THE HEALTHCARE LAW REVIEW

Sixth Edition

Editor
Ulrich Grau

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SIXTH EDITION

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PREFACE

The sixth edition of *The Healthcare Law Review* covers six new jurisdictions and a total of 17 jurisdictions from Europe, North and South America and Asia. All chapters 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 that are of interest for healthcare providers and related businesses.

The past two years have been dominated by the covid-19 pandemic. The pandemic not only affected all healthcare providers and staff working in health and social care but also scientists, public health officials and politicians throughout the world. Each country was hit hard by the pandemic, some countries were even overwhelmed, and major sources of the healthcare systems had to focus on maintaining the functioning of the health systems even in this exceptional situation. Therefore, all countries took additional exceptional measures to fight the pandemic. According to the reviews from the individual countries, these exceptional measures have now largely been scaled back or totally withdrawn, even though the pandemic is not yet over.

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 greater digitisation and use of telemedicine. This is not only about supplementing or replacing face-to-face doctor visits with communication options via telephone or video consultation. Many countries have also introduced electronic patient files, regulations for the exchange of health data and other digital communication channels. The next few years will show whether these innovations can also be successfully implemented 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.

Even if individual countries solve their 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 Healthcare Law Review* will be particularly helpful in that respect.

I am more than happy to take over the editorship from Sarah Ellson from Fieldfisher LLP, London. I would like to sincerely thank her for her commitment over the past years. It is 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

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healthcare systems of the countries covered. We will continue our efforts to include more countries to this publication to be able to give a comprehensive worldwide approach to healthcare issues by each country.

Ulrich Grau
D+B Rechtsanwälte Partnerschaft mbB
Berlin
August 2022

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Chapter 5

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 (SHIs) spend approximately €220 billion a year on services for their insured. Hence, SHIs have an important impact on all stakeholders in the German life sciences business. This leads to a highly regulated life science industry with a major emphasis on the cost-benefit ratio of services provided.

II THE HEALTHCARE ECONOMY

i General

At 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, 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

On 1 January 2009, health insurance became mandatory for everyone registered or usually resident in Germany, depending on further conditions either within the SHI or a private health insurance fund (PHI). Almost all employees (those who are self-employed, and some other groups such as civil servants, are exempt) are required to join an SHI if their income is below a certain level (in 2022, the threshold was €64,350 per year).[2] Above this level, a person can decide to become a member of a PHI, or to voluntarily join an SHI. In Germany, there is a wide range of options between the different SHIs, which currently total 103 funds.[3]

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

2 www.bundesregierung.de/breg-de/suche/beitragsbemessungsgrenze-2022-1970116.

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

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

iii Funding and payment for specific services

SHIs and PHIs are funded by contributions or premiums from their members. Whereas contributions to a 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 SHIs, 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 to an 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 one per cent and of which the employer also pays half.[4] Besides this, the premiums only scale up to a certain income level, above which the premium does not rise any further.

While in a PHI this depends essentially on the assumption of a medical need and the concrete contract conditions, payments for specific services are exceptional within the framework of an SHI. 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 over-the-counter (OTC) medications with a few exceptions, which are defined by the Federal Joint Committee. There are certain co-payments that an SHI-insured person must bear, for example, 10 per cent of the price with a minimum co-payment of €5 and a maximum of €10 per product.[5]

III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

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

SHI-insured patients have, in principle, a free choice of physicians, psychotherapists, dentists, pharmacists and urgent or 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 within the healthcare system, they are not the official gatekeepers.[7]

Besides this, SHIs also cover a wide range of inpatient and outpatient medical rehabilitation (largely covered by Social Code Book IX). Rehabilitation facilities provide

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

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

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

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

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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 important ones:

a the Federal Institute for Drugs and Medical Devices (BfArM);

b 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

c 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 practising), using needs-based population–physician ratios.[9]

In its by-laws and rules of procedure – both of which must be approved by the BMG – the Federal Joint Committee defines the details of these statutory regulations. Resolutions and directives passed by the Federal Joint Committee 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]

The Federal Joint Committee also compiles the evidence base necessary for decisions and is supported by The Institute for Quality and Efficiency in Healthcare, which 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 is responsible for developing tools and indicators to secure an appropriate level of quality across hospital and outpatient care.[11]

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

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

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

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

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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 specialty 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]

It is a similar situation for pharmacists in Germany – they either need governmental approval (an 'approbation') or a permit to practise as a pharmacist. The approval or permit should be made by the competent authority of the German state where they wish to practise.[13] Since 2004, the German Pharmaceuticals Act and the German Pharmacy Act have allowed mail-order sales, such as online sales of prescription-only and OTC medications, subject to the receipt of specific regulatory permissions. Online pharmacies located in the EU or EEA can sell medications across borders 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 further regulatory requirements.

According to Section 108 SGB V, licensed hospitals in Germany are differentiated as 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 direct ownership by 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 (including corporation). Investors' activities have increased even during the covid-19 pandemic. After market consolidation in the areas of radiology, laboratory medicine and dialysis services, the focus has shifted to opportunities for investment in orthopaedic service providers. The legislator is still assessing this development closely because there are concerns that the prospect of profits might outweigh the quality of the provision of care. Hence, legislative impediments should be foreseen and considered.

German pharmacies must comply with the ban on corporate ownership stipulated, in particular, in Section 7 Sentence 1 of the German Pharmacy Act, according to which the licence shall oblige the holder to manage the pharmacy personally on his or her own responsibility. Therefore, an investor cannot purchase a German pharmacy, and is dependent on the pharmacist holding the pharmacy licence. As a result, pharmacies based in Germany can only sell medications via mail order if they operate a brick-and-mortar pharmacy.

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

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

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A possible method of investment might be a complementary arrangement, for example, the purchase of 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 by the professional codes of the different healthcare providers. The UWG was reformed in 2022, particularly strengthening consumer rights in online marketplaces but also introducing a legal basis for consumers to claim for 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) on 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 private health insurance for the 'digital physician visit' via app (remote treatment by physicians from Switzerland) violates Section 9 HWG, as it advertises comprehensive primary medical care (diagnosis, therapy recommendation, sick leave) but fails 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 impossible to provide.

Besides, 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 German Criminal Code (Sections 299(a) 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, but only under the respective professional codes and laws. In the meantime, the apparently small number of criminal procedures do not seem to fit to the discussions and consultations about this reformation 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 healthcare providers. See, for instance, Section 82 SGB V for physicians and Section 129 Paragraph 2 SGB V for pharmacies.

Besides this, single SHIs can conclude selective contracts for special goods or services with single or several healthcare providers. Rebate contracts for generic medicinal products according to Section 130 Paragraph 8 SGB V are the most famous and probably the most frequently used example. Also, selective contracts for 'special care provisions' according to Section 140a SGB V increased in recent 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 92(a) and (b) SGB V, which established a special grant programme for innovative concepts in 2016.

When procuring through selective contracts, SHIs need to observe the European-wide harmonised rules for public procurement. For example, the conclusion of such contracts usually requires a prior public tender. In the medicinal products sector, following Decision

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C-148/15 of the European Court of Justice in 2016, the procurement of 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. Particularly when it comes to a partial loss of exclusivity of certain medicinal products or patents, SHIs must consider the possibility that a remaining exclusivity of such products might still 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 of the SHI system, the procurement of services and goods is highly regulated with regard to pricing. For example, the German Drug Price Ordinance provides, with few exceptions, for determined price margins in the entire distribution channel of medicinal products supply (pharmaceutical companies, wholesalers and pharmacies).

In 2016, the European Court of Justice 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 European Court of Justice held that Article 34 of the Treaty on the Functioning of the European Union 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 with equivalent effect to a quantitative restriction on imports. However, in reaction to this, the German legislator passed the German law to Strengthen Local Pharmacies 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 being compliant with European law.

VIII REIMBURSEMENT OF SERVICES AND GOODS

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

With regard to hospitals, reimbursement by an SHI is based on the German Diagnosis Related Groups (G-DRG) system. According to the G-DRG system, the hospital only gets one flat fee for the whole treatment of the patient from admission until discharge, covering all costs of the hospital. Approximately 1,200 different diagnosis groups with up to five complication levels allow for defined invoicing, which is prepared by specialists in the hospitals who use procedure classification (or '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]

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

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The German approach to reimbursement of medicinal products of 2010 – the Act on the Reform of the Market for Medicinal Product (AMNOG) – is noteworthy because it is constantly developing. 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]

This system, however, provides no clear solutions for advanced medicinal therapies (ATMP), which are regularly orphan designations that rarely have sustainable data and appropriate comparators. For this reason, AMNOG's approach was to assume the additional benefit of orphan drugs up to a threshold of €50 million sales-worth per year (which should, however, be reduced to €20 million sales-worth per year according to the latest draft of the Financial Stabilisation of the Statutory Health Insurance System Act, see Section XI). Since the pharmaceutical companies are relatively free to determine their reimbursement price until then, this system is, however, being reconsidered. For example, the legislator introduced a requirement for data collection during an application in 2020, giving the Federal Joint Committee the opportunity to force the respective pharmaceutical company to a quicker and parallel data collection to allow an earlier appropriate benefit assessment.

There have been attempts to find individual solutions for high-priced ATMP through selective contracts with innovative payment models, such as pay-for-performance, 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.

IX DIGITAL HEALTH DEVELOPMENTS

Digitisation of service providers and their means of communication with all stakeholders is an important challenge for the healthcare sector in Germany. This is strongly emphasised in the legislator's agenda, and developments are monitored closely so that reactions can be on short notice; all parties need to be agile. However, the implementation of main instruments like the electronic patient health register and electronic prescriptions faced a lot of – particularly technical – problems in the past years and are still not fully introduced in Germany. According to the current plans of gematik GmbH (which was founded in 2005, mainly by the German Ministry of Health and self-administrated 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 will be usable in all German pharmacies from 1 September 2022.

With the implementation of Digital Health Applications (DiGA) on panel doctors' prescriptions, leading to reimbursement by the SHI, a world novelty was introduced by the legislator in Germany at the end of 2019 (Sections 33(a) and 139(e) SGB V). DiGA are CE-marked medical devices that open a wide range of possibilities, regarding the diagnosis and

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

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treatment of diseases as well as supporting a self-determined, healthy lifestyle. 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 has required constant action and consideration by legislators. It presents challenges to all stakeholders, including the new Minister of Health, Professor Karl Lauterbach, who was installed at the end of 2021. The last big effort was 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, and finally refused by the German parliament in April 2022.

Worth mention is the installation of the Center for Pandemic Vaccines and Therapeutics (ZEPAI) and its conclusion of pandemic preparedness contracts signed for the 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 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.[17]

XI FUTURE OUTLOOK AND NEW OPPORTUNITIES

As the financial situation of SHIs has worsened in recent years (most recently, during the covid-19 pandemic), the legislator is considering, as a measure to stabilise this, avoiding a permanent rise of the premiums to be paid by its members. Correspondingly, the latest draft of the Financial Stabilisation of the Statutory Health Insurance System Act from 30 June 2022 provides many further cost-reducing measures that would essentially affect many healthcare providers. Among other things, the draft provides for the set-up of a 'solidarity fund' of €1 billion yearly for 2023 and 2024, applying to companies obtaining reimbursement within the statutory health insurance system for orphan drugs and patented medicines.

Besides this, healthcare providers are occupied with the implementation of several important European regulations. Manufacturers of medical devices still are faced with the challenge of adapting to the Medical Devices Regulation, setting a 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 Device, as well as implications for the certification process and the design of quality management systems. In parallel, the In Vitro Diagnostics Regulation (IVDR) started to apply for IVDs from 26 May 2022. Due to the objections of many stakeholders, and intense

16 For further information, see www.bfarm.de/EN/Medical-devices/Tasks/Digital-Health-Applications/node.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.

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lobbying and advocating, a legal proposal to extend the transitional provisions of the IVDR was previously adopted, aiming to allow for an easier transition to the new legal framework from the prior IVD Directive. In particular, the proposal foresees that certain IVDs that are classified as high-risk IVDs through the IVDR may still be brought into the market, mainly under the IVD Directive requirements, until May 2025 and 2026 respectively. This is, for example, the way that many covid-19-tests legally remain on the market in Germany. Another big change in the IVDR is the reformation of the companion diagnostics authorisation procedure, which will also have essential impacts on German healthcare providers.

Further, the long-awaited Clinical Trials Regulation has finally come into application (foreseeing a three-year transition period), with the Clinical Trials Information System (CTIS) going live on 31 January 2022. CTIS is a single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trials data. Instead of submitting clinical trial applications separately to national competent authorities and ethics committees in each country to gain regulatory approval to run a clinical trial, as has been done in the past, sponsors can now apply for authorisations in up to 30 EU or EEA countries at the same time and with the same documentation. The German national competent authority (BfArM) has implemented the respective pathways.[18]

Furthermore, the European Commission has put forward a legislative proposal for a new Health Technology Assessment (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. In December 2021, the European Parliament formally adopted the respective Regulation on HTA, which will apply from January 2025. The legislation will first apply to cancer medicines and ATMPs, starting from January 2025, 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.

Finally, on 3 May 2022, the European Commission released a proposal for a regulation introducing the European Health Data Space, aiming to enable better exchange and access to different types of health data, and to foster healthcare delivery (primary use of data) as well as health research data (secondary use of data). This will be the second European-wide big data reformation after the General Data Protection Regulation in 2018 and will have many impacts on German healthcare providers.

XII CONCLUSIONS

While still providing for a reliable supply, Germany's healthcare system has challenges to face in the healthcare sector, including the structure of self-administration and its broad general insurance. Legislation has been more prevalent in recent years, particularly due to the pandemic on the one hand, and European regulations on the other. The task of finding new, specific and better pathways to react to rising costs and peculiarities will be challenging in future years.

18 See www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/CTIS-Clinical-Trials-Information-System/node.html;jsessionid=244308F0AEB4F162DFEF855E73931C24.intranet252.

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Appendix 1

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Tobias's main areas of consultancy include medicinal products, in particular advanced therapy medicinal products; medical devices, in particular in vitro diagnostics; clinical studies with medicinal products and medical devices; pharmacies; and the statutory health insurance system. He holds a Doctor of Laws (*Dr iur*) from the University of Cologne (2009) and has been admitted to practise as an attorney since 2010. He has been a specialised attorney for medical law since 2017. He joined D+B Rechtsanwälte as an attorney in 2010.

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