COUNTRY COMPARATIVE GUIDES 2024

# The Legal 500 Country Comparative Guides

# Germany

# LIFE SCIENCES


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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in Germany.

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# GERMANY
# LIFE SCIENCES

## 1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

Medicinal products for human use (including biologicals) are regulated by the German Drug Act (*Arzneimittelgesetz*, "**AMG**"), which implements the Directive 2001/83/EC on the Community code relating to medicinal products for human use. The German Drug Act is complemented by a number of German regulations which regulate in further detail *inter alia* the manufacture, distribution, and prescription of medicinal products, the pricing of prescription-only medicinal products, and compassionate-use-programs. Medicinal products for veterinary use are regulated by the Regulation (EU) 2019/6 on veterinary medicinal products as well as by the complementing German Veterinary Drug Act (*Tierarzneimittelgesetz*, "**TAMG**").

Medical devices (including in-vitro diagnostics) are regulated by the Regulation (EU) 2017/745 on medical devices ("**MDR**") and the Regulation (EU) 2017/746 on in-vitro diagnostics ("**IVDR**"), respectively, as well as by the complementing German Medical Device Law Implementation Act (*Medizinprodukterecht-Durchführungsgesetz*, "**MPDG**"). In addition, several German regulations further regulate the dispensing and operation of medical devices. With respect to certain notification obligations, the provisions of the legacy German Medical Device Act (*Medizinproduktegesetz*) continue to apply until the EUDAMED database is functional.

Food is chiefly regulated by the Regulation (EC) No. 178/2002 on the general principles and requirement of food law (General Food Law Regulation, "**GLFR**") and a number of EU Regulations further regulating the labelling of, health claims for, and the flavouring, enzymes, additives, contaminants in food as well as hygiene requirements. The German Food and Feed Act (*Lebensmittel- und Futtermittelgesetzbuch*, "**LFGB**") and a number of German regulations contain complementing rules.

Food supplements are regulated by the German Food Supplements Regulation (*Nahrungsergänzungsmittelverordnung*, "**NemV**"), which implements the Directive 2002/46/EC on food supplements.

## 2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

Medicinal products under development are, before being studied in clinical trials with humans, typically studied in animal trials which must be authorized by the competent regulatory authority and comply with the animal welfare requirements set out in the German Animal Protection Act (*Tierschutzgesetz*). The following clinical trials of the medicinal product in humans are regulated by the Clinical Trials Regulation (EU) No. 536/2014 and complementing German laws and regulations (*see* answer to question 7 for details). The marketing authorization ("**MA**") necessary for placing the medicinal product on the market is based on the generated pre-clinical and clinical data (except for well-established substances where bibliographical evidence is sufficient) and can be issued centrally by the European Commission for the entire European Union or nationally by the competent federal regulatory authority (*see* also answer to question 5). Marketing authorization holders ("**MAH**") must comply with post-marketing vigilance (pharmacovigilance) obligations (*see* also answer to question 4).

Medical devices under development must undergo a conformity assessment procedure by its "**Manufacturer**" (the person identified on the labelling as manufacturer, i.e. as the person responsible for the design and manufacture of the device and who markets it under its name or trademark) to determine that it meets the applicable safety and performance requirements for its intended purpose. Such conformity

 

assessment requires a clinical evaluation of the available data, and may require a clinical investigation (clinical trial) of the medical device in humans. Except for low-risk class I devices, the conformity assessment requires the involvement of a notified body and the issuance of a CE certificate by that notified body. The medical device may be placed on the market if the device is lawfully CE-marked by the Manufacturer on the basis of the completed conformity assessment and, where applicable, the CE certificate issued by the notified body. The Manufacturer must comply with vigilance and post-market surveillance obligations.

### 3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

Food supplements must be developed such that their composition and their labelling complies with the requirements of the NemV. Prior to their first placing on the market, food supplements must be notified to the competent federal authority *Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* ("**BVL**").

Once placed on the market, as with other food the manufacturer of food supplements must implement a risk management process based on HACCP (Hazard Analysis and Critical Control Point) principles to identify hazards to the safety of the food supplements and ensure the traceability of the distributed products. These requirements stem from the GLFR (*see* question 1) and implementing regulation, including Regulation (EC) no. 852/2004 on the hygiene of foodstuffs.

### 4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

The holders of a MA for a medicinal product must comply with the post-market surveillance (pharmacovigilance) obligations. In particular, the MAH must establish and maintain a pharmacovigilance system, appoint a qualified person for pharmacovigilance (*Stufenplanbeauftragter*, sometimes also referred to in English as Graduated Plan Officer) and comply with associated reporting requirements. In addition, the MAH must appoint an Information Officer (*Informationsbeauftragter*) who is responsible for ensuring compliance of the labelling, package insert leaflets, SmPC and all advertising with the terms of the MA. The MAH must take special product liability insurance to cover its no-fault medicinal product liability (*see* answer to question 18). Furthermore, the MAH must maintain the dossier underpinning the MA and notify to, or request approval of, the competent regulatory authority of any relevant changes to the content of the MA.

Manufacturers of medical devices must comply with the Manufacturer obligations set out in Art. 10 MDR/IVDR. These include the maintenance of a quality management system as well as a risk management system, maintenance of the technical documentation, implementation and maintenance of a post-market surveillance system, and sufficient financial coverage for its product liability. Beyond those comprehensive MDR/IVDR requirements, the MPDG provides for certain additional reporting and cooperation obligations of Manufacturers.

### 5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

For medicinal products, the federal regulatory authorities BfArM (*Bundesinstitut für Arzneimittel und Medizinprodukte*) and PEI (*Paul-Ehrlich-Institut*) are responsible for issuing national MAs, approving clinical trials, and for pharmacovigilance. PEI assumes these responsibilities for biological medicinal products, such as vaccines and advanced therapy medicinal products ("**ATMP**"), while BfArM is competent for all other types of medicinal products (centralized MAs are issued by the EU Commission based on the evaluation of the European Medicines Agency ("**EMA**") under the Regulation (EC) No. 726/2004). The state level regulatory authorities are responsible for issuing manufacturing, wholesale distribution and import licenses, and for overseeing, ascertaining through inspections, and for the regulatory enforcement of, compliance with applicable drug laws.

For medical devices, the BfArM is responsible for classification decisions, clinical trial approvals and vigilance, whereas the state level authorities are responsible for general oversight, inspections and enforcement.

For food and food supplements, the state level regulatory authorities are responsible for overseeing, ascertaining through inspections, and the regulatory enforcement of, compliance with applicable food laws.

 

The federal authority BVL (*see* answer to question 3) receives the food supplement notifications and has a coordinating role with respect to the oversight and monitoring by the state level regulatory authorities.

## 6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

The addressee of a binding decision (administrative act) by a regulatory authority, and any third party having standing, may lodge an objection against the decision with the issuing regulatory authority. Such objection must be lodged in writing or electronically within one month of its notification to the addressee (or the third party having standing). If the objection is sustained and the decision is reversed by the regulatory authority, the procedure ends. If the objection is rejected and the decision affirmed by the competent regulatory authority, the addressee (or the third party having standing) may file a lawsuit against the decision with the competent administrative court. The administrative court will either lift or uphold the regulatory decision, and the losing party may appeal to the competent administrative court of appeals.

While an objection or a lawsuit against the regulatory decision is pending, such legal action has by default suspensory effect which impedes enforcement of the challenged regulatory decision. However, the regulatory authority can order the immediate execution of its decision, notwithstanding the pending objection or lawsuit. In such a case, the addressee of the administrative act (or a third party having standing) may submit a request to the competent administrative court to (re-)establish the suspensory effect of the objection, which, if successful, precludes enforcement until a final decision is obtained.

The aforementioned procedure applies to medicinal products, medical devices, and to other regulated products.

## 7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

Clinical trials with medicinal products are governed by the Regulation (EU) No 536/2014 on clinical trials ("**CTR**"). The sponsor of the clinical trial must submit an application dossier electronically through the Clinical Trials Information System ("**CTIS**", https://euclinicaltrials.eu/). The application in CTIS covers both the scientific review of the clinical trial by the competent federal regulatory authority (BfArM or PEI) as well as the ethical review by the competent ethics committee. Under a new legislative proposal, the role of BfArM in the clinical trial shall be expanded to streamline the approval process (both for medicinal products and medical devices). Most substantive application requirements as well as the application and approval timelines are set out in the CTR. The timelines within which the ethics committee must provide its opinion are aligned to meet the timelines set out in the CTR. In addition, the German AMG provides that trial participant insurance coverage must be provided and, if the sponsor is not established in the EU/EEA, a EU/EEA-based legal representative must be appointed.

Clinical investigations with medical devices are governed by the MDR/IVDR and complementing provisions in the MPDG. The applications for authorisation of clinical trials with medical devices by the BfArM, as well as for the prerequisite positive opinion by the competent ethics committee, shall be submitted electronically through the German Medical Devices Information and Database System (DMIDS) portal (until the respective EUDAMED database functionality becomes available). Most substantive application requirements as well as the application and approval timelines are set out in the MDR and IVDR. The ethics committee must provide its opinion within 30 days of receipt of a complete application, or 45 days if expert consultation is needed. In addition, the MPDG requires that trial participant insurance coverage must be provided and, if the sponsor is not established in the EU/EEA, a EU/EEA-based legal representative must be appointed.

Denials of clinical trial/investigation authorization applications can be challenged as discussed in the answer to question 6.

## 8. Is there a public database for clinical trials in your country, and what are the rules for publication?

For clinical trials with medicinal products authorized under the CTR, clinical trial information is publicly available on the CTIS platform (https://euclinicaltrials.eu/). For clinical trials authorized

 

under the German AMG prior to CTR applicability, clinical trial information is publicly available under the EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/). Sponsors of clinical trials with medicinal products must submit to the CTIS, within one year (or within six months for clinical trials governed by legacy AMG rules) of completion, a report of the clinical trial results, which is then published on the aforementioned databases.

In accordance with its Policy 0070, the EMA publishes – though temporarily suspended during the COVID19 pandemic – clinical data which pharmaceutical companies have submitted to support their centralised MA applications under https://clinicaldata.ema.europa.eu/web/cdp .

Information on clinical trials with medical devices is currently not made available in free public databases. However, MDR and IVDR provide for the transparency of clinical trial information through the EUDAMED database. The obligations of sponsors of clinical trials with medical devices to submit clinical trial results will come into force six months after publication of the Commission notice that the clinical investigations and performance studies module of EUDAMED database has achieved full functionality, which is currently not expected before 2026/2027.

## 9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

The use of data from clinical trials must, unless the data is anonymized, comply with applicable data privacy law, namely the General Data Protection Regulation (EU) 2016/679 ("**GDPR**") and the German data privacy laws at federal and state level. Unlike in other EU member states, German law explicitly requires that the personal data of the clinical trial participants is based on informed consent (as opposed to e.g. public health interests or scientific research purposes). The secondary use of clinical data not covered by the informed consent under which they were originally collected is a legally challenging.

## 10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

The clinical trial application process is already digitalized (*see* answer to question 7). In addition, an early draft proposal for a Medical Research Act (*Medizinforschungsgesetz*) published in January 2024 aims to lower some of the hurdles for implementing decentralized or hybrid clinical trials identified during the COVID pandemic. Specifically, the draft proposal allows the electronic consent of the trial participant (using a qualified electronic signature) and the shipping of the investigational medicinal product to the trial participant's home.

## 11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

The manufacture of medicinal products (which includes also packaging, labelling and final release of the finished product) requires manufacturing license to be issued by the competent authority of the federal state in which the manufacturing site is located. The applicant must:

- appoint an experienced and reliable Qualified Person, a qualified Head of Production and a qualified Head of Quality Control, and have other appropriately qualified and trained personnel to conduct the manufacturing activities;
- have the appropriate premises for performing the manufacturing activities; and
- set up and maintain a quality system, consisting of standard operating procedures, which covers the manufacturing activities, and have the staff trained to its content.

The manufacturing license will be issued within 3 months from the complete application, subject to a successful on-site inspection of the manufacturing premises by the regulatory authority. The manufacturing license is granted for a specific site, specific manufacturing activities and types of medicines. It is issued for an unlimited time but remains subject to regular Good Manufacturing Practice ("**GMP**") inspections by the competent authority.

The manufacture of medical devices is not subject to a governmental authorization. The quality of the manufacturing processes is regulated indirectly through the conformity assessment of the respective device and the manufacturer's quality system which supports the conformity assessment.

The same applies to the manufacture of food and food supplements, for which no manufacturing license is required. Food manufacturers must comply with the

 

Food Hygiene Regulation (EU) No 852/2004, and their compliance is controlled through regular inspections by the competent authorities.

## 12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

Medicinal products are initially placed on the market by the MAH or by a distributor with the MAH's consent (except for parallel-traded medicinal products) and sold and supplied mostly to wholesalers. Wholesalers, i.e. any entity who procures, sells, supplies, handles, stores and/or transports medicinal products without supplying to the end user, must hold a wholesale distribution license. The supply of medicinal products to the end user (patients or healthcare professionals) is reserved to pharmacies, except for freely sellable medicinal products.

Medical devices are placed on the market by the Manufacturer or, if the Manufacturer is located outside of the EU/EEA, by the importer. However, the distribution of medical devices is not subject to a governmental authorization or license, but distributors are subject to certain obligations to ensure that only compliant medical devices are made available on the market (*see* Article 14 MDR/IVDR, and also answer to question 23).

The distribution of food supplements does not require a governmental authorization or license. However, food distributors must usually register with the competent state authority.

## 13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

Generally, only prescription-only medicinal products dispensed in pharmacies are subject to price controls whereby the pharmaceutical company's sales price and the margins of wholesalers and pharmacies are fixed. Non-prescription medicinal products, prescription-only medicinal products dispensed directly to hospitals, medical devices and food supplements are exempt from general statutory price controls.

For medicinal products reimbursed through the public health insurance system (i.e. generally prescription-only medicinal products), different price control mechanisms apply:

- Prices for medicinal products with a new active substance are negotiated under the so-called "AMNOG process" between the MAH and the Central Federal Association of Health Insurance Funds (*GKV-Spitzenverband*) on the basis of an "early benefit assessment" (*Frühe Nutzenbewertung*). This benefit assessment is a health technology assessment based on the MAH's provided clinical data to determine the additional therapeutic benefit of the new medicinal product in comparison to the appropriate comparator therapy, i.e. current standard treatment. Without proven additional benefit, the negotiated price of the innovative medicinal product must not result in higher annual therapy cost than the most economic standard therapy; if the comparator therapy is still patent-protected, the annual therapy cost of the new medicinal product must even be at least 10% lower than the comparator. While the MAH can upon market launch freely set the price, the negotiated reimbursement price will retroactively apply from the 7$^{th}$ month of the market launch.
- Established medicinal products (mostly generics) can be grouped based on their active substance or therapeutic effect, and for such groups reimbursement price caps (*Festbeträge*) will be set and regularly reviewed (typically within the lower third of the range between the lowest price and the highest price of all medicinal products in that group). Public health insurances will only reimburse these medicinal products up to the cap; if the MAH sets a higher price, the patient will need to pay the difference.
- MAHs must reimburse a statutory rebate of 7% (temporarily raised to 12% for the 2023 calendar year) for patent-protected medicinal products and 16% for generics and the corresponding off-patent reference medicinal products to public health insurance funds. Statutory rebates do not apply for medicinal products in established therapeutic classes subject to the reimbursement price caps.
- A prize freeze mechanism in effect since 1 August 2010 and at least until 2026 requires MAHs to pay back to public health insurance funds any increase in price beyond the price effective on 1 August 2009 or market launch. Since 1 August 2018, the reference price level is adjusted annually for inflation. The price freeze does not apply where a reimbursement price is AMNOG-negotiated or capped for an established therapeutic class, nor for certain supply-critical, off-patent medicinal products.

 

For medical device no common reimbursement and pricing mechanism exists. Rather:

- where medical devices are part of the outpatient medical therapy, the healthcare provider is generally reimbursed for the purchase price by the public health insurance fund, subject to regional collective agreements which may provide for particular reimbursement requirements and price caps; and
- medical devices prescribed by a healthcare provider to secure the medical therapy, or mitigate or compensate the effects of injuries, are qualified as auxiliary devices (*Hilfsmittel*). Suppliers of auxiliary devices must meet pre-qualification requirements and enter into supply agreements with public health insurance funds in order to be entitled to supply, and be reimbursed for, auxiliary devices to insured patients. Auxiliary devices may be grouped in established therapeutic classes similarly to medicinal products, with a view to capping the reimbursement price.

No pricing or reimbursement rules exist for food supplements.

## 14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

The advertising for medicinal products is regulated by the German Health Product Advertising Act (*Heilmittelwerbegesetz*, "**HWG**"). It prohibits misleading and off-label advertising, regulates mandatory product information in advertising as well as advertising with third-party scientific assessments, prohibits advertising of prescription-only medicinal products to the public, and regulates advertising for (non-prescription) medicinal products to the public. Advertising claims regarding the effectiveness or safety of a medicinal product are considered misleading already when they are not backed up by best scientific clinical evidence, except if the supporting lesser scientific evidence standard is made transparent. Comparative advertising is regulated by the German Unfair Trade Act (*Gesetz gegen den unlauteren Wettbeweb,* "**UWG**").

MDR and IVDR prohibit advertising claims which may mislead about a device's purpose, safety and/or performance. In addition to this MDR/IVDR-specific prohibition, the HWG rules on advertising with third-party scientific assessments and advertising to the public, as well as the UWG rules on comparative advertising, apply also to medical devices.

Health claims for food supplements must comply with the Health Claims Regulation (EC) No. 1924/2006. Misleading advertising for food supplements is prohibited by the Food Information Regulation (EU) No. 1169/2011 ("**FIR**"). In addition, the UWG advertising rules apply to food supplement advertising.

## 15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

Patents for medicinal products, medical devices, and food supplements are regulated by the German Patent Act (*Patentgesetz*). In addition, the patent protection term for medicinal products can be extended by up to five years through a supplementary protection certificate ("**SPC**") pursuant to Regulation (EC) No 469/2009.

Trademarks for these products can be registered as a national trademark under, and protected by, the German Trademark Act (*Markengesetz*) or as a European Union trademark under, and be protected by, the Trademark Regulation (EU) 2017/1001.

## 16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

The manufacturing, offering, placing on the market or use of a patent-protected product, as well as importing or possessing it to these ends, constitute infringing actions.

Patent holders and the exclusive licensee can bring proceedings for patent infringement. The action can include claims for injunctive relief, rendering of accounts, recall and destruction of infringing products as well as damages.

Patent holders can request these actions as preliminary measures, in which case the courts would generally require that the patent in suit has survived an inter partes validity attack (despite the ECJ decision C-44/21 now possibly suggesting the contrary). However, this requirement is often not applied to preliminary measures against generic entrants, thus preliminary injunctions can be granted. However, patent holders enforcing a

 

preliminary measures are liable to the alleged infringer for damages if the enforced patent is ultimately held invalid.

Since Germany has a bifurcated patent system, invalidity is not available as a defence in infringement proceedings on the merits. The alleged infringer must bring a separate nullity action before the Federal Patent Court to invalidate the patent.

### 17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

Medicinal products may not use names which are misleading, particularly regarding the efficacy and safety of the product (§ 8 AMG). Similarly, for medical devices no trademark, name or text may be used in the labelling, instructions claims, marketing and promotion which may mislead the patient regarding the intended purpose, safety or performance of the device (Art. 7 MDR/IVDR). Food supplements, like other food, may not be marketed under a misleading name (Art. 7 FIR).

Specifically for medicinal products, EMA (for centrally authorized medicinal products) and BfArM and PEI (for nationally authorized medicinal products) have issued guidelines on the acceptability of names or human medicinal products which set out further requirements and recommendations for developing an invented name for the medicinal product. The German guideline (newly revised in July 2023) also addresses under which conditions one brand name can be used as an umbrella brand for several products of a product family.

### 18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

Holder of MAs for medicinal products are subject to a special no-fault liability regime set out in § 84 et seq. AMG instead of the general product liability law set out in the German Product Liability Act (*Produkthaftungsgesetz*, "**ProdHaftG**"). The special liability regime for medicinal products goes beyond general product liability law insofar as it allows liability for development risks, sets higher liability caps for mass damages, and provides for a presumption of causality as well as a patient's right to information against the pharmaceutical company. On the other hand, the liability cap for individual damages is lower than under general product liability law. MAHs must take out and maintain corresponding special product liability insurance.

For medical devices and food supplements, the general product liability rules of the ProdHaftG apply, which implements the Product Liability Directive 85/374/EEC (due for replacement likely in 2024).

### 19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

Non-compliance with the applicable regulatory laws (*see* answer to question 1) may result in administrative enforcement and potentially in administrative fines. Non-compliance with regulatory laws typically also entails criminal liability, but enforcement by public prosecutors is limited. However, where a company violates regulatory laws which are also intended to protect the competition (e.g. basis marketability requirements such as a marketing authorization or lawful CE-marking, labelling requirements), competitors and fair competition watchdog organizations have a claim under the German Unfair Trade Act (UWG) against the company to cease and desist of the violation (e.g. immediately stop the commercialization of the non-compliant product) and to pay damages. Such cease-and-desist claims can also be enforced within a matter of days through a warning letter, followed by an application for a temporary injunction with the competent civil court.

Non-compliance with advertising laws (*see* answer to question 14) is typically enforced through UWG competitor claims only (*see* above). While unlawful advertising is also subject to regulatory oversight and can also entail administrative sanctions, such are rarely enforced.

In addition to the statutory rules on advertising (*see* answer to question 14), § 7 HWG generally prohibits all gifts and benefits which serve to promote medicinal products and medical devices, except for certain low-value gifts, certain monetary rebates ("10% off") and rebates in kind ("buy 2, get 1 free") and customary ancillary services. Any benefit or transfer of value offered, promised or given to healthcare professionals in exchange for preferential treatment is sanctioned by criminal anti-bribery laws. Non-compliance with § 7 HWG is typically enforced only by competitors through UWG claims, whereas violations of anti-bribery laws can be prosecuted by public prosecutors.

 

For product liability, *see* answer to question 18.

Non-compliance with data privacy laws may result in substantial administrative sanctions.

### 20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

Medical apps may qualify as medical devices and are subject to MDR regulation if the app meets the definition of a medical device.

A medical app regulated as a medical device of class I or IIa (and going forward also IIb), can qualify for reimbursement purposes as a Digital Health Application ("**DiGA**") and be eligible for prescription by physicians and reimbursement by the public health insurance system ("app on prescription"). To be included in the DiGA directory of reimbursable apps, the manufacturer must submit an application to BfArM showing that (1) the app achieves its main medical purposes through digital technologies and functions, (2) meets security and functionality (evidenced through the CE mark) additional quality, data protection, data security and interoperability requirements; and (3) provides positive healthcare effects (patient-relevant medical benefit, structural and procedural improvements in health care). If positive care effects are possible, but not yet proven by supporting data, DiGAs can be temporarily admitted to the DiGA directory for up to usually 12 months to generate such data. Once the data is available, the reimbursement price for the DiGA will be negotiated in a process which is comparable to the AMNOG process for innovative medicinal products (*see* answer to question 13).

Since 2021, the DiGA concept is extended to Digital Nursing Apps ("**DiPA**"), such as fall prevention apps or personalised memory games for people with dementia.

### 21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

German law does not provide for general stockpiling obligations in case of supply shortages (except since July 2023 in tendered rebated supply agreements for generic medicinal products). MA holders of medicinal products are subject to supply shortage notification requirements towards BfArM. In case of shortages, BfArM may exceptionally order stockpiling or supply quota of medicinal products with active substances ("**API**") included in a list of critical API, but has so far rarely made use of this authority. In addition, BfArM may also allow that medicinal products with non-German labelling are placed on the market.

### 22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

For medicinal products, the German industry compliance associations FSA (which implements the requirements of the European industry association EFPIA) and AKG have each developed codes of conduct which contain further rules specifically on advertising and interactions with healthcare professionals, and on transparency disclosures of these interactions. These codes of conduct only bind member companies of the respective association.

For medical devices, a similar code of conduct applies to member companies of the German industry association BVMed (the German affiliate of the European industry association MedTech Europe).

### 23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

The German Federal Court of Justice (*Bundesgerichtshof*, "**BGH**") decided on 8 February 2024 that early payment discounts (*Skonti*) for price-controlled medicinal products (*see* answer to question 13) are not permissible if they result in an effective sales below the statutory minimum price. The decision can have substantial impact on existing rebate schemes and agreements for price-controlled medicinal products.

The German Federal Social Court (*Bundessozialgericht*, "**BSG**") decided on 22 February 2023 that a new medicinal product may not be AMNOG-assessed (*see* answer to question 13) against a standard therapy consisting of "off-label" use. The AMNOG rules have since been amended to exceptionally allow for an AMNOG-assessment against an "off-label" standard

 

therapy.

BGH has submitted to the European Court of Justice on 21 December 2023 a request for preliminary ruling to which extent medical device distributors must assess the compliance of their devices before making them available on the market (*see* answer to question 12). The outcome can substantially impact diligence obligations of medical device distributors.

The Munich District Court I (*Landgericht München I*) has held on 4 August 2023 that regulatory market exclusivity for orphan drugs give the holder a claim to enjoin a competitor from entering the market and to seek damages. The decision, while not final, sets an important precedent for originators seeking to prevent early market entry from generic competitors.

### 24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

The German public health insurance system, which covers about 90% of the population, is being significantly digitalized since several years. Since January 2024, prescriptions for prescription-only medicinal products shall only be issued electronically, allowing the patient to fill their e-prescription via app, electronic health card or paper printout at the pharmacy of their choice. Furthermore, the electronic patient record is being rolled out and shall be widely implemented by 2025. However, the legal limitations to telehealth services and online pharmacy services are still substantial, and liberalization efforts remain few and incremental so far.

As regards the use of patient data, Germany has taken steps to make patient data centrally available for medical research and development, including through a new Act which will create a near equivalent in Germany to the planned European Health Data Space.

The use of artificial intelligence in life sciences will be regulated by the EU AI Act.

### 25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.

The pharmaceutical industry, having first suffered a substantial AMNOG price curtailing through an legislative amendment in November 2022, now enjoys renewed attention by the German government who has unveiled its pharmaceutical strategy in December 2023. The strategy foresees a number of legislative measures to counter the dwindling significance of Germany as a strong hub for pharmaceutical innovation. These measures include:

- Strengthening clinical research, including by streamlining approval processes (*see* answer to question 7) and offering a model clinical trial agreement to expedite contract negotiations;
- Subsidies especially for investments in manufacturing sites for antibiotics and oncology medicines;
- Re-assessing again the AMNOG assessment and price setting mechanisms; and
- Political support against the shortening of regulatory data protection periods proposed in the EU Commissions proposal for a EU pharmaceutical legislation package, as well as continued opposition against TRIPS waivers and mandatory technology transfers.

Medical device companies in Germany (as across the EU) using artificial intelligence in their devices will face the challenge of meet the requirements of both MDR and the EU AI Act.

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