Commercialisation of healthcare in Germany: overview

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REGULATORY OVERVIEW

1. What is the regulatory framework for medical products?

Legislation

The healthcare system is characterised by different systems of market access for medical products and different reimbursement methods. These systems differ for pharmaceuticals and medical devices. In EU member states, the decision to issue market authorisations is mainly dealt with at EU level, whereas the reimbursement decision is still a national issue. The German Drugs Act (AMG) sets out the regulatory framework for obtaining a marketing authorisation. The following are set out in the Social Code Book V (SGB V):

- The legal framework of the organisation of the statutory health insurance system (GKV).
- The responsibilities of the Federal Joint Committee (G-BA) and the other self-governing bodies.
- The provisions for medical care.

Since about 85% of the population are insured within the GKV, the reimbursement decision is crucial for manufacturers of medical products. Regarding the GKV, legislation creates the legal framework for the medical self-governing bodies, such as associations (at a federal and regional level) of physicians, the statutory health insurance funds (SHI funds) and the German Hospital Federation, to formulate and implement in detail which healthcare services will be provided and under what conditions they are reimbursed.

Regulatory authorities

The Federal Institute for Drugs and Medical Devices (BfArM) is competent for the authorisation of finished medicinal products, unless either the Federal Institute for Vaccines and Biomedicines (Paul-Ehrlich-Institut) (PEI) or the Federal Office of Consumer Protection and Food Safety (BVL) are competent. The PEI is competent for (section 77, AMQ):

- Serums.
- Vaccines.
- Blood preparations.
- Bone marrow preparations.
- Tissue preparations.
- Allergens.
- Gene transfer medicinal products.
- Somatic cell therapy products.
- Xenogeneic cell therapy products.

- Blood components manufactured using genetic engineering.

The BVL is responsible for medicinal products that are intended for administration to animals.

Most pharmaceuticals are now approved at EU level by the European Medicines Agency.

The G-BA is an association of all relevant parties of the statutory healthcare sector and, therefore, the most relevant regulatory body in the system. It represents:

- Physicians.
- Hospitals.
- Sickness funds.
- Patients.

The G-BA regulates detailed reimbursement matters, as it issues directives about relevant questions and determines the benefits package of the GKV. The Federal Ministry of Health has supervisory control over the G-BA.

For more information on the BfArM see box: The regulatory authorities

2. What types of medical products are regulated?

The market introduction of all medicinal products, medical devices and other medical products is regulated on different scales. Pharmaceuticals must go through a sophisticated approval procedure, and the reimbursement decision represents another hurdle for medicinal products.

Currently, most pharmaceuticals are approved at EU level by the European Medicines Agency, rather than at the national level by the Federal Institute for Drugs and Medical Devices.

Medical devices must go through the conformity assessment procedure to obtain a CE mark. They can then be placed on the market.

All other products (for example, biological and homeopathic preparations) must be approved in the same way as medicinal products, but with certain specificities and by other authorities.
DRUGS

3. What are the general requirements for a drug to be manufactured, advertised and sold?

Manufacturing

A manufacturing licence from the competent local authority is generally required for the commercial manufacturing of (section 13, German Drugs Act (AMG)):

- Medicinal products.
- Test sera.
- Antigen tests.
- Active substances that are of human, animal or microbial origin or are manufactured using genetic engineering.
- Other substances of human origin intended for the manufacture of medicinal products.

Manufacturing includes the production, preparation, processing, transfilling, pre-packaging, marking and release of a medicinal product. An authorisation must be granted if the manufacturer comply with all applicable requirements.

No manufacturing licence is required for blood and tissues, which require a specific authorisation and are subject to specific rules. In addition, a licence is not required for the procurement and laboratory tests of autologous blood for the manufacture of biotechnologically processed tissue products, tissue preparations and reconstitutions, provided that these are not intended for use in clinical trials.

Owners of pharmacies are also exempt from the requirement of a manufacturing licence for:

- Manufacturing medicinal products within the scope of the normal operation of a pharmacy.
- Reconstituting or packaging (including labelling) medicinal products intended for clinical trials, provided that they comply with the trial protocol.

In addition, the following persons do not generally need a manufacturing licence:

- Entities responsible for hospitals, in relation to medicinal products intended for clinical trials, provided that they comply with the trial protocol.
- Veterinarians operating a veterinary practice.
- Wholesalers decanting, packaging or labelling medicinal products without altering them.
- Retailers with expert knowledge (as defined in section 50 of the AMG) that decant, package or label medicinal products without altering them for direct distribution to consumers.
- Manufacturers of active substances that are intended for use in the manufacture of medicinal products under a procedure described in the homeopathic section of the pharmacopoeia.

Advertising

In addition to the regulatory system for market authorisation and market access discussed below, there is also a stringent legal framework for advertising medical products. The legal requirements for marketing activities of pharmaceutical companies addressed to healthcare professionals or the general public are set out in the Advertisement of Medicinal Products Law (HWG).

However, a marketing activity generally falls within the scope of the HWG only if the relevant activity is product-related and intended to increase the sales of a respective product. If the marketing activity is solely company-related, the rules of the Act against Unfair Competition (Gesetz gegen den unlauteren Wettbewerb (UWG)) are applicable. Finally, the AMG also imposes legal requirements for interactions with healthcare professionals and patient organisations.

Several industry guidelines also apply to product or company-related marketing activities of pharmaceutical companies, whether addressed to healthcare professionals or the general public. In particular, the following are relevant:

- The Code of Conduct of the Drugs and Co-operation in the Healthcare Sector Association (Ärzteverband der Krankenpflege und Kooperation im Gesundheitswesen e.V.) (AKG), issued by the German Pharmaceutical Industry Association (BPI).
- The FSA Code of Conduct of Healthcare Professionals, issued by the Association of Research-Based Pharmaceutical Companies (VFA).

The industry guidelines discussed below are binding on members of the BPI and the VFA, and compliance is monitored and sanctioned by the Voluntary Self-Regulation for the Pharmaceutical Industry Association (Freiwillige Selbstkontrolle der Arzneimittelindustrie e.V.) (FSA) and the AKG arbitration board.

Even pharmaceutical companies that are not member of the BPI or the VFA must comply with these regulations, as these industry guidelines serve as a means of interpretation for the courts when assessing whether or not a marketing activity infringes the applicable legal provisions. The industry guidelines are specific and detailed on the activities in the pharmaceutical industry. Therefore, it is expected that judges use the conclusive guidelines to assess whether a certain practice in the pharmaceutical industry infringes the general legal provisions (that also apply to other industry sectors).

Sale

Both the AMG and the Social Code Book V (SGB V) set out the regulatory framework for obtaining a marketing authorisation and placing medicines on the market. A finished medicinal product can only be placed on the market after a marketing authorisation has been granted by the German Higher Federal Authority or the European Commission (section 21, paragraph 1, AMQ). Placing on the market is defined as (section 4, paragraph 17, AMQ):

- Keeping in stock for sale or for other forms of supply.
- Exhibition and offering for sale.
- Distribution to others.

The legal requirement to obtain an authorisation before placing a medicinal product on the market also applies to (section 21a, paragraph 1, AMQ):

- Tissue preparations that are not manufactured in an industrial process.
- The essential processing procedures that are sufficiently well known in the EU.
- The effects and side effects that are known and evident from scientific data.

As well as the AMG, the Good Manufacturing Practice, which is a relevant legal prerequisite for the placing of medicines on the market, is laid down in certain national directives, such as the German Medicinal Products and Active Ingredients Manufacturing Decree.

The most relevant procedure for obtaining a marketing authorisation for human medicinal products is the national authorisation procedure, which is applicable to finished medicinal products (section 21, paragraph 1, AMQ). Finished medicinal products are (section 4, paragraph 1, AMQ):
• Medicinal products that are first manufactured and then placed on the market in packaging intended for distribution to the consumer.
• Other medicinal products intended for distribution to the consumer, where any form of industrial process is used to prepare them.
• Medicinal products that are produced commercially, except in pharmacies.

In addition, if the pharmaceutical manufacturer applies for a marketing authorisation in more than one member state (provided that the respective medicinal product does not fall within the scope of Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency) and chooses Germany as the reference member state, the decentralised procedure (DCP) and the mutual recognition procedure (MRP) apply (section 25b, AMQ). The DCP member states’ standard operating procedures or the Best Practice Guide for DCP and MRP, issued by the Coordination Group for Mutual Recognition and Decentralised Procedures, are also relevant.

For doctors, the approval is also an indication of the probability that the drug is effective in the specified indication and therefore can be prescribed. However, the drug is only reimbursable by the statutory health insurance (SHI) for the first year after market access. This is a major amendment under the Pharmaceuticals Market Reorganisation Act (Arzneimittelmarkt-Neuordnungsgesetz) (AMNÖG). After the first year, the reimbursement decision depends on a legal instrument. Depending on whether or not the active substance is new, there are legal instruments (in particular for the outpatient sector) that have a direct impact on the price setting of medicines within the SHI. These instruments are stipulated in the SGB V, as follows:

• The reference price system (section 35, paragraph 1, SGB V).
• The early benefit assessment (section 35a, SGB V).
• The efficiency principle (section 2, paragraph 12, SGB V).
• The therapy information (section 92, paragraph 2, SGB V).

A reference price system can be set by the Federal Joint Committee (G-BA) for medicines with:

• The same active substance.
• Therapeutically and pharmacologically comparable active substances.
• Therapeutically comparable effects.

The reference price is based on the price of all products of the group into which the medicines are categorised and constitutes the maximum amount being reimbursed for the respective medicines by the SHI. If the price has been set at a higher level by the pharmaceutical company, the difference must be paid by the patient receiving the medicine. However, according to the Basis for Decision-Making by the Subcommittee-Medicines for Defining Reference Prices dated 19 July 2007, no reference price should be set for patented medicines based on a new principle and deemed to represent a significant therapeutic advance.

The AMNÖG proposes a new form of price setting for innovative medicinal products and sets new conditions for pricing and reimbursement of medicinal products. Since 2011, the reimbursement of a new medicinal product has been aligned on its therapeutic value. According to the AMNÖG, the value of an innovative medicinal product is determined in comparison with existing therapies. A higher price can only be negotiated with the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) (GKV-SV) if an additional benefit can be proven to the G-BA for existing therapies. Medicinal products without any additional benefit are only reimbursed at the level of comparable products or therapies.

The efficiency principle can also be specified or defined by therapy information. The result is that the medicine for which therapy information exists (issued by the G-BA) is only reimbursed for certain therapy applications. The Drug Price Ordinance sets out certain conditions for the pricing of medicines.

There is a list of medicinal products that can be placed on the market without being approved (section 21, paragraph 2, AMQ). The most relevant exemption is set out in the AMG (section 21, paragraph 2, No. 1). This applies to products for which the essential manufacturing stages are carried out in a pharmacy. Similarly, no approval is needed for products for which up to 100 packages are produced in one day that are dealt with within the framework of the pharmacy operating licence.

4. Are there different requirements for patented and generic drugs?

Market authorisations for generic pharmaceuticals have only been available since 2005 (section 24b, paragraph 5, German Drugs Act (AMQ)). A generic drug only needs to be similar, not identical, to the patented product. However, the manufacturer must submit documentation of pre-clinical and clinical trials.

Biomedical scientific progress allows the development of advanced therapy medicinal products such as:

• Gene therapy.
• Somatic cell therapy.
• Tissue engineering.
• Biotechnology.
• Molecular biotechnology.

Therefore, a special legal category of biologics was created for “advanced therapy medicinal products” under Article 2, paragraph 1(a) of Regulation (EC) 1394/2007 on advanced therapy medicinal products, which are (section 4, paragraph 9, AMQ):

• Gene therapy.
• Somatic cell therapy.
• Tissue engineered products.

These include drugs from substances of biological origin, as well as tissue preparations, blood preparations and immunological medicinal products. Since the Regulation directly binds all member states, special German regulations no longer apply.

5. What authority is responsible for regulating the manufacture, advertising and sale of drugs?

The competent authorities for regulating the manufacture and sale of drugs are the Federal Institute for Drugs and Medical Devices (BfArM) and the Federal Joint Committee (G-BA) (see Question 1).

Advertising is mainly regulated through relevant court proceedings regarding competition law cases. In practice, authorities do not regulate violations of the pharmaceutical advertising law.

6. Are there fewer or different requirements for drugs that have already been licensed or approved in another jurisdiction?

If a pharmaceutical has been approved in another EU member state, the manufacturer can apply for approval under the mutual recognition procedure. Basic arrangements for implementing the
mutual recognition procedure that are laid down in Directive 2001/83/EC on the Community code relating to medicinal products for human use have been made in all member states. To be eligible for this procedure, a medicinal product must have already received a marketing authorisation in one member state.

The applications submitted must be identical and all member states must be notified of them. Once a member state decides to evaluate the medicinal product (at which point it becomes the “reference member state”), it notifies its decision to the other member states (which become the “concerned member states”) to whom applications have also been submitted. Concerned member states then suspend their own evaluations and wait for the reference member state’s decision on the product. Less information needs to be provided since the reference member state examines all documents and grants the approval. The concerned member states must refer to this approval unless there are severe safety restrictions.

7. Is it possible to sell drugs to or buy drugs from other jurisdictions?

Medicines can be imported into Germany if they comply with the provisions of the German Drugs Act (AMG) or if they are registered under Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMA Regulation). Medicines that are not approved or registered cannot be sold or bought in Germany, even if there are comparable drugs available (section 73, AMG).

However, there are some exemptions for personal use and travel needs. In addition, small amounts of drugs can be ordered from foreign countries by a German-based pharmacy if the active substance is not available in Germany (section 73, paragraph 3, AMG).

8. Is it permitted to advertise drugs to consumers? Are there restrictions on advertising?

Generally, product-related advertisements (section 3, Advertisement of Medicinal Products Law (HWG)) and company-related advertisements (section 5, Act against Unfair Competition (UWG)) addressed to healthcare professionals must not be misleading or unfair, which means the promotional statement must be correct and, if necessary, verifiable. HWG and UWG contain concrete examples of misleading or unfair competition. For product-related advertisements, most importantly, the law requires that the promoted medicinal product must not be described as having therapeutic efficacy or effects that it does not possess, and that the advertisement does not give a false impression that success is guaranteed or that the recommended use has no side effects (section 3, Nos. 1 and 2, HWG). A respective list of legal examples is set out in the UWG, which applies to company-related advertising statements (sections 4 and 5, UWG). Other important principles applying to product-related advertisements are that:

- The advertisement must always mention the mandatory information regarding the promoted medicine.
- The promoted indications must be in line with the marketing authorisation, the summary of product characteristics and the package leaflet.

Promotional statements addressed to the general public and healthcare professionals must not be misleading or unfair. However, further legislative provisions apply to enhance the protection of the general public, as the public is considered to have no (substantial) medical knowledge. For example, the HWG sets out that the advertising of prescription-only medicines to the general public is prohibited (section 10, HWG). This prohibition ensures that healthcare professionals decide independently on the prescription of certain medicines based solely on medical considerations that are not influenced by the patient. In addition, the HWG contains a list of examples of advertisements that must not be directed to people other than healthcare professionals, as they are potentially misleading or manipulative. These include advertisements containing:

- Scientific or professional publications.
- Statements alleging that the medicine is recommended, tested or used by healthcare professionals.
- Foreign or professional terminology, where these have not become part of general German vocabulary.
- Publications that suggest self-diagnosis and treatment by the advertised medicinal product.

MEDICAL DEVICES

9. What is the definition of medical device in your jurisdiction?

Medical devices are products that have a medical purpose and are intended by the manufacturer for use in or on humans. In contrast to drugs, which act pharmacologically, immunologically, or metabolically, the main intended purpose of medical devices is primarily achieved through physical means.

Medical devices are defined as instruments, apparatus, appliances, software, substances or preparations made from substances or other articles, used alone or in combination, including the software intended by the manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for the medical device’s proper application, intended by the manufacturer to be used in or on human beings, by virtue of their functions, for any of the following purposes (section 3, paragraph 1, German Act on Medical Devices (Medizinproduktegesetz)):

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation or compensation of injuries or handicaps.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception.
- Additionally, a medical device must not achieve its principal intended action in or on the human body through pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

Medical devices currently include (among others):

- Implants.
- Products for injection, infusion and so on.
- Medical instruments intended for use in humans.
- Software.
- Catheters.
- Artificial cardiac pacemakers.
- Dental devices.
- Bandaging material.
- Corrective lenses.
- X-ray machines.

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A product that contains or is coated with a substance or preparations of substances that are considered to be medicinal products or components of a medicinal product (including plasma derivatives) can also be considered a medical device (under certain conditions).

10. What are the general requirements for a medical device to be manufactured, advertised and sold?

Manufacturing
Under Regulation (EU) 2017/745 on medical devices (Medical Devices Regulation), a medical device is an instrument, apparatus, appliance, software, material or other article that is used alone or in combination, including software specifically used for diagnostic or therapeutic purposes, that the manufacturer intends for use in human beings. For these devices, the German Medical Devices Act implements the requirements of EU directives. See Question 9 for further detail on the definition of medical device.

Generally, medical devices must be approved. However, there are no comparable restrictions regarding clinical testing or additional benefit. If medical devices have passed the conformity assessment procedures, they obtain a CE mark. If the CE mark and the summary of product characteristics are submitted in the respective member states' language, the device can enter the market. No restrictions can be established within any single member state, and the CE mark constitutes the market authorisation. The core legal framework comprises the following legal instruments:

- Medical Devices Regulation.
- Directive 93/42/EEC concerning medical devices and Directive 90/385/EEC on active implantable medical devices, which will continue to apply during a transition period (namely, until spring 2020 and spring 2022 respectively).

These are aimed at providing a high level of protection of human health and safety, and the good functioning of the single market. Under the above regulations and directives and the German Medical Devices Act, a class system differentiates four risk classes, which are set out in Annex VIII of the Medical Devices Regulation:

- All non-invasive devices are in class I, unless another class refer to such devices.
- The devices in class IIa or IIb are as follows:
  - all non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are generally in class IIa; and
  - all non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are generally in class IIb.
- All invasive devices are generally in class III.

The requirements for the conformity assessment procedures differ depending on the respective classes. Products in class I must pass the conformity assessment procedures at the manufacturer’s own risk, who must prepare documentation, including risk management, to be submitted to the authorities if requested. The state authority must also regularly certify the products in classes IIa, IIb and III. However, the manufacturer remains in charge of safety risks of the product and retains ownership. The manufacturer is the person or company that first places the product on the market, regardless of the producer.

The Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation will be directly binding on member states and all applicants. In contrast, the previous directives had to be implemented into each of the national legal systems, which allowed different interpretations across EU member states. One of the main amendments is to make clinical testing to be obligatory in all member states to obtain a market authorisation.

The approval decision is made by the notified body, that is, the Technical Inspection Association (TÜV). However, the CE mark of all EU-notified bodies is recognised.

Regarding reimbursement, the Federal Joint Committee (G-BA) decides whether a medical device must be reimbursed if a benefit assessment is applied for.

Advertising
See Question 14.

Sale
The sale of medical devices depends on the classification of the device. If introduced to the outpatient sector, a device can only be reimbursed if there is a specific code number in the fee schedule of office-based doctors. In the inpatient sector, any device can be reimbursed under the diagnosis-related group system, unless the G-BA decides that no reimbursement for this device was possible.

For treatment methods, benefit assessments by the G-BA and Institute for Quality and Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) also involve decisions about reimbursement.

11. What authority is responsible for regulating the manufacture, advertising and sale of medical devices?

Notified bodies are in charge of the manufacture decision. The Federal Joint Committee (G-BA) gives the decision on reimbursement (however, the statutory health insurance is responsible for individual cases of reimbursement).

There is no authority specifically responsible for regulating the advertising of medical devices.

In practice, competition law cases are decided by the courts.

12. Are there fewer or different requirements for medical devices that have already been licensed/approved in another jurisdiction?

As the CE mark is acknowledged in all EU member states, there are no further restrictions in member states beyond the requirement to submit the CE mark and translate the summary of the product characteristics. For reimbursement, the manufacturer must apply to the Federal Joint Committee (G-BA) (see Question 10).

13. Is it possible to sell devices to or buy devices from other jurisdictions?

It is possible to sell devices to and buy devices from all EU member states, provided that they have CE marks. To achieve reimbursement in Germany, internationally produced medical devices must be introduced to the European system, as the statutory health insurance does not directly refund products, but refunds the implantation procedure.

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14. Is it permitted to advertise medical devices to consumers? Are there restrictions on advertising?

The restrictions on advertising of drugs apply equally to medical devices (section 1, No. 1a, Advertisement of Medicinal Products Law (HWG)) (see Question 8). However, there are a number of exceptions, as not all of these provisions are suitable for medical devices. It is permissible to promote medical devices to the public (in contrast to pharmaceuticals) in certain cases because there is less danger that patients will avoid doctors and of self-diagnosis (section 11, paragraph 1, sentence 2, HWG). The HWG only applies to:

- Advertisements that lead to the assumption that health risks will occur if a medical device is not used.
- Cases where medical devices are offered in connection with advertising events.
- Cases of publications where the promotional purpose is not clearly recognisable.

The HWG also applies to publications of third parties that are conducted in misleading ways and advertisements that are only addressed to children below the age of 14 years.

BIOLOGICAL PRODUCTS

15. What are the general requirements for a biological product to be manufactured, advertised and sold?

Manufacturing

Biological products are not clearly defined under German or EU legislation. They can be identified as pharmaceuticals the active substances of which are gained from recombinant cell cultures. Apart from examples of biologics, there is no legally binding definition of such products. There is also a catalogue of pharmaceuticals manufactured by biotechnological procedures in the Annex to Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMA Regulation). These pharmaceuticals must be marketed according to the centralised procedure before the European Medicines Agency (EMA), not national authorities.

Regarding the legal regulation of biologics, national rules only apply to the regulatory outlines. The EMA Regulation sets the legal framework regarding market authorisation and market access of all preparations that contain a biologic substance. Under the EMA Regulation, a biological product can be seen as one of the active substances produced by, or extracted from, a biological system, and requires, in addition to physico-chemical testing, biological testing for full characterisation. The characterisation of a biological medicinal product is a combination of testing the active substance and the final medicinal product, together with the production process and its control. Regarding the production process, a biological product can be derived from biotechnology or other new technologies. It can also be prepared using more conventional techniques, as is the case for blood or plasma-derived products and a number of vaccines.

Therefore, a biological product can consist of:

- Entire micro-organisms or mammalian cells.
- Nucleic acids or proteinaceous or polysaccharide components originating from a microbial, animal, human or plant source.

For its mode of action, a biological product can be:

- A therapeutic medicinal product.
- An immunological product.
- Gene transfer material.
- Cell therapy material.

The legal framework relevant to pharmaceuticals also applies to reimbursement (see Question 3, Manufacturing).

Advertising

There are no specific requirements for advertising. These are generally the same as for medicinal products (see Question 3, Advertising).

Sale

If a biological product is approved for use in human beings, the same legal framework applies as for pharmaceuticals (see Question 3, Sale).

16. What authority is responsible for regulating the manufacture, advertising and sale of biological products?

The Federal Institute for Vaccines and Biomedicines (Paul-Ehrlich-Institut) (PEI) and the Federal Office of Consumer Protection and Food Safety (BVL) are the competent authorities. The PEI is competent for (section 77, German Drugs Act):

- Serums.
- Vaccines.
- Blood preparations.
- Bone marrow preparations.
- Tissue preparations.
- Allergens.
- Gene transfer medicinal products.
- Somatic cell therapy products.
- Xenogeneic cell therapy products.
- Blood components manufactured using genetic engineering.

17. Are there fewer or different requirements for biological products that have already been licensed/approved in another jurisdiction?

The same applies as for pharmaceutical products (see Question 8).

18. Is it possible to sell biological products to or buy biological devices from other jurisdictions?

There are no specific regulations on biological products on this matter. Therefore, it is generally not permitted to import a biological product without a marketing authorisation for Germany.

19. Is it permitted to advertise biological products to consumers? Are there restrictions on advertising?

There are no specific regulations concerning the advertising of biological products. Therefore, the requirements for pharmaceuticals also apply to biological products (see Question 8). The Advertisement of Medicinal Products Law regulates the advertising of “other products”, such as cosmetic or food products, and therefore applies to biological products.
NATURAL HEALTH PRODUCTS

20. Is there a category for natural health products (including, for example, traditional medicines, homeopathic medicines, supplements, vitamins and minerals)?

Under the law, natural health products are not classified into a definable group of medical products. However, certain regulations exist for homeopathic and traditional products, as well as dietary or food products, regarding the specific procedures to be applied to patients.

Regarding vitamins and dietary products, there is a sophisticated legal framework that distinguishes between pharmaceutical and food products. Dietary and dietary supplement products are regularly classified as food products, and therefore do not need to be approved under the system for pharmaceuticals. A clear line cannot be drawn between these two categories, as the distinction between food and pharmaceutical products depends on individual cases that are covered by the relevant EU regulations’ terminology. However, the following criteria are applied to distinguish pharmaceuticals from food products:

- Definition of purpose.
- Product design.
- Market appearance

21. What are the general requirements for natural health products to be manufactured, advertised and sold?

Manufacturing

Generally, natural health products must be approved (section 21, German Drugs Act (AMG)). Quality, effectiveness and safety must be demonstrated for all marketed drugs based on pharmacologic and clinical studies, as well as all data available on the specific procedures to be applied to patients. However, traditional products do not need to be approved, but registered (section 39a–d, AMG). Quality, effectiveness and safety must be proven, but clinical trials are not required.

In addition, non-prescription homeopathic preparations must be registered (sections 38 and 39, AMG). They can also be approved on the manufacturer’s choice (section 21, AMG). However, prescription drugs must be approved rather than just registered. If they are only registered, they must be declared as homeopathic and cannot be advised for certain indications. Studies on safety must be submitted, but the manufacturer does not need to prove the effectiveness of a registered homeopathic product.

If homeopathic products are approved under section 21 of the AMG, the homeopathic therapeutic benefit must be proven and all documents must be submitted. The homeopathic therapeutic benefit should not be mistaken with the additional benefit to be proven for pharmaceuticals under the early benefit assessment. If the manufacturer obtains market authorisation, the area of application must be indicated as the approval is only effective for the relevant area of application. If the homeopathic product is only registered, no indication can be specified.

Advertising

The manufacturer cannot advertise a homeopathic drug with an indication unless it is registered and not approved (section 5, Advertisement of Medicinal Products Law (HWG)). If the product is approved, the manufacturer must indicate the areas of application and must not indicate that the product is homeopathic to avoid confusion.

There are no further regulations concerning the advertising of other natural health products. Therefore, the requirements that apply to pharmaceutical products also apply to those products that are determined to cure, and so are classified as pharmaceutical products (section 2, AMG). As the HWG regulates the advertising of “other products”, such as cosmetic or food products (even if they are not classified as pharmaceutical products), it therefore applies to natural health products.

Sale

Natural health products are mostly over-the-counter preparations and are therefore not reimbursable.

22. What authority is responsible for regulating the manufacture, advertising and sale of natural health products?

The Federal Institute for Drugs and Medical Devices is responsible for the registration of homeopathic products, in the same way as for other pharmaceuticals.

23. Are there fewer or different requirements for natural health products that have already been licensed or approved in another jurisdiction?

All pharmaceuticals must be approved under German or EU law to be marketed in Germany. There is no express exemption for natural health products, so that regulations for pharmaceuticals also apply to natural health products that are considered to be pharmaceuticals (section 2, German Drugs Act).

24. Is it possible to sell natural health products to or buy natural health products from other jurisdictions and/or electronically?

Generally, it is possible to sell or buy natural health products from other jurisdictions, depending on the market authorisation in Germany. The exemptions under section 73 of the German Drugs Act also apply to these products, although none are specific to natural health products.

25. Is it permitted to advertise natural health products to consumers? Are there restrictions on advertising?

The restrictions mentioned in Question 8 apply to natural health products depending on the product in question, as there is no definable group of natural health products, although regulations differ depending on the respective preparations (see Question 20).

REFORM

26. Are there any plans to reform the rules on the development, manufacture, advertising and sale of medical products?

The German pharmaceuticals market has been subject to constant changes over the last few years, and 2017 was no exception in this regard.

The Pharmaceuticals Market Reorganisation Act (Arzneimittelmarkt-Neuordnungsgesetz-AMNOG), which requires drug manufacturers to submit evidence to the Federal Joint Committee (Gemeinsamer Bundesausschuss) to show that their new products are more effective than previous products, was substantially amended with effect from January 2011.
In 2017, the German Bundestag passed a heavily debated bill to strengthen pharmaceutical supplies in statutory health insurance (Gesetz zur Stärkung der Arzneimittelversorgung in der Gesetzlichen Krankenversicherung). The new Act entered into force in May 2017 and introduced minor changes to market access and pricing legislation for pharmaceuticals, including:

- The extension of the price moratorium for prescription drugs until 31 December 2022.
- The introduction of the physician information system, which is designed to provide information to statutory general practitioners about decisions taken by the Federal Joint Committee regarding the increased effectiveness that new products must show.
- The extension of the drugs early benefit assessment under section 35a of the Social Code Book V (SGB V).
- Price reductions in the case a missing or incomplete dossier is submitted for the benefit assessment of a new product.
- Price setting on the basis of previous experience, if a product is not proving to be more effective than previous products.

The German Act on Medical Devices (Medizinproduktegesetz) (MPG) entered into force in May 2017. The MPG transposes:


The tasks of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) with regard to medical devices are primarily set out in the MPG. In addition, the Ordinance on the Medical Device Safety Plan (Medizinprodukt sicherheitsplanverordnung) and the Ordinance on Clinical Investigations with Medical Devices (Verordnung über klinische Prüfung von Medizinprodukten) were enacted in 2017.

The German Bundestag also approved changes to the Act on Devices for Healing and Aids to Living (Heil- und Hilfsmittelversorgungsgesetz). The amendments are intended to improve the quality of care for patients who are treated with, or need to use, medical devices.

As far as it is reasonably foreseeable without a new federal government in place, changes are expected to continue, although no major reform is expected in the near future.
THE REGULATORY AUTHORITIES

Federal Ministry of Health (BGM)

Principal responsibilities. The BGM mainly focuses on the drafting of bills, ordinances and administrative regulations.

Federal Institute for Drugs and Medical Devices (BfArM)
W www.bfarm.de/EN/Home/home_node.html

Principal responsibilities. The BfArM, which operates under the BGM, is the competent authority for the marketing authorisation of pharmaceuticals for human use. However in practice, market authorisations are mainly applied for at EU level, to the European Medicines Agency.

Paul Ehrlich Institute (PEI)
W www.pei.de/EN/Home/node.html

Principal responsibilities. The PEI is competent to deliver marketing authorisations for specific groups of medicinal products (such as vaccines for humans and animals, medicinal products containing antibodies, allergens for therapy and diagnostics, blood and blood products, and tissue and medicinal products for gene therapy, somatic cell therapy and xenogeneic cell therapy. The PEI is also responsible for approving trials. The PEI is a research institution and a World Health Organization Collaborating Centre for quality assurance of blood products and in vitro diagnostic devices.

Federal Office of Consumer Protection and Food Safety (BVL)
W www.bvl.bund.de/EN/Home/homepage_node.html

Principal responsibilities. The BVL fulfils many tasks in the area of food safety. It is the competent authority for the marketing authorisation of veterinary medicinal products.

Federal Joint Committee (G-BA)
W www.english.g-ba.de

Principal responsibilities. The G-BA (consisting of the National Associations of Statutory Health Insurance Physicians and Dentists, the German Hospital Federation and the Central Federal Association of Health Insurance Funds) can adopt binding regulations and routine decisions regarding healthcare in Germany. The G-BA issues directives that govern statutory health insurance and regulates which medical treatments are paid for by the statutory health insurance. In addition, the G-BA decides on quality assurance measures in the inpatient and outpatient healthcare sectors.

National Association of Statutory Health Insurance Funds (GKV)
W www.gkv-spitzenverband.de/english/english.jsp

Principal responsibilities. The GKV has taken on a central role in the German healthcare system since 1 July 2008. It is the central association of health insurance funds at federal level.

Drug Commission of the German Medical Association (AKDÄ)
W www.akdae.de/en/index.html

Principal responsibilities. The AKDÄ is the scientific expert committee for drug-related matters of the German Medical Association. It consists of 40 full members and about 135 associate members from all areas of medicine and pharmacy.
ONLINE RESOURCES

**German Drugs Act (AMG)**

*W* [www.gesetze-im-internet.de/englisch_amg](http://www.gesetze-im-internet.de/englisch_amg)

**Description.** This website is maintained by the Federal Ministry of Justice and Consumer Protection and is updated regularly. All recent amendments are included. Only the AMG is available in English. All other regulations are only available in German.

**Benefit assessment of pharmaceuticals**

*W* [www.english.g-ba.de/benefitassessment/information](http://www.english.g-ba.de/benefitassessment/information)

**Description.** This page compiles information on the benefit assessment of pharmaceuticals in accordance with the Act on the Reform of the Market for Medicinal Products (including further information for pharmaceutical companies). All English translations on this page are for guidance only. Only German versions are binding.

**Portal of the justice authorities of the federal and state governments**


**Description.** This website provides access to the e-justice services and information provided by the Federal Ministry of Justice and Consumer Protection and the justice administrations of the federal states.

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