Distribution and marketing of drugs in Germany: overview

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distribution

Pre-conditions for distribution

1. What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

Authorisation

Under section 21(1) of the Medical Products Act (Arzneimittelgesetz) (AMG), a finished medicinal product can only be placed on the market after marketing authorisation has been issued by the competent German higher federal authority or the European Commission. Finished medicinal products as defined in section 4(1) of the AMG are medicinal products that are manufactured in advance and placed on the market in packaging intended for distribution to the consumer. Finished medicinal products are not intermediate products intended for further processing by a manufacturer.

Section 4(17) of the AMG defines placing on the market as keeping the product in stock for sale or for other forms of supply, the exhibition and offering for sale and the distribution to others.

Exceptions

Two types of medicinal products described in section 21(2) of the AMG can be placed on the market without a marketing authorisation:

- Medicinal products for which the essential manufacturing stages are carried out in a pharmacy and no more than 100 packages in one day are produced, and are permitted by the pharmacy operating licence. In a recent proceeding before the Court of Justice of the European Union (CJEU), the author represented a community pharmacy in a case in which the CJEU confirmed that this exemption is in line with Directive 2001/83/EC on the Community code relating to medicinal products for human use (C-267/19).

- Medicinal products that are intended for use in clinical trials on human beings.

Section 21(2) No. 6 of the AMG permits the provision of medicinal products to patients for a compassionate use (that is, if patients have a seriously debilitating disease or whose disease is life-threatening, and who cannot be treated satisfactorily with an authorised medicinal product) to be made available free of charge. The Federal Ministry of Health (Bundesgesundheitsministerium) issued the Ordinance for Compassionate Use (Arzneimittel-Härtefällieverordnung) in 2010, which sets out the legal requirements for placing unlicensed medicinal products on the market in Germany before a marketing authorisation has been obtained by the pharmaceutical company. See Question 2.

2. Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

There are provisions under German law for both named patient supplies and compassionate use programmes.

Article 5(1) of Directive 2001/83/EC on the Community code relating to medicinal products for human use on named patient supplies is implemented into German law, among others, by section 73(3) of the Medical Products Act (Arzneimittelgesetz) (AMG) and the judgement of the ECJ in case C-143/06, Rosenapotheke. This legal provision stipulates the following requirements for distributing medicinal products under the conditions of named patient supply:

- The medicinal product in question is a finished medicinal product.

- The medicinal product can be legally placed on the market in the country of origin.

- The ordering and acquisition of the medicinal product is carried out by a pharmacy.

- The medicinal product is imported only in small quantities.

- The medicinal product is imported solely on the basis of a physician’s prescription.

- A supply deficit exists, that is, no identical medicinal products with respect to active substances, and no comparable medicinal products with respect to strength, are available.

Separately, compassionate use programmes are in place for patients suffering a life-threatening disease or a disease leading to severe disability, such as some types of cancer, pulmonary infections and life-threatening types of influenza. The conduct of compassionate use programmes must be notified beforehand to the higher federal authority, which is either the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) (BfArM) or the Federal Institute for Vaccines and Biomedicines (Paul-Ehrlich-Institut) (PEI).

Otherwise, the requirements for compassionate use programmes are, among others, as follows:

- The patients suffer from a life-threatening disease or a disease leading to severe disability.

- There is no other satisfying treatment option with medicinal products approved in the EU.

- An authorisation application for the medicinal product is pending or clinical trials (Phase III) for this medicinal product are still ongoing.
Licensing

3. What is the procedural structure regarding licensing a drug for distribution?

The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) (BfArM) is the competent authority for the authorisation of finished medicinal products in Germany, unless either the Federal Institute for Vaccines and Biomedicines (Paul-Ehrlich-Institut) (PEI) or the Federal Office of Consumer Protection and Food Safety (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz) (BML) is competent.

Under section 77(2) of the Medical Products Act (Arzneimittelgesetz) (AMG), the PB is competent for the licensing of sera, vaccines, blood preparations, bone marrow preparations, tissue preparations, allergens, gene transfer medicinal products, somatic cell therapy products, xenogenic cell therapy products and blood components manufactured using genetic engineering.

The BML is responsible for the authorisation of medicinal products that are intended for administration to animals only (section 77(3), AMG). Any product placed on the market in Germany and that is the subject of a marketing authorisation, whether from the German authorities or the European Medicines Agency (EMA), must have reports on all the results of confirmatory clinical trials substantiating the efficacy and safety of the medicinal product at the disposal of the competent higher federal authority. These reports must be made available within six months following the granting of the marketing authorisation/centralised marketing authorisation. This obligation applies regardless of whether any of the trial sites used were located in Germany.

4. Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs which have already been licensed for distribution in another jurisdiction?

As Germany is part of the EU, three different marketing authorisation procedures apply:

- Centralised procedure.
- Mutual recognition procedure.
- Decentralised procedure.

Any of these can be used, as well as a standalone national authorised procedure.

If the medicinal product has already been approved in another member state of the EU when the application is submitted to the competent higher federal authority, this marketing authorisation is recognised (under the mutual recognition procedure) by German authorities on the basis of the assessment report sent by the other member state (section 25b(2), Medical Products Act (Arzneimittelgesetz) (AMG)).

There is a simplified licence procedure for parallel imported drugs that have already been licensed for distribution in another EU country. The European Medicines Agency (EMA) must be notified about the parallel import. Under section 13 of the AMG, the parallel importer needs a manufacturing authorisation for repacking, labelling and adding the package leaflet to the medicinal product.

For generics, a simplified licence procedure is described in section 24b(1) of the AMG. When applying for a marketing authorisation of the generic product, reference can be made to the documents, including the expert report, for the previous applicant's medicinal product (reference medicinal product). The previous applicant's agreement with the use of the reference documents is not necessary. The reference medicinal product must have already been authorised for at least eight years before such an application will be considered.

5. Is virtual drug distribution possible from your jurisdiction?

A marketing authorisation obtained in Germany gives the market authorisation holder the right to sell the authorised medicinal product in Germany. The question of whether the medicinal product may be distributed in another country based on the German authorisation must be answered based on the law of that country.

6. What is the procedure to appeal (legal remedy) a licensing decision?

It is possible to appeal (Widerspruch) against the federal drug administration's decision not to grant a licence. The competent authority will give judgment itself on the appeal by either rejecting it or declaring it to be founded. Additionally, an action can be brought before the local administrative courts (Verwaltungsgericht).

7. What are the costs of obtaining licensing?

The costs of obtaining a centralised marketing authorisation as laid down by the European Medicines Agency (EMA) are:

- A basic fee of EUR251,600 per application based on a completed dossier. This fee will be increased by EUR25,200 for each additional dosage/pharmaceutical form.
- A reduced fee of EUR97,600 for an application regarding a generic pharmaceutical product.
- A special reduced fee of EUR162,600 for biological medicinal products. There could be additional charges up to EUR75,500 for the amendment/extension of an already existing authorisation.

The costs for obtaining a national marketing authorisation vary depending on the nature of the product. The maximum fee is EUR57,500.

Distribution to consumers

8. What are the different categories of drugs for distribution?

In Germany, there are four different categories of drugs for distribution:

- General sales list medicines (freiverkäufliche Arzneimittel), which do not need to be sold in pharmacies.
- Medicines that can be sold by pharmacists only (apothekeonly). Prescription drugs (verschreibungspflichtig), which are available under a doctor's prescription only.
- Narcotic drugs (Betäubungsmittel), which are available under a special narcotic prescription only.

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9. Who is authorised to distribute prescription drugs and over-the-counter drugs to consumers?

Prescription drugs
Under section 43(3) of the Medical Products Act (Arzneimittelgesetz (AMG)), medicinal products can only be dispensed by pharmacies on prescription. Pharmacies must have an authorisation as described in the Pharmacy Act (Apothekengesetz (ApoG)). The authorisation is granted by the competent higher federal authority of the state where the pharmacy is established. The applicant must fulfil certain criteria, such as being licensed to practise pharmacy and being sufficiently reliable to operate a pharmacy. The authorisation to distribute prescription drugs in pharmacies can be granted as well if the applying pharmacist states that he or she operates a pharmacy in another member state of the EU.

Over-the-counter drugs
In relation to over-the-counter drugs, a distinction must be made between general sales list medicines (freiverkäufliche) and medicines that can be sold by pharmacists only (apothekenpflichtige).

General sales list medicines (freiverkäufliche Arzneimittel) can be retailed outside pharmacies, provided that the owner is in possession of the necessary expert knowledge (section 50(1), AMG). To be considered as possessing the necessary expert knowledge, the person in question must provide proof of experience and skill in respect of the proper filing, packaging, labelling, storing and marketing of medicinal products that are released for trade outside pharmacies. Additionally, knowledge of the existing regulations applicable to these medicinal products is required.

Only pharmacies are entitled to distribute apothekenpflichtige drugs to consumers. Generally, there is no price reimbursement for over-the-counter drugs by statutory health insurance (section 34(1), Social Code Book 5 (Sozialgesetzbuch V) (SGB V)).

10. What drugs can an attending physician distribute and under what circumstances?

Physicians are not allowed to distribute drugs. There is only an exception for free samples that are handed to patients when consulting a physician.

11. Who is authorised to prescribe prescription drugs to consumers?

Under section 1 of the Ordinance regarding the prescription of medicinal products (Arzneimittelverschreibungsverordnung), drugs can only be prescribed by physicians or dentists within their professional field.

Unlike in other countries, in Germany nurses are not allowed to write prescriptions. Physicians working in hospitals are only allowed to make prescriptions for the duration of the patient’s stay in hospital. The German legislator introduced an exception to this rule in 2017 to close the gap between in-patient and out-patient care, which applies under certain conditions (Hospital Discharge Management (Entlassmanagen)).

12. Is direct mailing/distance selling of drugs permitted in your jurisdiction?

Conditions
Under section 11a of the Pharmacy Act (Apothekengesetz (ApoG)), an authorisation for direct mailing/distance selling of medicinal products can be granted by the federal higher state authority if the applicant already holds a permission to distribute drugs to consumers and confirms in writing that:

- Direct mailing/distance selling will take place in addition to the normal course of activities of the pharmacy.
- A quality assurance system is established to ensure that:
  - medicinal products are packed, transported and delivered properly to maintain the quality and efficacy of the drugs;
  - shipped medicinal products are delivered only to the person listed in the order form;
  - patients are asked to consult a physician if they have any problems related to the use of the medicinal product; and
- an advisory service is provided to patients in German.

Additionally, pharmacies must ensure that:

- Medicinal products are mailed out to the patient within two days after receipt of the customer order.
- A system is established to inform patients about risks of medicinal products.
- A tracking system is maintained.
- Transport insurance is arranged.

Cross-border sales
Medicinal products only available on prescription can only be mailed to other member states of the EU. Over-the-counter drugs can be mailed to patients worldwide, but the import regulations of the receiving country should be verified in advance.

13. What regulatory authority is responsible for supervising distribution activities?

Federal higher state authorities are responsible for the supervision of distribution of drugs to consumers.

14. What is the procedure to appeal (legal remedy) a distribution decision?

Depending on the state where the drugs are distributed, it may possible to appeal against the competent federal higher state authority’s decision. Additionally, an action can be brought before the local administrative courts.

15. What are the legal consequences of non-compliance with consumer distribution laws?

In the case of non-compliance, the penalties can include imprisonment or a fine. In particularly serious instances, the penalty can be imprisonment from one to ten years. In addition, administrative fines of up to EUR25,000 may be imposed.

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16. What is the legal regime regarding wholesale distribution of drugs?

Any person/company that engages in the wholesale trading of medicinal products, test sera or test antigens, requires an authorisation to do so (section 52a(1), Medicinal Products Act (Arzneimittelgesetz [AMG])). The wholesale of drugs is defined in section 4(22) of the AMG as any professional or commercial activity for the purpose of doing business that consists of the procuring, storing, dispensing or exporting of medicinal products, with the exception of the dispensing of medicinal products to consumers other than physicians, dentists, veterinarians or hospitals.

The applicant must:
- Name the specific sites for which the authorisation is to be issued.
- Submit evidence that he or she is in possession of suitable and adequate premises, installations and facilities to ensure the proper storage and distribution and, where envisaged, proper decanting, packaging and labelling of medicinal products.
- Appoint a responsible person who possesses the required expert knowledge to perform the activity.
- Enclose a statement in which he or she commits himself in writing to observe the regulations governing the proper operation of a wholesale enterprise.

The decision on granting the authorisation is taken by the competent federal higher state authority of the state in which the wholesaler is established. The authorisation can be refused if facts justify the assumption that the applicant or the person responsible for the wholesale does not possess the necessary reliability to perform the activity.

17. What regulatory authority is responsible for supervising wholesale distribution activities?

Regulatory authority
The federal higher state authorities of the state in which the wholesale is established supervise the distribution activities.

Supervision
See above, Regulatory authority.

Rights of appeal
Depending on the state where the drugs are wholesaled, it may be possible to appeal against the competent federal higher state authority’s decision. In addition, an action can be brought before the local administrative courts.

18. What are the legal consequences of non-compliance with wholesale distribution laws?

In the case of non-compliance, penalties can be imprisonment for a term not exceeding three years or a fine. In particularly serious instances, the penalty can be imprisonment from one to ten years. In addition, administrative fines of up to EUR25,000 can be imposed.

MARKETING Promotion

19. What is the general legal regime for the marketing of drugs?

Legal regime
The Advertisement of Healthcare Products Act (Heilmittelwerbegesetz [HWG]) contains the legal requirements for marketing activities of pharmaceutical companies addressed to health care professionals or consumers. In general, a marketing activity only falls within the scope of the HWG if the marketing activity is product-related and intended to increase sales of a respective product. The rules of the Act Against Unfair Competition (Gesetz gegen den unlauteren Wettbewerb [UWG]) are applicable if the marketing activity is solely company-related, for example, if no direct and/or indirect product-related information is given and only the general research activity of the company is mentioned.

Finally, the Medicinal Products Act (Arzneimittelgesetz [AMG]) also imposes legal requirements for interactions with health care professionals and patient organisations.

Limits to marketing activities
The legal limits for product-related marketing activities addressed to health care professionals and/or the general public are outlined below.

20. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

There are several industry guidelines applicable to product or company-related marketing activities of pharmaceutical companies. Those industry guidelines are either addressed to health care professionals or the general public. The following are particularly relevant:
- AKG Code of Conduct (Arzneimittel und Kooperation im Gesundheitswesen e.V.), issued by the German Pharmaceutical Industry Association (Bundesverband der Pharmazeutischen Industrie [BPI]).
- FSA Code of Conduct of Health Care Professionals (Freiwillige Selbstkontrolle für die Arzneimittelindustrie), issued by the Association of Research-based Pharmaceutical Companies (Verband forschernder Arzneimittelhersteller e.V.) [VIA].

The above industry guidelines are binding on members of the BPI and the VIA. Compliance is monitored and enforced by the FSA and AKG arbitration board. In case of non-compliance, fines of up to EUR400,000 can be imposed by one of the arbitration boards. In particularly serious cases, the arbitration board can publicly reprove the pharmaceutical company.

Industry codes are not compulsory but serve as a means of interpretation for the courts when assessing whether a marketing activity infringes the applicable legal provisions. For this reason, judges have found them useful and refer to them in judgments on breaches of the law. However, decisions have objected to the general application of such industry guidelines for non-members of the VIA. It is possible that judges will continue to use such conclusive guidelines to assess if specific practices in the field of the pharmaceutical industry infringe the general legal provisions (which apply also to other industry sectors).
21. What is the legal regime for marketing to consumers?

Legal regime
The Advertisement of Healthcare Products Act (Heilmittelwerbegesetz) (HWG) describes in detail which advertising activities are permitted with regard to consumers.

Products
Under section 10(1) of the HWG, prescription drugs can only be advertised to health care professionals. In addition, treatments against insomnia and sleep disorders cannot be advertised to consumers. Under section 3(a) of the HWG, marketing activities for unlicensed medicines are prohibited, as well as marketing activities regarding off-label use of licensed medicines.

22. What kinds of marketing activities are permitted in relation to consumers and the products which may be advertised to them?

The following marketing activities in relation to consumers are prohibited, among others (section 11(1), Advertisement of Healthcare Products Act (Heilmittelwerbegesetz) (HWG)):

- Marketing activities referring to scientific studies and professional publications.
- Marketing activities referring to an individual's medical history.
- Marketing activities that can give rise to uncertainty and anxiety.
- Promotional contests, drawings, and raffles.

Under section 4(3) of the HWG, all marketing activities to consumers must include the following notice: “For information on risks and side effects please read the pack insert and ask your doctor or pharmacist”.

23. Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, “buy-one-get-one-free”)?

It is not permitted to provide consumers with free samples of drugs (section 11(1) No. 14, Advertisement of Healthcare Products Act (Heilmittelwerbegesetz) (HWG)).

Under Article 7(1) of the HWG, special offers such as “buy-one-get-one-free” are prohibited. The Federal Supreme Court (Bundesgerichtshof) ruled that discounts and bonuses are only permissible regarding insignificant gratuities, such as consumer magazines or small advertising gifts whose value is below EUR 1.

24. Are there particular rules of practice on the use of the internet/social media regarding drugs and their advertising?

Generally, there are no specific rules on the use of the internet/social media in respect of drugs and their advertising. Only section 1(6) of the Advertisement of Healthcare Products Act (Heilmittelwerbegesetz) (HWG) states that the HWG does not apply to order forms of online pharmacies regarding the information necessary for ordering of drugs online.

25. What regulatory authority is responsible for supervising marketing activities to consumers?

Regulatory authority
The competent authorities for supervising marketing activities are the higher regional authorities in the federal states in which the pharmaceutical company is established.

Infringements of rules for the protection of fair competition by pharmaceutical manufacturers can be pursued by the competent national authorities. Under section 64(3) of the Medicinal Products Act (Arzneimittelgesetz) (AMG), the competent authority must ensure that the provisions relating to advertisements of medicines are observed. In practice, the higher regional authorities rarely pursue pharmaceutical manufacturers for infringements of unfair competition law. Instead, the German market for medicinal products is mainly self-regulated, and it is common practice that competitors apply for preliminary injunctions or initiate regular court proceedings if a competitor fails to comply with the rules for the protection of fair competition.

Supervision
See above, Regulatory authority.

Rights of appeal
In the case of an infringement, the competent authority will issue a prohibition order. This enforcement act can be objected to by the addressee, first in an administrative procedure (Widerspruch) and subsequently, if necessary, through a court procedure (Anfechtungsklage).

26. What are the legal consequences of non-compliance with consumer marketing laws?

In the case of misleading marketing activities addressed to consumers, the infringing company and person in charge can be punished with imprisonment for up to one year or fines. It is more likely that a competitor will apply for a preliminary injunction or initiate regular court proceedings if a pharmaceutical company fails to comply with the rules of the Advertisement of Healthcare Products Act (Heilmittelwerbegesetz) (HWG) see Question 23.

Marketing to professionals

27. What kinds of marketing activities are permitted in relation to professionals?

Product-related advertisements (section 3, Advertisement of Healthcare Products Act (Heilmittelwerbegesetz) (HWG)) and company-related advertisements (section 5, Act Against Unfair Competition (Gesetz gegen den unlauteren Wettbewerb) (UWG)) addressed to health care professionals must not be misleading or unfair, namely, the promotional statement must be correct and, if necessary, verifiable. The HWG and UWG contain concrete examples of misleading or unfair advertisements.

For product-related advertisements, the law requires, among other things, that the promoted medicinal product must not be ascribed therapeutic efficacy or effects that it does not possess, and that the advertisement gives no false impression that success is guaranteed or that the recommended use has no side effects (section 3 No. 1 and No. 2, HWG). In addition, product-related advertisements must always mention the mandatory information regarding the promoted medicine, and the promoted indications must be in line with the marketing authorisation, the summary of product characteristics and the package leaflet.

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A list of legal examples is set out in the UWG, which applies to company-related advertising statements (sections 4 and 5, UWQ).

### 28. Are there any restrictions on marketing to professionals?

#### Marketing activities

The legal requirements for the collaboration of pharmaceutical companies with health care professionals are partly laid down in the Advertisement of Healthcare Products Act (Heilmittelwerbegesetz (HWG)) and the Act Against Unfair Competition (Gesetz gegen den unlauteren Wettbewerb) (UWG). These statutes apply to health care professionals working in the outpatient sector as well as to health care professionals working in hospitals.

Health care professionals include (section 2, HWQ):
- Any members of health care professions and health care occupations.
- Organisations that serve human health.
- Other persons that are involved in the legal trade of medicinal products, procedures, treatment methods, objects or use such products in the course of their professional activity.

In addition, the German Criminal Code (Strafgesetzbuch) (StGB) sets out in sections 299 and 331 legal requirements regarding attempts to influence health care professionals who work in public hospitals. In June 2012, the Federal Supreme Court ruled that pharmaceutical companies cannot be punished for bribery in public affairs, under current legislation when offering money or so-called benefit programmes to physicians. Similarly, statutory health insurance physicians who accept money and gifts from pharmaceutical companies or sales representatives cannot be charged for bribery in public affairs. According to the Federal Supreme Court, physicians contracted by statutory health insurance companies are neither civil servants nor representatives of a state institution and so cannot be charged with bribery in public affairs. However, employed physicians working in medical institutions could be guilty of fraud (section 263, StGB) and breach of trust (section 266, StGB) when receiving kickback payments from pharmaceutical companies. The German legislator closed that gap in June 2016 by introducing the Law against Corruption in the German Healthcare System (sections 299a and 299b, StGB).

The Professional Code for Physicians (Musterberufsordnung für Ärzte) in its sections 33 to 35 stipulates rules and principles for the interactions of physicians, either from the in-patient or the hospital sector, with the pharmaceutical industry.

In addition, several industry guidelines govern the interaction between pharmaceutical manufacturers and health care professionals. These are the FSA Code of Conduct of Healthcare Professionals, the AKG Code of Conduct, and the Common Position Concerning the Consideration of Co-operation between Industry, Medical Institutions and Staff under Criminal Law. These industry guidelines are binding for members of the relevant industry associations, and must be observed by non-members since they serve as a means of interpretation for German courts when assessing if a certain collaboration with health care professionals infringes the respective legal provision (see Question 20).

As stipulated in the introduction of the FSA Code of Conduct, all interactions and collaborations with health care professionals “must remain within certain appropriate bounds and in accordance with the law”. In this respect, the principles of separation, transparency, documentation equivalence (as stipulated in the Common Position Concerning the Consideration of Cooperation between Industry, Medical Institutions and Staff under Criminal Law) outline valuable reference points for the collaboration of the pharmaceutical industry with health care professionals from the outpatient sector or those working in hospitals. The collaboration between pharmaceutical manufacturers and health care professionals must meet the following requirements:

- Under the separation principle, the fees paid by a pharmaceutical manufacturer for a service provided by a health care professional must not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.
- Under the transparency principle, all co-operation between pharmaceutical manufacturers and health care professionals must be notified to the administration of the professional’s medical association; usually, a prior approval is required.
- Under the documentation principle, all collaborations between pharmaceutical companies and health care professionals must be recorded in writing.
- Under the equivalence principle, the fee paid by a pharmaceutical manufacturer for the service provided by a health care professional must correspond to the market value of the service.

#### Frequency

There is no legal provision regarding how, when, or how often health care professionals can be visited by sales representatives of pharmaceutical companies.

The AKG Code of Conduct states that sales representatives should not unreasonably contact doctors during normal practice opening hours (section 25(5), AKG Code of Conduct).

#### Provision of hospitality

In most instances, contraventions result from travel and accommodation granted to health care professionals by pharmaceutical manufacturers for medical conferences. For example, health care professionals attending a job-related training event cannot be provided accommodation and hospitality that exceed a reasonable limit. Taking this into account, a dinner must not exceed EUR60 (cipher 5.1, FSA Code of Conduct), and hotel accommodation must be classified within business class, not luxury class, and should not provide any extra-ordinary entertainments or services (cipher 5.3, FSA Code of Conduct).

### 29. What information is it legally required to include in advertising to professionals?

Marketing to professionals must contain the following product information:

- Name of the medicinal product.
- Therapeutic target area.
- Warning notices.
- Name of the pharmaceutical companies.
- Composition of the drug.
- If applicable, rating as a prescription drug.
- Contraindications.
- Possible side effects.

### 30. Are there rules on comparisons with other products that are particularly applicable to drugs?

Provisions regarding comparisons with other medicinal products can be found in section 12 of the Advertisement of Healthcare Products Act (Heilmittelwerbegesetz (HWG)). Under this, comparisons with other medicinal products are allowed when used
for the purpose of marketing to professionals only. When advertising a product to consumers, comparisons with other medicinal products are not permitted.

### 31. What other items, funding or services are permitted to be provided to professionals?

**Discounts**

Discounts in kind and special offers are permitted on general sales list medicines only (see Question 2). Cash discounts are permitted on over-the-counter drugs only. This applies to marketing activities to both professionals and consumers. According to a judgment of the Higher Regional Court of Cologne, the promotion of drugs using rebates is only permissible if the rebates are product-related and not granted on products other than the promoted ones (Higher Regional Court of Cologne, judgment of 23 February 2011, ref. no. 6 W 2/11).

**Free samples**

Only medicinal sales representatives are allowed to provide health care professionals with free samples of medicinal products. Under section 47(4) of the Medicinal Products Act (Arzneimittelgesetz) (AMG), the number of samples per medicinal product and per health care professional is limited to two samples per year and can only be supplied in response to a written request. The samples cannot be larger than the smallest presentation of the medicinal product on the market. An adequate system to maintain control and accountability must be established which contains information about the date of supply and the amount of supply.

**Sponsorship of professionals**

The sponsoring of individuals is not allowed under the applicable industry guidelines. If a pharmaceutical company can only sponsor a clinic, hospital or medical association if the legal requirements are fulfilled, the financial benefit serves a medical purpose (for example, public health), it is documented, and does not constitute an undue influence on the prescription behaviour of health care professionals.

**Other items, funding or services**

It appears to be common for pharmaceutical companies to infringe the equivalence principle when co-operating with health care professionals (see Question 2). In many cases, the fee paid for the services provided by health care professionals is inconsistent with the market value of the service. According to a decision of the FSA Board of Arbitration, a remuneration of EUR80.45 for a 30-minute qualified consulting service rendered by a health care professional is considered appropriate and reasonable (FSA Board of Arbitration decision of 3 February 2009 (2008.1-220)). However, this decision can only serve as a benchmark for an assessment of the appropriate market value of such a service. The respective assessment must be carried out on a case-by-case basis and in consideration of numerous factors, such as the difficulty of the service and the qualification of the health care professional. The amount decided in the FSA Board of Arbitration decision above is, at the time of writing, the highest sum considered appropriate in Germany.

Many cases before the FSA Board of Arbitration result from gifts or services offered by pharmaceutical companies to health care professionals. As a general rule, the Advertisement of Healthcare Products Act (Heilmittelwerbegesetz) (HWG) and the respective industry guidelines prohibit the offering of products or services unless they are inexpensive and relevant to the practice of human medicine. According to established case law in Germany, a gift is considered as “inexpensive” if it does not exceed the value of EUR1 to EUR2 (purchase price).

### 32. What regulatory authority is responsible for supervising marketing activities regarding professionals?

**Regulatory authority**

Medical associations (Ärztekammern) and associations of statutory health insurance registered doctors (Kassenärztliche Vereinigung) are responsible for the supervision of marketing activities to professionals.

**Supervision**

See above, Regulatory authority.

**Rights of appeal**

In serious cases of breaches, disciplinary procedures can be started. Opposition to these procedures is possible as well as an appeal to the administrative courts (Verwaltungsgericht) against the decisions of medical associations and associations of statutory health insurance registered doctors.

### 33. What are the legal consequences in case of non-compliance with professional marketing laws?

Disciplinary procedures of medical associations and associations of statutory health insurance registered doctors can lead to administrative fines.

### 34. What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationship with patient organisations?

Engagement with patient organisations is regulated in the relevant industry codes. Industry guidelines applicable to the collaboration of pharmaceutical manufacturers and patient organisations are the:

- FSA Code of Conduct on Patient Organisations.
- AKG Code of Conduct on Patient Organisations.

These codes of conduct define the term "patient organisations" as "voluntary, non-profit organisations of patients and/or their families, whose activities involve group support in coping with diseases, disseminating information about diseases and therapy options, lobbying in health care and social policy, publishing of media to inform and support patients and/or providing advisory services".

The term "patient organisation" is also defined by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

As a main rule, the AKG and FSA Code of Conduct Patient Organisations provide that a pharmaceutical company cannot establish any patient organisation on their own (the separation principle). In addition, a pharmaceutical manufacturer must respect the neutrality and independence of a patient organisation, in particular regarding the events organised by the patient organisation (the principle of neutrality).

Pharmaceutical companies must also comply with principle of transparency, namely that collaboration and support must be executed in a transparent and open manner. As a result, pharmaceutical companies must make available to the public a list of the patient organisations that are financially supported in Germany and throughout Europe, or that receive indirect or non-financial benefits. Accordingly, the collaboration can only proceed
on the basis of a written agreement that spells out its basic elements.

Monetary contributions by member companies of the AKG and the FSA to patient organisations can only be made on the basis of a written request describing the fundamentals of the collaboration. Contributions made by member companies must be specified and described in detail.

Member companies must make available to the public a list of patient organisations to which they provide financial and non-financial support.

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**Professional qualifications.** Bar Admission, 2003

**Areas of practice**

- Particular expertise in unfair competition law, including advertisements of medicinal products and medical devices, as well as collaboration between the health care industry and health care professionals and patient organisations.

- Extensive experience in advising companies on all matters concerning pricing and reimbursement in the out- and in-patient sector (that is, AMNOG, NUB, rebates, reference pricing, DRGs and pre-market access strategies).

- Regulatory expertise covering, in particular, marketing authorisations, CE marking, distribution (agreements and GDP), placing medicinal products and medical devices on the market, compassionate use, named patient programmes, wholesaler licence, and clinical trials (applications and agreements).

- Regularly represents companies before the BFArM and PEI, and before regional authorities and courts.

**Non-professional qualifications.** University of Göttingen; Second State Examination (Higher Regional Court Berlin); Dissertation on European Medical Law, Faculty of Law of Göttingen; LL.M., Master of European Law, Kings College London

**Languages.** German, English

**Professional associations/memberships**

- Member of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE).

- Member of the Legal Working Group of the German Medical Technology Association (BVMed).

**RECENT DEVELOPMENTS AND OUTLOOK**

**35. Are there notable recent developments or regulatory projects in the field of distribution and marketing of drugs?**

There are currently no plans to reform the law on the distribution and promotion of drugs in Germany.