additional benefit over the appropriate comparator, which has to be proved by the respective pharmaceutical company, particularly by its pivotal study data.[15] The flexibility of AMNOG was reduced by the Financial Stabilisation of the Statutory Health Insurance System Act of 2022 introducing, among other things, certain 'price anchors' for defined comparison groups of benefit categories or comparators (see Section 130b Paragraph 3 Sentences 2–7 SGB V).

This system, however, provides no clear solutions for advanced medicinal therapies that are regularly orphan designations that rarely do not have sustainable data and appropriate comparators. For such reasons, AMNOG's approach was to assume the additional benefit of orphan drugs until a threshold of €50 million sales per year. Since the pharmaceutical companies are relatively free to determine their reimbursement price until then, this system is being reconsidered. For instance, the legislator introduced the requirement for data collection during application in 2020, giving the Federal Joint Committee the opportunity to force the respective pharmaceutical company to an earlier and parallel data collection to allow an earlier appropriate benefit assessment. Further, the threshold mentioned above was reduced to €30 million sales per year according to the Financial Stabilisation of the Statutory Health Insurance System Act of 2022.

There have been attempts to find individual solutions for high-priced advanced therapy medicinal products by selective contracts with innovative payment models, such as pay-for-performance (p4p), but this has not yet broken through, and it appears that there have not been many further efforts. This will hopefully change, since it still appears to be an appropriate approach with many opportunities.

14 See also https://www.dkgev.de/englisch/the-german-hospital-federation/mission-and-objectives/.

15 For further details, see https://www.g-ba.de/english/benefitassessment/.

IX DIGITAL HEALTH DEVELOPMENTS

Digitisation of service providers itself and their means of communication with all stakeholders is an essential challenge for the healthcare sector in Germany. The legislator strongly emphasises this in his agenda and monitors the development closely so reactions can be at short notice, and all parties always need to be agile. However, the implementation of the main instruments such as the electronic patient health register and the electronic prescription faced a lot of – particularly technical – problems in past years and are still not (fully) introduced in Germany. According to the most current plans of the gematik GmbH, which was founded in 2005 mainly by the German Ministry of Health and the self-administration actors to design the electronic health insurance card and the telematics infrastructure – as well as to approve telematics infrastructure products and operate the infrastructure, electronic prescriptions shall be useable in all German pharmacies from 1 July 2023.

With the implementation of digital health applications (DiGAs) on panel doctor's prescriptions, leading to reimbursement by the SHI, a world novelty was introduced by the legislator in Germany at the end of 2019 (Sections 33a and 139e SGB V). DiGAs are CE-marked medical devices open a wide range of possibilities, both regarding the diagnosis and treatment of diseases as well as supporting a self-determined, healthy lifestyle. A prerequisite for its reimbursement by the SHI is that a DiGA must have successfully completed the assessment of the BfArM leading to a listing in a directory of reimbursable digital health applications.[16]

X CORONAVIRUS

Since 2020, the covid-19 pandemic situation took the lead with regard to constant actions by the legislator and still challenges all stakeholders, recently refreshed by the new Minister of Health installed at the end of 2021, Professor Karl Lauterbach. The last big efforts were the implementation of vaccination by pharmacies. The enforcement of a higher vaccination rate by way of statutory general obligation, as well as its potential design in accordance with constitutional law, was politically discussed for a long time, but finally refused by the German parliament in April 2022. The legislative actions in this area have slowed down again.

Worth mention is the installation of the Center for Pandemic Vaccines and Therapeutics (ZEPAI) and its conclusion of Pandemic Preparedness Contracts Signed for Rapid Availability of Vaccines with several pharmaceutical companies to avoid long waiting times in future potential pandemic situations. ZEPAI represents the Federal Republic of Germany as the contracting authority with regard to the pharmaceutical companies. ZEPAI will audit and review the pandemic preparedness plans prepared by the companies. In the event of a pandemic, ZEPAI's responsibilities also include the procurement, supply and nationwide distribution of pandemic vaccines and therapeutics. ZEPAI will also collaborate with the European Health Emergency Response Authority (HERA).[17]

16 For further information, see https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_verteilerseite.html.

17 For further information, see https://www.pei.de/EN/newsroom/press-releases/year/2022/07-pandemic-preparedness-contracts-signed-rapid-availability-vaccines.html;jsessionid=D3254EF806DA64824F558CC575796766.intranet212.

XI FUTURE OUTLOOK AND NEW OPPORTUNITIES

Since the financial situation of the SHI worsened in the past years (at the latest during the covid-19 pandemic), the legislator still considers measures to stabilise their financial situation, by avoiding a permanent rise of the premiums to be paid by its members. The Financial Stabilisation of the Statutory Health Insurance System Act of 2022, which provides many further cost-reducing measures that would essentially affect many of the healthcare providers, is currently under evaluation.

In 2023, however, besides digitisation considerations, German health legislation focused on safeguarding the sufficient supply of medicines. Therefore, the Act to combat drug supply shortages and to improve drug supplies (ALBVVG) was adopted. The ALBVVG primarily introduces regulatory measures to improve drug supplies in the fields of paediatric medicines, antimicrobials and oncological drugs. A big reformation of the law on hospitals is also in preparation.

In addition, manufacturers of medical devices are still occupied with the implementation of the Medical Devices Regulation, setting the regulatory frame for the marketability of their products. This demands an understanding of the new legal requirements, including the German Act on the Implementation of EU Regulations Concerning Medical Devices, as well as the implications for the certification process and the design of quality management systems. In parallel, the In Vitro Diagnostics Regulation (IVDR) started to apply for *in vitro* diagnostics from 26 May 2022. Due to the objections of many stakeholders and intense lobbying and advocating, a legal proposal to extend the transitional provisions of the IVDR was adopted, aiming to allow for an easier transition to the new legal framework from the prior IVD Directive. Further, the industry is relieved (both in and outside Germany) about the good news that after months of discussions, the European Commission adopted a proposal to amend the transitional provisions of Regulation (EU) 2017/745 on medical devices (MDR). The Commission proposed to extend the validity of certificates issued under the previous directives until 2027 for high-risk devices and until 2028 for low-risk devices. It also aims to abolish the 'sell-off' deadline after which devices would have to be withdrawn.

Furthermore, Regulation 2021/2282 on Health Technology Assessment (the HTA Regulation), calling for a more collaborative framework in the EU, to improve business predictability and avoid duplication of work and discrepancies between HTA mechanisms, gets closer: in June 2023, an implementation rolling plan for 2023–2024 was published. The HTA Regulation will apply from 12 January 2025, starting with cancer medicines and advanced therapy medicinal products (ATMPs), expanding to cover orphan medicinal products in 2028 and finally to covering all centrally authorised medicinal products in 2030. This needs also to be observed and considered by the German healthcare industry.

The European Commission's proposal for a regulation introducing the European Health Data Space (EHDS) of 3 May 2022 is also on its way, aiming to enable better exchange and access to different types of health data, and foster healthcare delivery (primary use of data) as well as health research data (secondary use of data). At the time of writing, it is being discussed at the European Council. This will be the second EU-wide big data reformation after the General Data Protection Regulation in 2018 and will have many impacts, including on German healthcare providers.

Finally, on 26 April 2023 the European Commission presented a legislative proposal for the revision of the EU medicinal products legislation. First, the Commission submitted a proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use (Directive 2023/0132/COD). Second, the

Commission introduced a proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency (Regulation 2023/0131/COD). The proposals intend to repeal several European legal acts, such as Directive 2001/83/EC and Regulation (EC) 726/2004. This revision is part of the implementation of the Pharmaceutical Strategy for Europe and aims to promote innovation while reducing the regulatory burden and environmental impact of medicinal products. Of course, this will also have a huge impact on the pharmaceutical industry in Germany, and the proposals have already been heavily discussed.

XII CONCLUSIONS

While still providing for a reliable supply, Germany's healthcare system has its problems and faces new challenges in the healthcare sector with the structure of self-administration and its wide-ranging general insurance system. Legislation has been more prevalent in recent years, particularly due to the pandemic on the one hand, and European regulations on the other. The process of finding new, specific and better pathways to react to rising costs, supply shortages, digitisation and further peculiarities has started, but will still be challenging in the following years.