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Law & Practice

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Contents

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Regulatory Framework

1.1 Legislation

The legal environment for medicinal products is mainly regulated by the German Act on Medicinal Products (*Arzneimittelgesetz*, 'AMG'). The AMG prescribes, inter alia, the requirements for obtaining marketing authorisations and manufacturing authorisations, as well as wholesaler licences; it further lays down labelling and packaging requirements, the conditions for conducting clinical trials and distribution of medicinal products, as well as pharmacovigilance and import/export.

These legal provisions are supplemented by several ordinances such as the Ordinance on Good Manufacturing Practice (*Arzneimittel- und Wirkstoffherstellungsverordnung*, 'AMWHV'), the Ordinance on Good Clinical Practice (*Verordnung über die Gute Klinische Praxis bei der Durchführung von klinischen Prüfungen*, 'GCP-Verordnung'), the Ordinance on Brokering and Wholesaling of Medicinal Products (*Arzneimittelhandelsverordnung*, 'AM-HandelsV') and the Ordinance on Compassionate Use (*Arzneimittel-Härtefallverordnung*, 'AMHV').

1.2 Regulatory Bodies

The Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*, 'BfArM') is, most importantly, responsible for granting marketing authorisations for medicinal products and authorisations for conducting clinical trials. If sera, vaccines, blood preparations, bone marrow preparations, tissue preparations, tissues, allergens, advanced therapy medicinal products, xenogeneic medicinal products and blood components manufactured using genetic engineering are concerned, the Federal Institute for Vaccines and Biomedical Pharmaceuticals (*Paul-Ehrlich-Institut*, 'PEI') is competent (PEI and BfArM hereinafter as 'competent higher federal authority'). The local authorities of the *Länder* are competent for supervising and auditing (pharmaceutical) entrepreneurs in relation to good manufacturing practice, wholesaling and placing medicinal products on the market.

1.3 Challenging Decisions

The first step is to bring opposition proceedings (*Widerspruchsverfahren*) before the regulatory body within one month of its decision (administrative act, *Verwaltungsakt*). Should this challenge not be successful and the authority affirms its decision, this administrative act may be challenged at the administrative court, again within one month. If the authority declines to issue a requested decision, such as a marketing authorisation or a wholesaler licence, the applicant may file a lawsuit directly to the administrative court, in order to enforce the issuance by the authority of the requested administrative act. Both legal means are to be filed to the administrative court in written form within one month of the notification of the administrative act to the addressee/applicant.

As a general rule, challenging a decision has a suspensive effect on the authority's decision. However, a legal exemption to this is, for instance, if the BfArM/PEI has withdrawn or revoked a marketing authorisation due to safety concerns. In such a case, the administrative decision will be enforced with immediate effect, and the marketing authorisation holder (or other bodies placing the respective medicinal product on the market) must promptly stop selling/distributing the product.

1.4 Life Sciences Products

German law provides for legal definitions of medicinal products (Section 2 [1] AMG; implementing Article 1 [2] of Directive 2001/83/EC into German law), medical devices (Section 3 [1] of the German Act on Medical Devices, 'MPG'; implementing Article 1 [2a] of 93/42/EEC into German law), cosmetics (Section 2 [5] of the German Act on Food, Consumer Goods and Feed, *Lebensmittel- und Futtermittelgesetzbuch*, 'LFGB'; implementing Article 2 [1a] of Regulation [EC] No 1223/2009 into German law) and nutritional products (Section 2 [2] LFGB; referring to Regulation [EC] No 178/2002). The respective legal definitions are as follows:

'**Medicinal product**' means either any substance or combination of substances presented for treating or preventing disease in human beings (so-called medicinal product by presentation), or any substance or combination of substances which may be administered to human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a

medical diagnosis (so-called medicinal product by function).

'**Medical device**' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process; or control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

'**Cosmetic product**' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

'**Food product**' means any product which is intended to be, or might reasonably expected to be, ingested by humans.

Based on these legal definitions, the manufacturer has to determine in which classification its product belongs, and which regulatory regime applies accordingly. With this discretion, such assessments by manufacturers may deviate from the view the supervising authorities or courts may take, or a manufacturer may intentionally misclassify a product in favour of a less restrictive regulatory regime offered by the incorrect product classification.

In such cases, competitors may notify such practice to the competent authority, or may file for a preliminary injunction at a civil court, issuing a cease-and-desist order to the manufacturer in order to prevent them from placing the wrongly classified product on the German market.

1.5 Pharmaceutical Categories

In Germany there are four categories of medicinal products: (i) general sales list medicinal products (*freiverkäufliche Arzneimittel*) which do not need to be sold in pharmacies; (ii) medicinal products which can be dispensed only by a pharmacist, but no prescription is required (*apothekenpflichtig*); (iii) medicinal products only available on prescription (*verschreibungspflichtig*); and narcotic medicinal products (*Betäubungsmittel*) which are available only by special narcotic prescription.

Clinical Trials

2.1 Regulation

Clinical trials with medicinal products for human use are ruled by sections 40 to 42a AMG, as well as the German GCP-Ordinance. These legal provisions mainly rule the legal requirements for obtaining an approval from the BfArM or PEI, and obtaining a favourable opinion from the competent Ethics Committee. The legal regime for conducting clinical trials in Germany is highly harmonised in relation to the EU standard and mainly implements or refers to Regulation (EG) 2001/20/EC and EudraLex – Volume 10 Clinical Trials Guidelines.

2.2 Securing Authorisation

The sponsor, or its legal representative with its permanent place of business in the EU/EEA, has to submit a clinical trial application ('CTA') to the BfArM or PEI, as well as a request for a favourable opinion to the local competent Ethics Committee. The sponsor, the clinical research organisation, the principal investigator and/or the principal institution may only begin the clinical trial if the competent authority and the Ethics Committee have issued an authorisation.

The CTA is to include, inter alia, (i) EudraCT-number, (ii) the trial protocol, (iii) the investigational medicinal product dossier, (iv) proof of insurance, (v) informed consent forms, (vi) name and address of the sponsor, the principal investigator and the principal institution, (vii) inclusion criteria of the

clinical trail subjects, (viii) the aim of the clinical trial, etc.

2.3 Conduct and Results

The sponsor is required to list the conduct of active/ongoing clinical trials in the publicly available database called EudraCT; the respective EudraCT number becomes part of the clinical trial application to the competent higher federal authority.

In addition, since 1 January 2011, pharmaceutical entrepreneurs who place a medicinal product on the German market that requires a marketing authorisation are to publish reports on all results of confirmatory clinical trials substantiating the efficacy and safety of the medicinal product. The publication is to be placed on the database of the German Institute of Medical Documentation and Information ('DIMDI'). These reports are to be made available on the DIMDI database within six months subsequent to the granting of the marketing authorisation or modification of the marketing authorisation, if the modification is based on confirmatory clinical trials. If a clinical trial is conducted with a medicinal product which has already been granted a marketing authorisation and if this medicinal product is not being used as the comparator medicinal product, the sponsor is to make the results of the clinical trial available within one year of its completion. This disclosure obligation includes all clinical trial results, whether they are favourable or not.

Furthermore, the sponsor has to submit a summary of the clinical trial report to the BfArM or PEI, and the applicant has to submit the results of the clinical trial as part of the marketing authorisation application ('MAA').

Marketing Authorisations

3.1 Classification as a Pharmaceutical

A product is to have either a pharmacological, immunological or metabolic effect in human beings in order to be classified as a medicinal product (medicinal by effect), or is to be presented as a product for treating or preventing disease in human beings (medicinal by presentation).

There is no regulatory authority assessment procedure for products before they are placed on the market. The responsibility lies with the manufacturer to determine whether its product has a pharmacological, immunological or metabolic effect in human beings, or whether it has a mainly a physical/mechanical effect, in which case the regime for medical devices will apply. Such borderline issues are often subject to court cases in Germany.

3.2 Types of Marketing Authorisation

There are a number of different routes through which medicinal product marketing authorisation can be obtained: the centralised procedure, the national procedure, the mutual recognition procedure or the decentralised procedure.

The 'centralised procedure' is a single application made to the European Medicines Agency ('EMA') and covers marketing in the EU. The EMA (Committee for Human Medicinal Products) issues an 'opinion' as to whether the authorisation should be granted; this recommendation is usually followed by the European Commission. It should be noted that the centralised procedure is mandatory for (i) medicinal products developed by biotechnological processes, (ii) medicinal products containing a new active ingredient for the treatment of certain diseases, and (iii) orphan medicinal products (ie medicinal products intended for the diagnosis, prevention or treatment of life-threatening or very serious diseases affecting fewer than five in 10,000 persons in the community). The centralised procedure is *optional* for (i) medicinal products containing a new active ingredient, (ii) medicinal products that are shown to constitute a significant therapeutic, scientific or technical innovation, or (iii) where the granting of the authorisation is in the interests of patients at community level.

For those products where the centralised procedure is not mandatory, there are three further options for authorisation:

- The 'national authorisation' is made to the BfArM or PEI, and covers only Germany.
- The 'mutual recognition procedure' can be used where the applicant has already obtained an authorisation in one EU member state (Reference Member State). That authorisation is then relied upon by the holder to obtain further marketing authorisations in other member states (Concerned Member States).

- The 'decentralised procedure' can be used where the applicant does not yet have any marketing authorisation. It is, however, useful where a limited number of authorisations is required, as multiple applications must be sent to all member states of interest. The designated Reference Member State performs an initial assessment of the medicinal product and then sends the report and materials to the other member states involved.

3.3 Validity of Marketing Authorisations

A marketing authorisation issued by the BfArM or PEI (ie national authorisation/mutual recognition/decentralised procedure authorisation) is valid for five years. The marketing authorisation holder ('MAH') may file a request for renewal to the BfArM or PEI at least six months before the marketing authorisation expires; this has the effect that the MAH may continue to place the product on the market until the decision of the competent authority. The first renewal after five years is valid without time limitation, unless the competent authority expressly decides to cap the further period at five years' validity.

Several conditions exist under which the marketing authorisation may terminate: (i) BfArM/PEI will revoke marketing authorisation if the MAH does not place the medicinal product on the market within three years of the marketing authorisation having been issued, or does place it on the market but then discontinues it for three successive years (so-called sunset clause), (ii) the MAH waives the authorisation, or (iii) the BfArM/PEI suspends or withdraws the marketing authorisation, eg for safety reasons.

3.4 Obtaining a Marketing Authorisation

Pharmaceutical entrepreneurs have to apply for a national marketing authorisation at the BfArM/PEI. Within the MAA, the applicant must provide, inter alia, evidence of the pharmaceutical quality, efficacy and safety of the medicinal product. As regards the form and content of the MAA, further requirements are stipulated in the Guidelines for the Testing of Medicinal Products (*Arzneimittel-Prüfrichtlinie*) which implement Directive 2007/63/EC into German law. The competent authority has seven months to decide whether or not the pharmaceutical entrepreneur has provided sufficient clinical evidence on the quality, efficacy and safety of the medicinal product. Such evidence shall ideally be based on controlled clinical trials that are randomised and are versus placebo and versus an established medicinal product of proven therapeutic value (as appropriate). Any other study design needs to be justified by the applicant.

Variations to medicinal products which have already been authorised have to be notified to the BfArM/PEI. Significant variations of medicinal products can only be implemented by the MAH after the authority has given authorisation. A transfer of the marketing authorisation from the MAH to another pharmaceutical entrepreneur requires only a notification from the MAH to the competent authority.

3.5 Pharmaceuticals Not Subject to Authorisation

There are various exemptions from the rule that only medicinal products with marketing authorisation may be placed on the market. The most relevant exemptions are compassionate use programmes (*Härtefallanwendung*), named patient programmes (*Einzeleinfuhr*), investigational medicinal products, and pharmacy bulk production (*magistral formula*).

Pharmacy bulk products may be supplied directly to patients if certain requirements are fulfilled: (i) the essential manufacturing steps are carried out in a community pharmacy, (ii) in an amount not exceeding 100 packages per day, and (iii) the dispensing takes place within the framework of the existing pharmacy operating licence (ie including mail-order selling). Furthermore, such pharmacy bulk products are not subject to the prescription-only requirement, but the pharmacist should be able to document the constant demand by existing prescriptions.

Importing and placing unlicensed medicinal products on the German market under the regime for named patient programmes requires the following: (i) the medicinal product in question is a finished medicinal product, (ii) the medicinal product may be legally placed on the market in the country of origin (note: this does not necessarily require a marketing authorisation in the country of origin), (iii) the ordering and acquisition of the medicinal product is carried out by a pharmacy, (iv) the medicinal product is imported only in small quantities, (v) if the country of origin is a third country, the

medicinal product is imported solely on the basis of a physician's prescription, and (vi) a supply deficit exists, ie no identical medicinal product with respect to the active substance and no comparable medicinal product with respect to the strength are available in Germany.

Compassionate use programmes are in place for patients suffering life-threatening disease or a disease leading to severe disability, ie according to established case law in Germany some types of cancer, pulmonary infections and life-threatening types of influenza. Besides that, the requirements for compassionate use programmes are that (i) there is no other satisfactory treatment option with medicinal products approved in the EU; and (ii) an authorisation application for the medicinal product is pending or clinical trials (Phase III) of this medicinal product are still ongoing.

3.6 Pharmacovigilance

The MAH is obliged to set up and operate a pharmacovigilance system. This includes appointment of a qualified 'graduated plan officer' who is resident in a member state of the EU, and who has the required expert knowledge and the reliability necessary for exercising his/her function to set up and manage a pharmacovigilance system and to collect and evaluate notifications on medicinal product risks that have become known and co-ordinate the necessary measures.

Furthermore, the operation of a pharmacovigilance system includes several documentation and notification obligations towards the competent higher federal authority. For instance, the MAH has to notify (i) any changes to the information and documentation on which the marketing authorisation was based, (ii) any prohibitions or restrictions on the pharmaceutical in any other country in which the pharmaceutical is marketed, as well as any other new information which could affect the risk/benefit ratio of the medicinal product, (iii) the first date of marketing of each of the different approved dosage forms and strengths, (iv) any temporary or permanent cessation of the marketing of the pharmaceutical, (v) any serious adverse effect. The MAH has to document, inter alia, all suspected adverse events which have occurred in the EU and/or another country.

The competent higher federal authority may impose conditions on the MAH when granting the marketing authorisation, eg that the MAH is to conduct additional analytical and pharmaceutical-toxicological tests or clinical trials and to report the respective results. Furthermore, the competent higher federal authority sets the MAH certain obligations to perform, such as (i) a risk management plan to ensure the safe use of the medicinal product, or (ii) post-authorisation safety studies, if such conditions are necessary in the interest of medicinal product safety.

3.7 Third Party Access to Pending Applications

The German Freedom of Information Act (*Informationsfreiheitsgesetz*, 'IFG') allows anyone access to governmental information. The scope of the IFG also covers the BfArM and PEI, and anyone can access the BfArM in order to receive information about pending MAA on the basis of the IFG. Such a Freedom of Information request is limited to protect individual interests, as well as to protect commercially confidential information.

Furthermore, the AMG entitles anyone to request from the competent higher federal authority information with regard to pending MAA.

In any case, the competent higher federal authority is obliged to publish in the Federal Gazette (*Bundesanzeiger*) the following information: (i) the granting and prolongation of a marketing authorisation, (ii) the withdrawal of a marketing authorisation, (iii) the revocation of a marketing authorisation, (iv) the suspension of a marketing authorisation, and (v) the expiry of a marketing authorisation.

3.8 Wholesale Licences

A wholesale licence is required for companies that buy and sell medicinal products, unless the company possesses a valid manufacturing licence in Germany for that particular medicinal product.

Wholesale trade with medicinal products is legally defined as 'any professional or commercial activity for the purpose of doing business which 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 hospi-

tals'. According to legal commentators and established case law in Germany, the requirement 'doing business' includes any kind of trade, and includes such trade that only happens by way of paper correspondence, or electronic mail exchange, without de facto physical possession of the products being traded.

Wholesale distribution in Germany requires an authorisation from the competent authority of the federal state in which the applicant is located. The application for authorisation should include the following information: (i) the address of the specific site(s) for which the authorisation is to be issued; (ii) evidence that the applicant is in possession of suitable and adequate premises, installations and facilities in order to ensure the proper storage and distribution and, where envisaged, the proper decanting, packaging and labelling of medicinal products; (iii) the appointment of a responsible person who possesses the required expert knowledge to perform the activity; and (iv) the applicant's written statement undertaking to observe the regulations governing the proper operation of a wholesale enterprise.

The authorisation should be granted within three months of the submission of the application to the federal state competent authority. Please note that a wholesale authorisation would not be required if the applicant were in possession of a manufacturing licence for the medicinal product in question. Applying for and holding a wholesale distribution licence requires the applicant to have a permanent place of business in Germany. According to established case law in Germany, the requirement 'having a permanent place of business' in Germany is not fulfilled if the company in question stores its product in a site run by a third-party company.

Pharmaceutical Pricing and Reimbursement

4.1 Extent of Price Control

Several price regulations for medicinal products exist in Germany applying to the outpatient sector: the AMNOG procedure, reference pricing and the regime for manufacturer's rebate.

Since the Act for Restructuring of the Drug Market in the Statutory Health Insurance ('AMNOG') came into effect on 1 January 2011, the price for innovative medicinal products in the outpatient sector is subject to negotiations between the pharmaceutical entrepreneur and the statutory health insurance (*Gesetzliche Krankenversicherung*, 'SHI').

Reference price groups may be established by the Federal Joint Committee (*Gemeinsamer Bundesausschuss*, 'G-BA') if at least three medicinal products are available on the German market that provide for (i) the same active substance (first level), (ii) a therapeutically and pharmacologically comparable active substance (second level), or (iii) a therapeutically comparable effect, in particular combinations (third level).

The German legislator introduced a so-called manufacturer's rebate (*Herstellerrabatt*) in 2003. With effect from 1 January 2014 onwards, a seven per cent discount on the ex-factory price is granted to SHI. The manufacturer's rebate applies to patented medicinal products available on prescription only and to which no reference pricing applies. Furthermore, the manufacturer's rebate applies to medicinal products dispensed by community pharmacies and by hospital pharmacies for outpatient care.

Once a price is determined, the German Drug Price Ordinance (*Arzneimittelpreis-Verordnung*) regulates the respective overheads to be charged within the distribution chain in the outpatient sector, ie pharmaceutical entrepreneurs, wholesalers and community pharmacies.

4.2 Price Control Procedure

The pharmaceutical entrepreneur has to list the ex-factory price in the official German price list (*Große Deutsche Spezialitätentaxe*).

4.3 Initial Price Negotiation

For newly launched medicinal products containing new active substances, the AMNOG procedure requires that the pharmaceutical entrepreneur negotiates the price for its innovative medicinal products with the SHI Head Association. The first twelve-month marketing period price may be determined by the pharmaceutical entrepreneur alone (ie its first listing in the official price list called *Große Deutsche Spezialitätentaxe*). Meanwhile, within

this twelve-month period, the price reimbursed within the system of the SHI is negotiated between the pharmaceutical entrepreneur and the SHI Head Association, on the basis of, inter alia, the decision of the G-BA as to whether the innovative medicinal product has additional benefit in relation to its comparative therapy. Other relevant criteria for the negotiations are the 'actual sales prices' in other European countries (the so-called country basket, including the actual sales prices in Belgium, Denmark, Finland, France, Greece, Great Britain, Ireland, Italy, the Netherlands, Austria, Portugal, Sweden, Slovakia, Spain and the Czech Republic).

The price agreed upon between the SHI Head Association and the pharmaceutical entrepreneur, or alternatively determined by the competent arbitration board, applies from the 13th month onwards.

4.4 Reimbursement from Public Funds

As a general rule, medicinal products are included in the catalogue of benefits of the SHI, if they are only available in pharmacies, if they are prescription-only medicinal products, and if they are not classified as lifestyle products (such as Viagra or hair restorer). In addition, reimbursement of the product is conditional on the efficiency principle (*Wirtschaftlichkeitsprinzip*), ie that the physicians' prescription must be sufficient, appropriate and economically efficient and must not exceed the extent of the medically necessary. For example, it is established case law of the Federal Social Court that only licensed medicinal products are in line with the efficiency principle.

4.5 Cost Benefit Analysis

Health technology assessment is relevant for pricing of innovative medicinal products (ie with a new active substance). The AMNOG procedure includes a so-called early benefit assessment procedure of innovative medicinal products conducted by the G-BA. The result of this assessment serves as a relevant criterion when the pharmaceutical entrepreneur negotiates the price with SHI Head Association.

4.6 Prescribing and Dispensing Regulation

In general, a physician in Germany can either issue a prescription for a specific medicinal product and thus exclude substitution (aut idem), or a physician can issue a prescription without excluding substitution.

If substitution is not excluded by the physician, the pharmacist must dispense the prescribed medicinal product or one of the three cheapest alternatives. In this respect, discount products have priority. This means that a pharmacist is obliged to substitute the medicinal product stated on the prescription with an equivalent discounted medicinal product (often generic products) if the patient's statutory health insurance company has a discount agreement with another manufacturer. Thus, in all other cases, when there is no discounted medicinal product, the pharmacist will choose the prescribed product or one of the three cheapest alternatives.

However, a substitution is applicable only if the prescribed medicinal product and the substitute (i) contain the identical active substance and the identical amount of active ingredient per single dose, (ii) have the same or interchangeable form of presentation, (iii) have the same packaging size (so-called) N1, N2 or N3, and (iv) are for the same indication. This means, that having the same international non-proprietary name in two different medicinal products would generally not be sufficient to allow an automatic substitution at the pharmacy.

Pharmaceutical Distribution, Promotion and Marketing

5.1 Legal Governance

Any product-related advertisement for medicinal products (whether to the public or to healthcare professionals) is subject to the German Act on Advertisement in the Healthcare Sector (*Heilmittelwerbegesetz*, 'HWG'). The HWG applies only if the activity in question is product-related and intended to increase the sales of a particular product. Provided that the marketing activity is solely company-related, only the rules of the Act Against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb*, 'UWG') are applicable. Finally, the AMG also imposes legal requirements for promotional statements towards healthcare professionals and the general public.

The promotion of medical devices to healthcare professionals and the general public is less regulated. The HWG states that advertisement for medical devices should not be misleading and each promo-

tional claim should be based on sufficient scientific evidence.

In addition, several industry guidelines apply to product-related or company-related marketing activities of pharmaceutical companies. In particular, the FSA Code of Conduct of Health Care Professionals, issued by the Association of Research-based Pharmaceutical Companies (*Verband forschender Arzneimittelhersteller*, 'VfA') is relevant. If the pharmaceutical entrepreneur is a VfA member, the FSA arbitration board holds adjudications to determine whether such activities are acceptable and can issue sanctions if the rules have been breached (see below).

5.2 Enforcement

The German advertisement market for medicinal products is mainly self-regulatory, ie companies file lawsuits against competitors in order to discontinue the activity that infringes HWG or UWG. Consumer protection agencies (*Wettbewerbsvereine*) may also file for such remedies. While the authorities have the responsibility of enforcing administrative actions against companies which infringe the advertisement rules, in practice, this rarely happens.

5.3 Sanctions

The aforementioned industry guideline is binding for members of the VfA, and compliance is monitored and sanctioned by the FSA arbitration board, which can impose fines of EUR5,000 to EUR250,000. In severe cases, the FSA arbitration board will also publish details of the case and the infringer online.

If a pharmaceutical company infringes the legal advertisement provisions, a competitor may seek injunctive relief by way of preliminary injunction, or by way of main proceedings, at a civil court. A preliminary injunction may take only a few days, or weeks if a protective letter has been filed by the defendant and the competent court schedules an oral hearing of the parties. Any application for preliminary injunction should be filed to the court within four weeks of the applicant's knowledge of the infringement.

5.4 Common Issues

The most common infringements are product-related advertisements for medicines available on prescription only addressed to the general public (which is prima facie prohibited). This is due to established German case law on the wide interpretation of the requirement 'product-related'. For example, an advertisement is assessed as 'product-related' if information is indicated that easily enables the addressee to identify a particular medicine. In addition, companies may infringe the prohibition of off-label advertisement, ie advertisements for the administration of medicines outside the authorised indications.

Finally, promotional statements are often misleading with regard to the therapeutic effect of a medicinal product. German courts have a very strict approach regarding the necessary scientific evidence to found a promotional statement. Only if the promotional claim in question can be based on findings by way of randomised, controlled and double-blind clinical trials, and where the findings have been published in an acknowledged scientific journal in order to become part of the scientific discussion, is a claim assessed as not misleading.

5.5 Classifications

Different advertisement rules apply to medicinal products available on prescription only, and to OTC medicinal products. As previously mentioned, companies are not allowed to promote prescription-only products to the general public, only to healthcare professionals. OTC products may not be promoted by way of comparisons with competitor products and statements, or information relating to certain (severe) diseases, such as epidemics, tumour diseases, diseases of the metabolic system and internal secretion. There are also detailed regulations on the inadmissibility of marketing activities for OTC products using expert opinions, certain illustrations and samples.

5.6 Legislation and Procedures

The AMG prohibits the production, the placing on the market or the import of falsified medicinal products.

A falsified medicinal product is any medicinal product with a false representation of (i) its identity, including its packaging and labelling, its name or its composition as regards one or several of its constituents, including excipients, and the strength of those ingredients, (ii) its source, including its manufacturer, its country of manufacture, its country of origin or its marketing authorisation holder, or (iii) distribution channels described in the related records and documents.

A violation of this prohibition constitutes a criminal or administrative offence, depending on whether the violation has been conducted intentionally, and other constituent elements. The competent regional authorities are allowed to take all necessary measures to ensure the safety of patients.

Patents

6.1 Legislation

The requirements for German patents are contained in the German Patent Act (*Patentgesetz*) and the German Patent Ordinance (*Patentverordnung*). Medicinal products can be patented with the German Patent and Trademark Office (*Deutsches Patent- und Markenamt*) or the European Patent Office.

At the moment there is no unitary patent that exists across all EU member states, although this may change in the future with the coming into force of the Unified Patent. The Patent Cooperation Treaty ('PCT') at least provides a unified procedure for filing patent applications in its contracting states, for example with the European Patent Office.

6.2 Second and Subsequent Medical Uses

Second medical use claims are patentable according to Section 3 (4) German Patent Act. 'Second' means that the substance or compound is already known for one medical purpose, but can also be used for another purpose that was not previously known.

New dosage regimes as such are patentable in Germany, but might in a specific case not be novel. The German Federal Patent Court invalidated a patent based on lack of novelty because the dosage range of the claim was not found to be part of the patentable subject matter of the claims, as the method feature was considered to be performed by the practitioner and not related to the manufacture of the pharmaceutical (see *BPatG*, GRUR 2007, 404 – *Carvedilol II*). Therefore, it is recommended for German patent applications that second medical use claims be drafted in such a way that the dosage range is linked to the manufacture of the pharmaceutical and not to the treatment. This decision of the German Federal Patent Court coincided with a decision of the Enlarged Board of Appeal of the European Patent Office dated 19 February 2010 where it was held that, under Article 54 (5) European Patent Convention ('EPC'), a known substance can generally be patented for a specific second medical use even if the only new feature is a new dosage regime.

6.3 Patent Term Extension

A patent is granted for a maximum period of 20 years from application. EC Regulation No. 1768/92 provides the possibility to extend the patent protection for a further period of up to five years by applying for a supplementary protection certificate ('SPC').

To obtain an SPC, an application must be lodged within six months of the date on which the first market authorisation to place the product on the market was granted. If, however, the first market authorisation had been granted before the basic patent was granted, the application for an SPC must be filed within six months of the date on which the patent was granted.

A certificate will be granted if (a) the product is protected by a basic patent in force, (b) an appropriate and valid authorisation to place the product on the market has already been granted, (c) the product has not already been the subject of a certificate and (d) the authorisation referred to in (b) is the first authorisation to place the product on the market as a pharmaceutical.

6.4 Pharmaceutical Patent Infringement

Like the laws of the other EPC member states, German law also differentiates between direct and indirect patent infringements. Direct infringement is generally defined with reference to the two basic patent categories: product (device) claims and process (method) claims. Direct infringement requires (i) for a product patent, that the infringer offers, puts on the market or uses a product which includes the entirety of the features of an independent claim, or (ii) for a process patent, that the infringer offers or practises a process which includes all steps of an independent claim. Indirect infringement occurs when a third party supplies an unpatented part of a combination product.

Applying for marketing authorisation as such is not recognised as patent infringement in Germany. However, the grant of a marketing authorisation can result in the assumption that there is a threat of infringement. This means that at least at the point of marketing authorisation a claim to cease and desist might be brought against the marketing authorisation holder.

6.5 Defences to Patent Infringement

Section 11 of the German Patent Act provides for an experimental use exemption and for a regulatory approval exemption, also called the 'Bolar' exemption. Both exemptions are extremely important in relation to pharmaceuticals.

The experimental use exemption means that experimental use is exempt from patent protection, and is interpreted more broadly in Germany than in other European countries such as Italy or the UK. In Germany this exemption covers an experimental use which also generates data required for obtaining regulatory marketing approval, provided that the respective experiments are not performed solely for this purpose, but can be considered to also aim at discovering something unknown about the used drug invention.

The regulatory approval exemption applies not only to experimental use, but also to studies, trials and the consequent practical requirements necessary for obtaining an authorisation to market a drug. This exemption therefore also includes the manufacture of pharmaceuticals, provided that they are necessary to conduct studies and trials.

6.6 Patent Infringement Actions

As the registered owner of a patent, the patentee is entitled to initiate proceedings for patent infringement as well as the exclusive licensee, irrespective of whether or not the exclusive licensee is registered. A non-exclusive licensee requires the authorisation of the licensor in order to be allowed to start proceedings for patent infringement.

A feature of German law is that the 'bifurcated system' applies: it is not possible to combine patent infringement proceedings and nullity or opposition proceedings. Infringement proceedings are heard before specialist chambers at 12 civil courts that are competent for patent infringement proceedings by statutory law. Nullity and opposition proceedings are dealt with exclusively by the German Federal Patent Court (*Bundespatentgericht*).

Besides the proceedings in the main case, it is also possible to file an application for a preliminary injunction. Before doing so, it is recommended that a warning letter be sent to the infringer in order to avoid a negative cost order by the court if the infringer were to accept the claims asserted by the patentee in the application for a preliminary injunction. In order to obtain a preliminary injunction the patentee must prove by prima facie evidence that the patent in question has been infringed and that the enforcement of the patent is necessary by means of the preliminary injunction rather than by the slower proceedings in the main case.

6.7 Procedures Available to Generic Entrants

A generic company may file nullity actions against the infringed patent and also a declaratory action for non-infringement. It may also be advisable in specific cases to file a protective pleading in order to avoid a preliminary injunction including a cease-and-desist order for the generic company being issued.

The market entry of a generic company should in any case be accompanied by a freedom to operate analysis or a patent clearance analysis. The aim of such an analysis is to examine whether the generic company would infringe a competitor's patent with its product in development.

IP Other Than Patents

7.1 Legislation

German law provides the possibility that patent-infringing products may be seized at the German border. For such seizure the patentee must file an online application for seizure with the customs authorities. An order for seizure by the customs authorities remains valid for one year. Within this year, the patentee can initiate proceedings in the main case before the competent court or can take the simplified path to file an application with the customs authorities to destroy the seized patent-infringing products. The customs authorities may render an order to destroy the seized products if an expert opinion confirms that the respective products infringe a patent and if the owner of the products has given their consent to the destruction of the products. Such consent is deemed to have been given by the owner of the products if they do not oppose the destruction within a specific time period set by the customs authorities.

7.2 Restrictions on Trade Marks

All trademarks, including trade-marks for pharmaceuticals, must be distinctive and must not infringe trade-mark rights of third parties who had previously applied for registration.

The BfArM has the authority to refuse the marketing authorisation of a pharmaceutical if the applicant intends to market this product with a mark that is identical to a trade mark already used for another pharmaceutical (but with a different active ingredient or dosage). The BfArM is very strict in the application of this rule. This means that it is not possible to use umbrella brands for pharmaceuticals with different active ingredients.

7.3 Restrictions on Products from Other Markets

Parallel imports of pharmaceuticals are permitted within the EU if the product in question is identical to or largely equivalent to another product which is already marketable in the importing EU member state. Parallel imports from non-EU countries are prohibited. In Germany, the Federal Court of Justice (*Bundesgerichtshof*, 'BGH') has held that the doctrine of international exhaustion governs parallel import, subject to the EU rules mentioned above.

7.4 IP Protection

It is possible to protect the design of pharmaceuticals, medical devices or their packaging by a design patent, provided that they have an individual character. A design has individual character if the overall impression it gives to the informed user differs from the overall impression given to that user by any other design that has been made available to the public before. When assessing individual character of a design, the degree of freedom of the designer in developing the design shall be taken into consideration. A German industrial design can be filed with the German Patent and Trademark Office in Munich. The German Industrial Design Act also provides a grace period of twelve months for the designer's own prior use and publication before the filing date or priority date. Furthermore, the German Industrial Design Act provides for an 'exhibition priority' for presentation at an exhibition permitted by the German Ministry of Justice in the Federal Law Gazette for providing protection at exhibitions and an exhibition priority.

Competition Law

8.1 Infringing Activities and Agreements

In recent years in the field of pharmaceuticals, the German Federal Cartel Office (*Bundeskartellamt*, 'BKartA') has especially sanctioned price agreements as well as price recommendations for resellers and calls for boycott due to breach of the German Act against Restraints of Competition (*Gesetz gegen Wettbewerbsbeschränkungen*, 'GWB').

In 2007, the BKartA imposed fines amounting to a total of EUR150,000 on eight pharmacists due to price agreements on non-prescription medicines.

In 2008, the BKartA imposed fines amounting to a total of EUR465,000 on pharmaceutical and pharmacist associations, as well as pharmaceutical laboratories, due to calls to pharmacists to adhere to the price recommendations of pharmaceutical laboratories. Furthermore, the BKartA prevented price increases agreed between two further pharmaceutical laboratories in the field of colistin-containing antibiotics and enforced price reductions for the respective preparations.

Again in 2008, the BKartA imposed a fine amounting to EUR10.34 million on a German pharmaceutical company for influencing resale prices of non-prescription medicines in pharmacies in an anti-competitive manner.

In 2009, the BkartA imposed fines amounting to a total of approximately EUR1.2 million on pharmacist associations and private individuals due to a call to boycott a pharmaceutical wholesaler.

Further arrangements and activities that may violate the GWB are: agreements on sales quotas, allocation of sales territories or customer groups, tying arrangements and discount systems.

8.2 Pay-for-Delay Agreements

There is no case law yet existing in Germany with regard to 'pay-for-delay' agreements. However, the European Commission has already specifically examined 'pay-for-delay' agreements in 2013 in several cases (Lundbeck; Johnson & Johnson/Novartis), by which the market introduction of a generic was restricted by an originator's granting of financial advantages towards the generic company, and the Commission imposed fines. Thus it is only a matter of time before the BKartA will examine 'pay-for-delay' agreements in Germany.

8.3 Life Cycle Strategies

There is no case law existing yet in Germany with regard to life-cycle strategies of originators versus generic drug companies.

8.4 Procedure in the Event of a Breach

Proceedings for breach of competition law may be initiated by the BKartA or federal antitrust authorities themselves ex officio or on the basis of a (possibly anonymous) tip-off. Anyone can submit a complaint against a breach. In practice such complains are generally submitted by competitors or employees of the company in breach.

The BKartA is responsible if there are grounds for believing that the cartel-related offence has an overlapping effect in different federal states; otherwise, the respective regional cartel office is responsible. In cases where the breach is not limited to Germany but has relevant impact on other countries in the EU, the European Commission may also be responsible.

The antitrust authorities have extensive investigatory powers they can use to uncover infringements of antitrust law. The most important ones are an informal request of information and the disclosure obligation, the order to submit documents, accession and auditing rights as well as inspections and seizure.

Inspections ('dawn raids') of antitrust authorities will generally be made unannounced and simultaneously with inspections at all companies involved. The inspection right in principle requires a judicial injunction, but the antitrust authority may, in a case of imminent danger, also conduct an inspection without judicial injunction.

In general, there is no right to refuse the surrender of documents. Only confidential correspondence between the company and an external lawyer does not have to be disclosed ('legal privilege').

Should an antitrust authority detect an infringement of antitrust law, it may take different measures. The most important ones are an injunction to take measures to terminate the breach, an injunction to establish ex post an antitrust infringement, obtaining undertakings from the respective companies to refrain from the prohibited practices, the imposition of fines and the skimming-off of the economic benefits gained.

The BKartA may grant immunity from or a reduction of a fine to cartel participants that co-operatively helped to disclose a cartel. The so-called Leniency Programme determines the criteria for an immunity or reduction of a fine.

Transactions/Collaborations

9.1 Key Legal Provisions

In order to develop their business, pharmaceutical companies may purchase new products and/or technologies from third parties or they may just purchase another company which fits into their business strategy. Mergers and reorganisations might also be an option. Further to this, different forms of co-operation are available for German entities. Joint ventures could be an option, especially for research and development purposes but also for the purpose of distribution. Finally, licence agreements

as well as other commercial agreements, especially research and development agreements, are possible forms of co-operation in the pharmaceutical sector.

Acquisitions of other companies or parts of other companies can be effected by way of either a share or an asset deal in Germany. The contracting parties can freely decide which method they want to use. However, these methods vary significantly, from both a legal and a tax point of view.

An asset deal between the target company itself and the purchaser is characterised by the acquisition of assets and liabilities of the target company. These assets and liabilities must be specified as precisely as possible as well as entirely according to the German principles of legal certainty (*Bestimmtheitsgrundsatz*) and must be transferred on an individual basis. Accordingly, the assets are transferred according to their specific legal requirements, which vary depending on whether these are, for example, movable or immovable assets. Finally, the transfer of contracts with third parties usually requires the third party's consent to the transfer, ie a transfer of these contracts is conditional upon the third party's approval.

A share deal is agreed between the shareholders of the target company and the purchaser, ie the shareholders sell their shares in the target company. In contrast to an asset deal, the title to the assets and liabilities constituting the business is not affected by the acquisition of the shares in the target company. A share deal results in an exchange of the shareholders of the company but the assets remain with the target company and are not affected by the transaction.

In principle, acquisitions in the pharmaceutical sector follow the general rules for transactions. However, there are certain specifics, due to the strict regulatory rules in this sector. Depending on whether the products are medicinal products, more or less strict rules apply. With regard to the drafting of a sale and purchase agreement ('SPA') in the pharmaceutical sector, attention should be drawn in particular to the following issues: (i) the drafting of the guarantees and warranties section, (ii) the conditions for the sale of the business, especially with regard to the German merger control regulations, and (iii) the drafting of rules of conduct for the post-signing period of the transaction. The warranties and guarantees should cover additional and specific regulations with respect to the following issues: (i) obligatory approval of medicinal products, (ii) potential product liability issues and product recalls, (iii) intellectual property rights and (iv) pharmaceutical compliance issues.

From a German antitrust point of view, transactions/mergers must always be checked with regard to a potential merger control requirement. If the requirements for a merger control are met, the merger must be notified to the BKartA. In this case the completion of the transaction is conditional upon the BKartA's approval of the transaction. This entails consequences for the post-signing period. As this approval process and the completion of possible other conditions may take time, there should be a regulation in the SPA defining rules of conduct for both parties during this interim period.

With regard to German transactions, it should be noted that there is detailed and complex employee protection legislation in place which has to be considered and which may influence the transaction. With regard to the acquisition of shares in a company listed with the German stock exchange, the German Takeover Act (*Wertpapierübernahmegesetz*) has to be taken into consideration.

There are two different types of joint ventures in Germany: 'contractual joint ventures' and 'equity joint ventures'. A contractual joint venture is established by a joint venture agreement and lays down the basic principles of the parties' co-operation as well as the respective rights and duties. In contrast, an equity joint venture is accompanied by the establishment of a joint venture company. Accordingly, the contractual joint venture has only internal legal effects for the relationship between the parties. There are no specific legal requirements for establishing joint ventures in Germany. Essentially, the parties are free to choose the legal form of the joint venture company. However, this is usually a limited liability company (*GmbH*) or a limited partnership with a limited liability company as general partner (*GmbH & Co. KG*). Depending on the extent of the co-operation, the German merger control provisions must be complied with.

There are no specific legal provisions for licence agreements or research and development agreements. Due to the complexity of these contracts and the reference to different fields of law (especially intellectual property rights) such contracts have to be tailored for each specific case. However, the following issues are important for contracts in the pharmaceutical sector, for example: (a) regulations on confidentiality and (b) change of control clauses. The Employee Invention Act (*Arbeitnehmererfindungsgesetz*) has to be considered for research and development agreements.

9.2 Bridging the Valuation Gap between Buyer and Seller

If there are valuation gaps between the buyer and the seller, there are various customary options to bridge this gap.

A typical option is the agreement of an 'earn-out clause' in the SPA. 'Earn-out clauses' are often used when the contracting parties disagree about the expected development and performance of the target company after closing. An 'earn-out clause' forms part of the purchase price regulation in the SPA. One part of the purchase price would be performance-based, ie be conditional upon the target company achieving certain financial goals. These financial goals will be defined in the 'earn-out clause'.

An alternative option (but often combined with an 'earn-out clause') could be the agreement of a 'vendor loan'. The idea of a 'vendor loan' is that the seller grants to the purchaser a respite for the payment of the purchase price (part of the purchase price or the entire purchase price) by making a loan in the corresponding amount available to the purchaser. In fact, the seller lends money to the purchaser which is to be used by the purchaser to buy the target business. Such a 'vendor loan' is usually used when the seller's expectations of the development of the target's business are higher than those of the purchaser's bankers or when the purchaser does not have sufficient funds available to purchase the target business.

Finally, an alternative option to pay (part of) the purchase price could also be the agreement of 'options' for the seller, ie options for the seller to acquire/receive shares/interests in the purchaser or its affiliated companies as consideration for the transfer of the target business. This could especially be an option if the purchaser does not have sufficient funds available to finance the purchase price.

9.3 Purchase Price Adjustments

The SPA will either set the purchase price or alternatively provide for a purchase price mechanism to determine the purchase price further down the line.

There are two typical models for purchase price adjustments: the 'completion model' and the 'locked-box model'. If the parties agree to the completion model the preliminary purchase price is determined on the basis of preliminary financial figures (eg working capital, net debt, free cash flow) for the agreed transfer date and is adjusted after the closing date. In the case of a so-called 'locked box' the parties agree on a fixed purchase price at an economic transfer date which is a date prior to the transfer date agreed in the SPA. From the economic transfer date onwards, any profit and loss of the target company is attributed to the purchaser.

9.4 Deal Protection Agreements

Depending on the stage of the transaction, there are usually different agreements to protect the parties. Before the signing of the SPA it is usually of vital importance to the seller that the transaction itself, in addition to the information disclosed in the context of this transaction (especially in a due diligence process), is treated as absolutely confidential. To this end, the contracting parties, as well as their advisers, agree to 'Confidentiality Agreements'. By signing such an agreement the parties agree to keep both the transaction and the information disclosed confidential. Such agreements often include penalty clauses for the failure to comply with the provisions of the agreement.

Furthermore, the parties often agree upon an 'Exclusivity Agreement', which obliges the seller to enter into negotiations for the sale of the business only with a certain purchaser. Finally, the parties could agree upon 'Break-up Fees', which under certain conditions oblige the party terminating the negotiations to pay the costs caused by the unsuccessful negotiations.

After signing the SPA it is in the seller's interest to receive the whole purchase price. However, it might be in the interest of the purchaser to retain

part of the purchase price, because he might be entitled at a later date to reclaim parts of the purchase price (eg in case of violation of guarantees and warranties). In order to ensure sufficient funds at the seller's end to satisfy such claims, it could be advisable for the purchaser either to retain part of the purchase price or, as a compromise between the interests of the seller and the buyer, to make an 'Escrow Agreement'. Alternatively, the interests of the purchaser could also be secured by way of a bank guarantee of the seller or other securities.

9.5 Local Antitrust Approval

The regulations of the German merger control are laid down in Sections 35 to 43 of the GWB. Depending on whether or not the transaction has a 'Community dimension' (*gemeinschaftsweite Bedeutung*), it is either (in the case of a Community dimension) the European merger control according to the European Merger Regulation (*Fusionskontrollverordnung*) which is applied, or otherwise the German merger control.

The BKartA is exclusively responsible for the merger control. The BKartA distinguishes between mergers which are subject to a merger control and mergers which are not subject to such control. In the case where the requirements for a merger control are met, there is a duty to notify the proposed merger to the BKartA which then evaluates the proposed merger. Without an antitrust approval from the BKartA following its evaluation, a proposed transaction may not be implemented. The GWB distinguishes between four cases of merger: (i) acquisition of at least 25% of the capital/voting rights of the target, (ii) acquisition of the assets or of a substantial part of the assets of the target, (iii) acquisition of the control over another company, and (iv) any other agreement which leads to a dominant influence over the target entity.

However, a notification to the BKartA is required only if the following prerequisites are met: (i) the group revenues (worldwide) exceed EUR500 million, (ii) the revenue of at least one of the two parties exceeds in Germany EUR25 million, and (iii) the other company's revenue in Germany exceeds at least EUR5 million. These German merger rules also apply to mergers taking place outside Germany or involving non-German entities, provided that the merger has an effect on the German market and the above-mentioned requirements are met.

9.6 Tax Treatment

Under German tax law, a share deal and an asset deal may entail different tax implications for the seller and purchaser. In principle (and especially for the situation described below), an asset deal, from a mere tax perspective, is more favourable for the purchaser, whereas a share deal is in general in favour of the seller. However, this may vary, depending on the entities involved in the transaction and should therefore always be carefully analysed for each specific case.

Due to the complexity of the German tax law, for this description, we focus on the following situation: for the share deal, the shares in the target company (German limited liability company, 'GmbH') are owned by a German-resident corporation (ie GmbH) and are sold to a German-resident corporation (ie GmbH) whereas for the asset deal we assume that the target company is a German corporation (ie GmbH) and the assets are sold to a German corporation (ie GmbH). In these cases basically the following tax implications arise:

Any capital gains derived from the disposal of shares in the GmbH are generally tax-exempt except for 5% of the capital gain treated as a non-deductible business expense (*nicht abzugsfähiger Teil*), ie such structure is in general more favourable for the seller. The sale of the assets of the German GmbH to the purchaser would be subject to full taxation. For the purchaser, the asset deal is more favourable because they will be allowed to step up the acquired assets and gain a higher level of depreciation and amortisation. In contrast, a share deal would be disadvantageous for the purchaser as the shares (in principle) cannot be depreciated or amortised.

9.7 Licensor Insolvency

The protection of licensees granted by the German Insolvency Code is relatively weak when compared to the protection in other jurisdictions and thus is often seen as a disadvantage. Where a licence contract has not been completely performed by the parties, the insolvency receiver (for the licensor) may opt to refuse performance of such a contract. In such a case, the licensee may claim damages

for non-performance, but only by registering the claims to the insolvency table.

Due to this unsatisfactory situation, which has given rise to controversy for years, there have been a number of attempts to find contractual solutions providing protection to the licensee, some of which are regarded as watertight, albeit complex. However, there is an ongoing legal uncertainty, as the courts have decided on only some parts of these contractual solutions.

Investigations/White-Collar

10.1 Investigatory Focus

In comparison to other industries, the focus of white-collar crime in the pharmaceutical industry is on patent and trade-mark infringement as well as in corruption and bribery. Investigations by the public prosecutor focus on commercial activities of physicians but also pharmacists, often in respect of co-operations in the course of clinical observation studies and consultancy agreements.

10.2 Navigating the Investigation

The conduct in the course of investigations in the pharmaceutical industry does not differ from such conduct in investigations in other industries.

In the case of an inspection in the course of a criminal investigation, the reason for the visit should firstly be clarified, and the legal department and, where appropriate, an external lawyer, should immediately be notified. The officials should show their professional identity cards and the search warrant, and the officials' personal data should be noted or copied. The investigation should be continuously attended by a lawyer. The officials should be accompanied permanently and the course of the investigation be noted down. Under no circumstances must the officials be impeded. There is, however, no obligation for any person concerned to co-operate. A list of seized documents found during the investigation may be demanded. If possible, such documents should be photocopied.

There is no obligation on the part of a witness to appear at the police station and to testify. However, a witness must provide his/her personal data. Should a witness be summoned by the public prosecutor, he/she is under an obligation to appear and generally must provide witness statements regarding his/her person as well as in relation to the case. An accused person must also appear if served with a proper subpoena by the public prosecutor, but has the right to remain silent during all stages of a criminal proceeding. A witness or accused person should always consult their lawyer in the case of any interviews/hearings.

10.3 Landmark Cases

There have been a number of important decisions in the field of corruption and bribery in the field of pharmaceuticals in the last few years.

Wide publicity and numerous discussions have been caused by a decision of the BGH published in June 2012. According to this, physicians in private practice obtaining a commission for the prescription of pharmaceuticals are not guilty of corruption. The German government intends to eliminate this gap in German criminal law.

In 2013, a pharmaceutical company accepted a fine of EUR28 million due to a corruption scandal. The background to this affair was that employees of the company were accused of having paid bribes to an external consultant of a customer for orders awarded to the company.

Currently, there are investigations by public prosecutors against physicians, pharmacists and pharmaceutical companies due to alleged corruption offences throughout Germany in connection with anti-cancer medication.

10.4 Pharma Sector Investigations

Investigations in the pharmaceutical sector do not differ from investigations in other sectors.

Product Liability

11.1 Regime for Pharmaceuticals

The AMG provides for a strict liability regime for pharmaceuticals which takes priority over the German Product Liability Act. Liability according the AMG includes liability for development risks and requires a compulsory insurance to be in place.

11.2 Liability

In comparison to the liability for other products, the liability for pharmaceuticals under the AMG is a strict liability regardless of fault.

A claim under Section 84 of the AMG arises if (i) a person has suffered personal injury or death as a result of a defective pharmaceutical or of incorrect or insufficient product information; (ii) the pharmaceutical has or is deemed to have marketing authorisation; and (iii) the use of the pharmaceutical was appropriate and in accordance with the product information.

Under Section 84 of the AMG, the entity named on the packaging which placed the pharmaceutical on the German market is held liable for any damages that arise from that pharmaceutical. This means that importing companies or re-importers are also liable if the pharmaceuticals are sold under their name. If more than one party is responsible under these rules, each party is jointly and severally liable.

11.3 Standard of Proof

The claimant generally needs to prove a causal link between the defective pharmaceutical and the damage. However, the BGH ruled that, in a case of inadequate product information, it is the defendant who has to prove that the injured person would have used the pharmaceutical even if he had been fully and accurately informed.

Furthermore, the rules on causation for pharmaceuticals were changed by the German legislator in 2002. It is now stipulated that actual causation between the application of a pharmaceutical and the damage is presumed if the pharmaceutical is generally capable of causing such damage in the actual circumstances. This rule is not applicable if a different event could have caused the damage. However, the use of a further pharmaceutical cannot be classified as a different event.

In addition, please note that it is not clear at this point in time whether the causation rules described above are in line with EU law. These rules in the AMG may contravene the Product Liability Directive. Article 13 of the Product Liability Directive allows special product liability systems to remain applicable if they existed at the time when the Directive was notified in 1985. The AMG dates back to 1976. However, the relevant changes to the causation rules were made in 2002. The question is whether special liability systems existing in the time at which the Product Liability Directive was notified remain completely applicable, even if they have been amended after the notification of the Product Liability Directive. The BGH has filed a request for a preliminary ruling with the European Court of Justice in this regard. The decision of the European Court of Justice has not yet been rendered.

11.4 Specific Defences

The liability regime is one of strict liability and there is no separate development risks defence and no regulatory compliance defence. The defence that there is no liability for product defects which were not identifiable based on the state of scientific and technical knowledge at the time the pharmaceutical was put into circulation ('state of the art defence') is also not available regarding liability for pharmaceuticals in Germany.

11.5 Regulatory Compliance Defence

Due to the strict liability regime for pharmaceuticals regardless of fault there is no 'regulatory compliance defence' in Germany.

11.6 Market Share Liability

The actual causation between the application of a pharmaceutical and the damage is presumed if the pharmaceutical is generally capable of causing such damage in the actual circumstances. This rule would not be applicable if a different event could have caused the damage. However, the use of a further pharmaceutical cannot be classified as a different event.

11.7 Statute of Limitation Period

Product liability claims for pharmaceuticals have to be asserted within three years, either from the date at which the patient had knowledge of the damages caused by the pharmaceutical and of the liable party or from the date at which the damage was caused, but at which the patient had no knowledge due to negligent ignorance.

11.8 Claims Against Manufacturers or Public Authorities

A claim for information against manufacturers of pharmaceuticals and administrative bodies is stip-

ulated in Section 84a of the AMG. Such a claim has the following prerequisites: (a) proof of intake of pharmaceutical and damage and (b) availability of facts that support the assumption that the pharmaceutical has caused the damage. If the claim for information is granted, it comprises information on the efficacy of the pharmaceutical, adverse side effects and suspected cases of adverse events as far as necessary to substantiate the claim for damages. Information concerning trade or business secrets or personal data is excluded.

11.9 Damages

In the case of death, compensation is payable for the costs of an attempted cure as well as for financial loss incurred by the deceased party as a result of the suspension or reduction of his or her earning capacity or the resultant increase in needs during the disease. The defendant is also liable for funeral costs and for the legal obligation to support third parties.

In the case of injury to a person's body or damage to health, the costs of treatment have to be reimbursed as well as the financial loss incurred as a result of the temporary or permanent suspension of or reduction in earning capacity or the resulting increase in the person's needs.

Individual claims according to Section 84 of the AMG are limited to EUR600,000. If the claimant is awarded an annuity, such annuity is limited to EUR36,000 for each year. If the same pharmaceutical has caused injury to several persons, the liability is limited to EUR20 million in total and to EUR7.2 million per annum.

11.10 Recent Decisions

A landmark decision of the European Court of Justice as to whether the special strict liability system for pharmaceuticals in Germany is in line with the European Product Liability Directive or whether this regime will no longer be able to continue is awaited in the course of 2014.

11.11 Trial Structure

The trial is held before a chamber of the competent Regional Court (*Landgericht*) whereby the chamber comprises three judges.

As in other German civil law proceedings, there is no disclosure obligation for documents or other evidence for the parties (which is in contrast to jurisdictions such as the US or, with some modifications, the UK or Ireland).

11.12 Legal Developments

The special product liability system for pharmaceuticals in Germany might contravene EU law and might therefore have to be changed. A request for a preliminary decision on this issue submitted by the BGH with the European Court of Justice on 6 June 2013 has not been decided yet.

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