

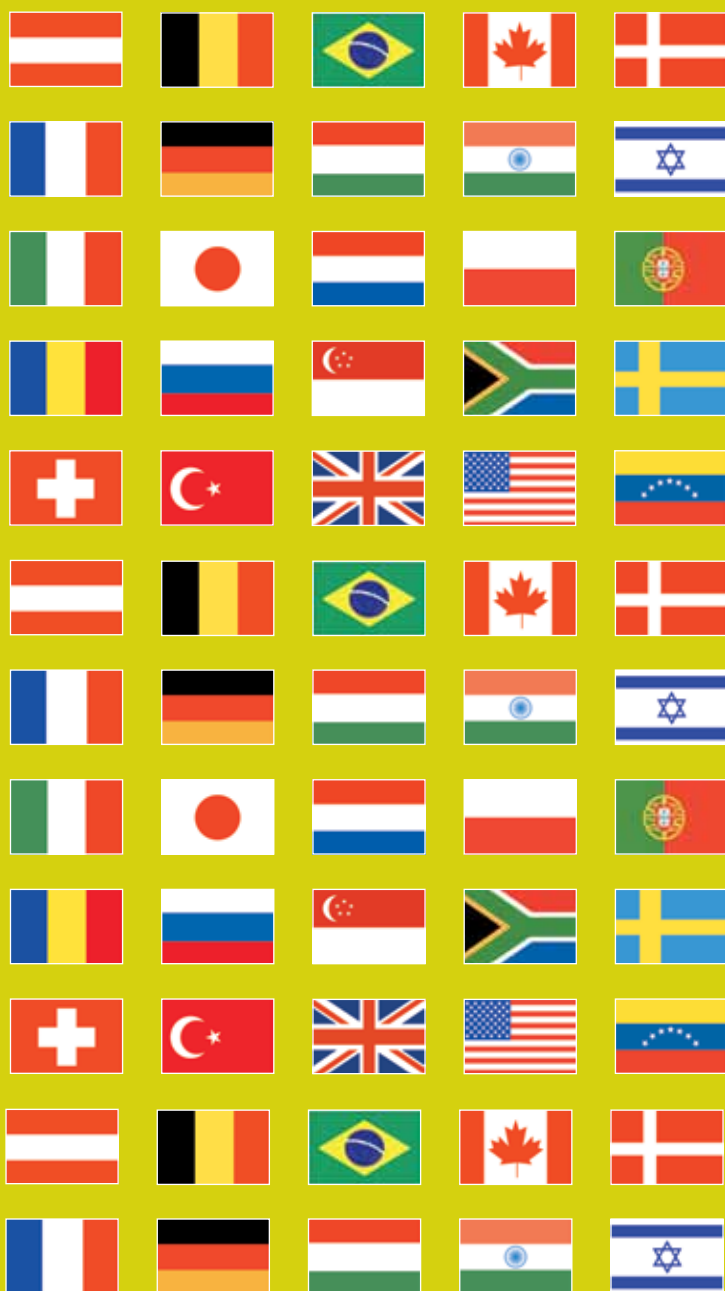


Life Sciences

in 25 jurisdictions worldwide

Contributing editors: Alexander Ehlers and Cord Willhöft

2012



Published by
Getting the Deal Through
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Life Sciences 2012

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Life Sciences 2012

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ISSN 2042-4329

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Germany

Alexander Ehlers and Cord Willhöft

Ehlers, Ehlers & Partner

Organisation and financing of health care

1 How is health care in your jurisdiction organised?

The health-care system in Germany is organised by the statutory health insurance system (GKV). Approximately 85 per cent of the population in Germany is insured within the GKV; the remaining population is privately insured. In the GKV, the legislature creates the legal framework for the provision of medical services and the medical self-governing bodies, such as the associations (on a federal and regional level) of physicians (KVs), the statutory health insurance funds (SHI funds) and the German Hospital Federation, formulate and implement in detail which health-care services will be provided and under what conditions.

The most relevant decision-making body in the system of the GKV is the Federal Joint Committee (G-BA), an association representing all relevant parties of the health-care sector such as physicians, hospitals, sickness funds and patients. The G-BA issues directives and determines the benefit package of the GKV. The organisation of the GKV, the responsibilities of the G-BA and the other self-governing bodies, as well as the provisions for medical care are laid down in the Social Code Book V (SGB V).

In addition, as a main principle, the SGB V sets out that the patient's entitlement for medical service within the system of the GKV is restricted by the 'efficiency principle', namely that the respective health care must be sufficient, appropriate and economically efficient, and must not exceed the extent of what is necessary. In the recent past, the SGB V has been subject to numerous legislative changes and amendments to enhance competition between the health-care providers and the sickness funds.

2 How is the health-care system financed in the outpatient and inpatient sectors?

In the system of the GKV, the provision of medical care is funded by a statutory contribution system, which constitutes the major system of financing the health care of the insured. The insured and their employers must pay contributions to SHI funds in Germany, which transfer the contributions to a health-care fund. The German Federal (Social) Insurance office administers this fund and transfers the contributions to the SHI funds, according to the structure of their insurance. The amount to be paid by each person is dependent on his or her income and not on individual health risks. Finally, the health-care insurance of an insured employee covers non-earning spouses and children, without any additional charges.

In the outpatient sector, the provision of health care is financed by payments of the SHI funds to the respective KV (see section 85(1) SGB V), which conveys the payments to the medical service provider in the outpatient sector. In the hospital sector, the payments of the SHI funds are transferred directly to the respective hospital. Costs incurred in the hospital sector are covered by diagnosis-related groups (DRG). A DRG is calculated in consideration of the primary

diagnosis, the necessary treatment, the co-morbidity, if relevant, and patient-related factors such as age and gender.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertisement of medicinal products to the general public and health-care professionals?

In Germany, the legal requirements for marketing activities of pharmaceutical companies addressed to health-care professionals or the general public are laid down in the Advertisement of Medicinal Products Act (HWG). However, a (marketing) activity in general falls within the scope of the HWG only if the activity in question is product-related and intended to increase the sales of a respective product. Provided that the (marketing) activity is solely company-related, the rules of the Act Against Unfair Competition (UWG) are applicable. Finally, the Medicinal Product Act (AMG) also imposes legal requirements for interactions with health-care professionals and patient organisations.

In addition, several industry guidelines apply to product or company-related marketing activities of pharmaceutical companies, either addressed to health-care professionals or the general public. In particular, the AKG Code of Conduct, issued by the German Pharmaceutical Industry Association (BPI) and the FSA Code of Conduct of Health Care Professionals, issued by the Association of Research-based Pharmaceutical Companies (VfA) are relevant. The aforementioned industry guidelines are binding for members of the BPI and the VfA, and the compliance is monitored and sanctioned by the FSA and AKG arbitration board. Even if a pharmaceutical company is not a member of the BPI or the VfA, these regulations shall be observed by pharmaceutical companies, as these industry guidelines serve as a means of interpretation for the courts when assessing whether a marketing activity infringes the applicable legal provisions or not. This assessment applies, in our view, although a recent court decision of the Higher Regional Court Munich has questioned the general application of such industry guidelines also for non-members of the VfA. The before mentioned industry guidelines are specific and detailed with respect to activities in the sector of the pharmaceutical industry. Therefore, one might expect, in our view, that judges may continue to use such conclusive guidelines to assess if a certain practice in the field of the pharmaceutical industry infringes the general legal provisions (which apply also to other industry sectors).

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

As a main rule and principle, product-related advertisements (section 3 HWG) and company-related advertisements (section 5 UWG) addressed to health-care professionals must not be misleading or unfair, namely, the promotional statement must be correct and, if necessary, verifiable. HWG and UWG contain concrete examples of misleading or unfair competition. As far as product-related advertise-

ment is concerned, most importantly, the law requires, *inter alia*, 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). A respective list of legal examples is set out in the UWG, which applies to company-related advertising statements (section 4 and section 5 UWG). In addition, as further main principles applying to product-related advertisements, the advertisement should 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.

5 What are the main rules and principles applying to advertising aimed at the general public?

The above-mentioned rules and principles with regard to advertisements addressed to health-care professionals also apply to advertisements addressed to the general public. Thus, the promotional statement addressed to the general public must not be misleading or unfair.

In addition, further legislative provisions apply to enhance the protection of the general public, as the public is considered to have no (profound) medical knowledge. For instance, the HWG sets out in section 10 that the advertisement of medicines available on prescription only is prohibited to the general public. This prohibition shall ensure that the health-care professional decides independently on the prescription of a certain medicine and solely based on medical considerations that are not influenced by the patient. Furthermore, the HWG stipulates a list of examples of advertisements that shall not be directed to persons other than health-care professionals, as they are potentially misleading or manipulative. These are, *inter alia*, advertisements containing:

- scientific or professional publications;
- statements alleging that the medicine is recommended, tested or used by health-care professionals;
- foreign or professional terminology, insofar as these have not become part of the general German vocabulary; or
- publications that suggest self-diagnosis and treatment by the advertised medicinal product.

6 What are the most common infringements committed by manufacturers with regard to the advertisement rules?

According to our experience, the most common infringements committed by manufacturers with regard to the advertising rules are product-related advertisements for medicines available on prescription only addressed to the general public. The high number of infringements is due to established case law in Germany whereupon the requirement of a 'product-relation' of advertisement is widely interpreted. According to established case law, an advertisement is not only product-related if the respective promotional activity contains 'a naming of a concrete product' but also if 'at least information that enables the addressee to identify a medicine' is given. Therefore, the naming of the manufacturer associated with an active substance (of a medicine available on prescription only) within a promotional activity addressed to the general public is not admissible due to established case law in Germany (eg, the decision of the German Federal Court of 15 December 1994; case I ZR 154/92).

Furthermore, advertisements for the administration of medicines outside its authorised indications can be observed in many cases. This is based on the fact that off-label use of medicines is a relevant factor in many indications, such as oncology, and that the manufacturers have, therefore, a significant economic interest in the advertisement of such an off-label use.

Finally, according to the nature of product-related advertisement, promotional statements are often not accurate due to exaggerations concerning the therapeutic effect or features of a medicine. Most

common are advertisements falsely implying success in treatment or containing an improper statement regarding the status of the medicine on the market, namely that the product is the best and maintains its position without competing products.

Provided that the competent local authority comes to the conclusion that an advertisement infringes legal provisions, it has the power to stop the further distribution and usage of such advertisement. The intentional infringement of legal provisions of the HWG may be sanctioned with imprisonment of up to one year, or with an administrative fine of up to €50,000, the negligent infringement may be sanctioned by an administrative fine up to €20,000.

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

The provision of information regarding off-label use to health-care professionals is allowed if such information is provided within correspondence of a non-promotional nature, and is needed to answer a specific question (of a health-care professional) about a particular medicine. This exemption is, *inter alia*, set out in section 1(5) HWG and section 1(3) No. 2 FSA Code of Conduct. However, if the pharmaceutical manufacturer provides off-label use information to health-care professionals by way of such correspondence, it is advisable for the manufacturer to keep the respective (written) request from the health-care professional in its records. If necessary, this enables the pharmaceutical manufacturer to prove that the information regarding off-label use has been given to the health-care professional solely upon request, and that the above-mentioned legal exemption applies.

Furthermore, the provision of information regarding off-label use is allowed provided that such information has non-promotional character, for example, copies of publications regarding the outcome of a clinical trial (but not in connection with reprint carriers containing any advertisement) or purely scientific information that solely mentions the international non-property name of the active substance.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals? Do different rules apply regarding physicians in the in-patient and outpatient sector?

As for advertisements, the legal requirements for the collaboration of pharmaceutical companies with health-care professionals are partly laid down in the HWG and the UWG. These statutes apply to health-care professionals from the outpatient sector as well as to health-care professionals who work in hospitals. Furthermore, the German Criminal Code (StGB) sets out in section 299 and 331 legal requirements regarding attempts to influence health-care professionals who work in public hospital in their prescription of medicines.

Currently, it seems that German courts increasingly tend to apply the respective legal provisions of the StGB to physicians in the outpatient sector, as they are seen as designee of the SHI. A decision that acknowledges this legal practice is expected from the Federal Civil Court in early 2012. Also, the Professional Code for Physicians (the official draft of the professional code for physicians, which is to a large extent implemented in the regional professional code) stipulates rules and principles for the interactions of physicians, either from the in-patient or the hospital sector, with the pharmaceutical industry, in its sections 33 to 35.

In addition, several industry guidelines govern the interaction of pharmaceutical manufacturers with health-care professionals. These are the FSA Code of Conduct of Health-care Professionals, the respective AKG Code of Conduct, and the Common Position Concerning the Consideration of Cooperation between Industry, Medical Institutions and Staff from the Aspect of Criminal Law. As mentioned, these industry guidelines are binding for members of these industry associations, and shall furthermore be observed since they

serve as a means of interpretation for German courts when assessing if a certain collaboration with health-care professionals infringes respective legal provision.

- 9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

The FSA Code of Conduct sets out in its introduction that all interactions and measures of 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 and, for mutual service, the principle of equivalence (as stipulated in the Common Position Concerning the Consideration of Cooperation between Industry, Medical Institutions and Staff from the Aspect of 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 the hospital. Accordingly, the collaboration between pharmaceutical manufacturers and health-care professionals must meet the following requirements:

- separation principle – the fee paid by the pharmaceutical manufacturer for the service provided by the health-care professional must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products;
- transparency principle – all collaborations with pharmaceutical manufacturers must be disclosed to the administration of the professional's medical institution; usually, a prior authorisation is required;
- documentation principle – all collaborations between pharmaceutical manufacturers and health-care professionals must be set out in writing; and
- equivalence principle – the fee paid by the pharmaceutical manufacturer for the service must correspond to the market value of the service rendered by the health-care professional.

- 10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

In our experience, it is most common that pharmaceutical manufacturers infringe the equivalence principle when collaborating with health-care professionals. In many cases, the fee paid for the service rendered is not in accordance with the appropriate market value of the service. According to the latest decision of the FSA Board of Arbitration (the body responsible for the observance of the FSA Code of Conduct), a remuneration of €80.45 for a 30-minute qualified consulting service rendered by a health-care professional is considered appropriate and reasonable (see decision of 3 February 2009 (2008.1-220)). However, this arbitration may only serve as a benchmark for an assessment of the appropriate market value of such a service. The respective assessment must, furthermore, 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. Please note that the above-mentioned amount is for the time being the highest sum considered appropriate in Germany.

With respect to the FSA Board of Arbitration, many cases result from gifts or services offered to health-care professionals. As a general rule, the HWG and the respective industry guidelines set out that it is not admissible to offer products or services unless they are inexpensive and relevant to the practice of human medicine. According to the FSA Board of Arbitration and cipher 9.2 of the FSA Guidelines pursuant to section 6(2) FSA Code of Conduct (the FSA Leitlinien), a gift is considered as 'inexpensive' if it does not exceed the value of €5 (purchase price).

In addition, numerous infringements result from travel and accommodation granted to health-care professionals by pharmaceutical manufacturers. For instance, health-care professionals attending a job-related or science-orientated training event may not be invited

to accommodation and hospitality that exceed a reasonable limit. In this respect, a dinner must not exceed the value of €60 (see cipher 5.1 FSA Leitlinien), and the hotel should be classified within business class, not luxury class, and should not provide any extraordinary entertainments or services (see cipher 5.3 FSA Leitlinien).

- 11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

In Germany, the relevant industry guidelines applying to the collaboration of pharmaceutical manufacturers and patient organisations are the FSA Code of Conduct on the Collaboration with Patient Organisations (FSA Code of Conduct on Patient Organisations) and the respective Code of Conduct issued by the AKG (AKG Code of Conduct on Patient Organisations). These codes of conduct define the term 'patient organisations' as follows:

Patient organisations are 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.

In our view, the scope of this definition is broader than the definition of patient organisations laid down in the EFPIA Code of Conduct on Relationships between the Pharmaceutical Industry and Patient Organisations (EFPIA Code of Conduct). Therefore, it has to be assumed that the German national Codes of Conduct also apply to interactions between patient organisations and pharmaceutical companies that are not subject to the EFPIA Code of Conduct.

As a main rule for the collaboration of the pharmaceutical industry with patient organisations, it is stipulated in the AKG and FSA Code of Conduct Patient Organisations that pharmaceutical companies may not establish any patient organisation on their own (separation principle). Further, the pharmaceutical manufacturer is obliged to respect the neutrality and independence of the patient organisation, in particular regarding the events organised by the patient organisation (principle of neutrality).

Besides these principles, pharmaceutical companies have to observe the principle of transparency, namely that the collaboration and support must be executed in a transparent and open manner. In consequence, pharmaceutical companies shall 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 benefit. Accordingly, in collaborations with health-care professionals, the documentation principle shall be observed by the pharmaceutical manufacturers, meaning that the collaboration may only proceed on the basis of a written agreement that spells out the basic elements of the collaboration, as far as a financial payment is provided.

- 12 Are manufacturers' infringements of competition law pursued by national authorities?

The competent national authorities in Germany are authorised to pursue infringements of rules for the protection of fair competition by pharmaceutical manufacturers. With respect to the HWG, it is laid down in section 64(3) AMG that the competent authority shall ensure that the provisions of advertisements in the field of medicines are observed. The competent authorities are the regional authorities in the respective federal states in which the pharmaceutical company is established, the regional administrative authorities (RPs).

However, in our experience, RPs only rarely pursue pharmaceutical manufacturers due to infringements of unfair competition law. In Germany, the market for medicinal products is mainly self-regulatory, 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.

13 Is follow-on private antitrust litigation against manufacturers possible?

A third party may claim that an infringement of antitrust constitutes a breach of fair competition legislation and may initiate respective legal proceedings against the infringer before civil courts. However, the Federal Cartel Office is the responsible body to observe a company's compliance with antitrust rules as such.

Compliance – medical device manufacturers**14** Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

The advertisement of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations is less regulated than it is in the pharmaceutical sector. For instance, it is not legally required that advertisements for medical devices display the mandatory information about the promoted product. Further, it is admissible to promote medical devices that are available on prescription only to the general public, and not solely to health-care professionals. In addition, it is possible to promote a medical device in Germany before obtaining the CE mark. However, according to section 12 of the German Act on Medical Devices, the respective medical devices may only be shown if a visible sign clearly indicates that the medical device does not conform to the prerequisites and cannot be purchased until full and due compliance. The reason for this more liberal approach of the legislature on advertisements and collaborations is a lesser risk of misuse. Medical devices function physically and side effects and misuse by consumers are therefore very unlikely.

Pharmaceuticals regulation**15** Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The AMG sets out the regulatory framework for obtaining a marketing authorisation and placing medicines on the market in Germany. According to the relevant section 21(1) AMG, a finished medicinal product may only be placed on the market after a marketing authorisation has been granted by the German Higher Federal Authority or the European Commission. Section 4(17) AMG defines placing on the market as the keeping in stock for sale or for other forms of supply, the exhibition and offering for sale and the distribution to others. The legal requirement to obtain an authorisation before placing the medicinal product on the market applies also to tissue preparations that are not manufactured in an industrial process, and whose essential processing procedures are sufficiently well known in the EU and whose effects and side effects are known and evident from scientific data (section 21a(1) AMG). In addition to the AMG, the Good Manufacturing Practice, as a relevant legal prerequisite for the placing of medicines on the market, is laid down in certain national directives, such as the German Medicinal Products and Active Ingredients Manufacturing Decree.

16 Which authorities may grant marketing authorisation in your jurisdiction?

In Germany, the Federal Institute for Drugs and Medical Devices (BfArM) is competent for the authorisation of finished medicinal products, unless either the Federal Institute for Vaccines and Biomedicines (PEI) or the Federal Office of Consumer Protection and Food Safety (BVL) is competent. According to section 77 AMG, the PEI is competent for 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 BVL is responsible for medicinal products that are intended for administration to animals.

17 What are the relevant procedures?

The most relevant procedure to obtain a marketing authorisation for human medicinal products is the national authorisation procedure according to section 21(1) AMG, applicable to finished medicinal products. Finished medicinal products are medicinal products that are manufactured beforehand and placed on the market in packaging intended for distribution to the consumer or other medicinal products intended for distribution to the consumer, in the preparation of which any form of industrial process is used or medicinal products which are produced commercially, except in pharmacies (section 4(1) AMG). Additionally, if the pharmaceutical manufacturer applies for a marketing authorisation in more than one member state (provided that the respective medicinal product does not fall within the scope of the Regulation 726/2004/EC) and chooses Germany as the reference member state, the decentralised procedure (DCP) and the mutual recognition procedure (MRP) apply (section 25b AMG; also see the DCP member states' SOP or the Best Practice Guide for DCP and MRP, issued by the Coordination Group).

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

The AMG sets out in section 31(1) No. 1 that a marketing authorisation expires if the authorised medicinal product is not placed on the market within three years after the marketing authorisation has been obtained, or if the medicinal product that was placed on the market in accordance with the marketing authorisation is not marketed for three successive years. The three-year period starts, according to the BfArM, on the date when the respective medicinal product could have been marketed. Therefore, the BfArM follows the EMEA view, see 4.1 of the EMEA Q&A document (Ref EMEA /180079/2005) of 23 February, 2006, and the Notice to Applicants (volume IIa, chapter 1 section 2.4.2). If a medicinal product was already on the market, the period will start from the time the medicinal product is no longer being marketed. However, the competent higher federal authority may allow exceptions to this 'sunset clause' if required to protect human or animal health (section 31(1) 2 AMG). In addition, according to the BfArM, this three-year period is suspended if the suspension of marketing authorisation took place due to pharmacovigilance reasons. In any case, the obligation of the marketing authorisation holder (MAH) to notify the cessation remains unaffected, that is, the MAH must notify the interruption of supply two months in advance to the competent authority (section 29(1c) AMG).

19 Which medicines may be marketed without authorisation?

Section 21(2) AMG provides a list of medicinal products that may be placed on the market without a marketing authorisation. The most relevant exemption (to the rule that medicines shall only be placed on the market after a marketing authorisation has been granted) is set out in No 1. Thereafter, medicinal products that are intended for administration to human beings, and of which the essential manufacturing stages are carried out in a pharmacy, in an amount of up to 100 packages in one day, and within the framework of the pharmacy operating licence, shall be placed on the market without a marketing authorisation. In addition, the exemptions set out in section 21(2) No. 2 and No. 6 AMG are of relevance. According to No. 2, medicinal products that are intended for use in clinical trials on human beings do not require a marketing authorisation as a prerequisite to be placed on the market. Finally, the same applies to medicinal products that are made available under conditions for compassionate use (section 21(2) No. 6 AMG). In this respect, the Federal Ministry of Health recently issued the Ordinance for Compassionate Use that

stipulates the legal requirements for placing unlicensed medicinal products on the market in Germany before a marketing authorisation has been obtained by the pharmaceutical company. Besides the requirement to notify the compassionate use programme to the higher federal authority (BfArM or PEI), the requirements are, inter alia, as follows:

- the existence of objective evidence that the patients suffer from a life-threatening disease or a disease leading to severe disability;
- the existence of objective evidence that there is no other satisfying treatment option with medicinal products approved in the European Community; and
- the existence of objective evidence that a marketing authorisation application has been submitted for the medicinal product or that clinical trials with this medicinal product are still ongoing.

20 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

The AMG states that finished medicinal products may only be placed on the market after a marketing authorisation has been granted. Named patient programmes are exempt from this general rule. The relevant legal provision of the AMG, which implements article 5(1) of Directive 2001/83/EC (see judgment of the ECJ in its decision dated 8 November 2007, C-143/06) reads as follows (non-official translation):

Section 73

(3) (...) finished medicinal products which are intended for use in human beings and which are not authorised for marketing (...) may be introduced into the purview of the present Act if

- 1. they are ordered by pharmacies on the basis of an order received from individual persons in a small quantity and are dispensed by these pharmacies within the framework of the existing pharmacy operating licence,*
- 2. they may be legally placed on the market in the State from which they were introduced into the territorial scope of the present Act, and*
- 3. no medicinal product for the therapeutic indication in question which is identical in terms of the active substance and comparable in terms of the strength is available in the territorial scope of the Act, (...). The ordering and dispensing of medicinal products from States others than Member States of the European Union or other States Parties to the Agreement on the European Economic Area require a prescription from a doctor or dentist. Further details shall be settled by the Pharmacies Operation Regulations.*

Against this legal background, medicinal products may be placed on the market in Germany under named patient programmes provided that the respective medicinal product is a finished medicinal product, in other words, a medicinal product that is manufactured beforehand and placed on the market in packaging intended for distribution to the consumer. In addition, the medicinal product intended for named patient programmes in Germany must be lawfully placed on the market in the (third) country from which it shall be imported. Furthermore, the ordering and dispensing of the respective medicinal product must be carried out by a pharmacy. Section 73(3) sentence 2 No. 1 AMG expressly states that dispensing may only be carried out within 'the framework of the existing pharmacy operating licence'. Therefore, the dispensing must be carried out in the pharmacy and only by pharmaceutical personnel. Furthermore, it is legally required that a supply deficit does exist, in other words, no identical medicinal product for the therapeutic indication with respect to the active substance and no comparable medicinal product for the therapeutic indication with respect to the strength are available. Finally, the medicinal product shall be imported solely in small quantities for a single patient and supplied solely on the basis of a physicians' prescription.

Section 8 HWG sets out that any promotion for the supply of

medicinal products pursuant to section 73(3) AMG is prohibited. However, it would be lawful to provide information such as the name of the medicinal product, international non-property name (INN), active substance, strength and price to health-care professionals, since such information is not considered promotional (see the ECJ judgment in its decision dated 8 November 2007, C-143/06).

Medicinal products supplied on a named patient basis according to section 73(3) AMG are only subject to reimbursement in the German statutory health system if certain requirements are fulfilled. According to the established case law of the German Federal Social Court (see decision dated 14 December 2009, B 1 KR 12/06 R), the medicinal product must be administered for the treatment of a chronic and serious disease, a seriously debilitating disease, or a disease that is life-threatening, for which no other satisfactory therapy is available and for which reliable safety data can be obtained.

Pricing and reimbursement of medicinal products

21 To what extent is the market price of a medicinal product governed by law or regulation?

In Germany, pharmaceutical companies are free to set their prices at will. However, some legal instruments do exist, in particular with regard to the outpatient sector, which might have an indirect impact on the price setting of medicines within the SHI. These instruments are stipulated in the SGB V, which are as follows:

- the reference price system (section 35(1) SGB V);
- the efficiency principle (sections 2, 12 SGB V); and
- the therapy information (section 92(2) SGB V).

A reference price system can be set by the G-BA for medicines with the same active substance, or medicines with therapeutically and pharmacologically comparable active substance, or medicines with therapeutically comparable effects. The reference price is based on the price of all products of the group into which the medicines are categorised and constitutes the maximum amount being reimbursed for the respective medicines by the SHI. If the price has been set at a higher level by the pharmaceutical company, the difference must be paid by the patient receiving the medicine. However, according to the Basis for Decision-making by the Subcommittee-Medicines for Defining Reference Prices dated 19 July 2007, no reference price should be set for patent medicines based on a new principle and deemed to represent a significant therapeutic advance.

With respect to the efficiency principle, please note the findings mentioned above. The efficiency principle can be specified or defined by therapy information. In consequence, the medicine for which therapy information exists (issued by the G-BA) would only be reimbursed in the case of a certain therapy application. The Drug Price Ordinance sets out certain conditions for the pricing of medicines.

Finally, please note that a current legislative initiative exists whereupon new conditions for pricing and reimbursement of medicinal products will be introduced. The Act for the Restructuring of the Drug Market (AMNOG) proposes a new form of price setting for innovative medicinal products. In 2011, the reimbursement of a new medicinal product shall be aligned regarding its therapeutic value. According to the AMNOG, the value shall be determined in comparison with existing therapies, and only if an additional benefit can be proven to the G-BA with respect to existing therapies, a higher price might be negotiated with the SpiBu. Medicinal products without any additional benefit are only reimbursed at the level of the comparable products or therapies.

22 Must pharmaceutical manufacturers negotiate the prices of their products with the public health-care providers?

Since the Act for restructuring of the drug market in the statutory health insurance (AMNOG) came into effect on 1 January 2011, new

legal requirements have applied regarding the pricing of medicinal products in the outpatient sector. The price for medicinal products is now subject to negotiations between the pharmaceutical manufacturer and the National Association of Statutory Health Insurance Funds (GKV-SV). In general, two different price negotiation procedures apply depending on whether or not innovative medicinal products (ie, with additional benefit) are concerned.

To identify additional benefit, medicinal products with new active ingredients or new areas of application are to be assessed by the Joint Federal Committee (G-BA) in 'early assessment procedures'. The G-BA is authorised to delegate the assessment to the Institute for Quality and Efficiency in Health Care or to another third party. The assessment is based on a dossier that is drafted by the pharmaceutical manufacturer. The dossier must be submitted to the G-BA before the medicinal product is placed on the market for the first time. According to section 4(1) of the Ordinance for the Assessment of the Benefit of Drugs with new Active Ingredients (AM-NutzenV), the dossier must contain the following information:

- authorised application areas;
- medical benefits;
- additional medical benefit compared with the suitable comparative therapy;
- number of patients and patient groups for which the therapeutically meaningful additional benefit exists;
- the costs for the therapy to the statutory health insurance; and
- the conditions for application in the requested quality.

If the pharmaceutical manufacturer submits no dossier to the G-BA, the additional benefit is deemed not proven. Provided that a dossier has been submitted by the pharmaceutical manufacturer, the G-BA conducts the assessment procedure within three months. As a matter of course, the G-BA notifies the result of the assessment to the pharmaceutical manufacturer, but publishes it also on its website.

According to section 2(4) AM-NutzenV, the additional benefit of a medicinal product is defined as any quantitatively or qualitatively improved patient-relevant therapeutic effect, compared with the effect of a suitable comparative therapy (such as improvement of health, reduction of illness duration, extension of survival, reduction of side effects or improvement of the quality of life). A suitable comparative therapy must usually be determined based on conditions that result from the international standards of evidence-based medicine. Provided that more alternatives exist, the more economical therapy should be selected, preferably a therapy with a reference price.

The price for medicinal products without additional benefits is limited to the costs of the comparative therapy, either by including the medicinal product in the reference price system or, if the requirements for reference price system are not fulfilled, by negotiating a respective price with the GKV-SV.

The price for medicinal products with additional benefit may be determined by the pharmaceutical manufacturer for a duration of 12 months, beginning when the medicinal product has been placed on the market. Within this 12-month period, the reimbursement amount is to be negotiated between the pharmaceutical manufacturer and the GKV-SV. This amount applies from the 13th month on.

According to section 130b of the Social Code Book 5 (SGB V), the GKV-SV and the pharmaceutical manufacturer must conclude a contractual agreement on a reimbursement amount. This contractual agreement applies to all health funds, in other words, to the statutory health insurance funds and to the private insurance funds. If no agreement is reached within six months, an arbitration board becomes involved and decides within three months. The arbitration board consists of seven members: three independent members, two members from the GKV-SV and two members from the pharmaceutical manufacturer. The applicable legal provisions provide no benchmark on how the price shall be stipulated by the arbitration board. With respect to medicinal products with additional benefit, the sales

price in other European countries shall be taken into account, see section 130b(4) SGB V.

Provided that orphan drugs pursuant to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products are concerned, the additional benefit of the authorised orphan medicinal product does not have to be proven by the pharmaceutical manufacturer. According to section 130b (1) sentence 10 SGB V, orphan medicinal products need not prove any medical benefit or any additional medical benefit compared with the suitable comparative therapy, since this is legally acknowledged for orphan medicinal products by the marketing authorisation.

However, this privilege does not apply to orphan medicinal products with a turnover in the statutory health insurance fund above €50 billion in the last 12 months. The turnover is calculated by considering the sales price including value added tax. In this case, the G-BA may request evidence from the pharmaceutical manufacturer within three months with respect to the additional benefit of the orphan medicinal product as under the above-mentioned procedure.

23 In which circumstances will the national health insurance system reimburse the cost of medicines?

According to section 27(1) SGB V, persons insured within the SHI are entitled to treatment if necessary to diagnose a disease, to heal a disease, to reduce its deterioration or to reduce clinical pain. This includes, pursuant to section 27(1) 2 No. 3 SGB V, the supply of medicines.

However, the reimbursement of medicines in the outpatient sector within the SHI is subject to numerous restrictions.

- the medicine supplied to the insured must be legally placed on the market in Germany;
- the supply of medicines must be in line with the efficiency principle set out in section 2, 12 SGB V;
- the medicine must be available in pharmacies only (see section 31(1) SGB V); and
- the reimbursement by the SHI must not be excluded by section 34 SGB V.

First, according to No. 3 of the Pharmaceutical Guideline issued by the G-BA, persons statutorily insured are entitled to the supply of medicines provided that the respective medicines are legally placed on the market in Germany, that is, with a marketing authorisation or another respective authorisation (eg, a registration), or none is required due to section 21(2) AMG. With respect to the efficiency principle, please note the above. Third, persons statutorily insured are entitled to medicines within the SHI solely if these medicines are classified as 'pharmacy-only medicine'. Fourth, according to section 34 AMG, the medicine is excluded from the supply within the SHI if the medicine is not available on prescription, if the medicine is intended for the treatment of a minor ailment, or if the medicine can be classified as a 'lifestyle' medicine.

With respect to off-label use, the administration of a medicine outside its licensed indications can be reimbursed by the SHI, provided that certain conditions are fulfilled. In many rulings, German courts have laid down that if a medicine is administered for the therapy of a chronic and serious disease, a seriously debilitating disease or a disease that is life-threatening, for which no other satisfactorily therapy is available and for which reliable safety data can be obtained, the medicine will be reimbursed within the system of the SHI. With respect to medicines administered in a compassionate use programme, the reimbursement (within the system of the SHI) has been subject to even stricter requirements than those applying to the reimbursement of medicines for off-label use. However, since the 15th amendment of the AMG has been enacted (September 2009), medicines administered in compassionate use programmes are excluded from reimbursement within the system of the SHI.

The costs for medicines in the hospital sector are covered by

Update and trends

The pharmaceutical package included, inter alia, amendments of Directive 2001/83/EC with respect to pharmacovigilance requirements as well as measures for the prevention of falsified medicinal products in the legal supply chain. In 2012 and early 2013, most of the transitional periods for transforming this EU legislation into the national law of the member states expires. Therefore, the AMG will be substantially amended and numerous new legal obligations for pharmaceutical entrepreneurs, manufacturers, wholesalers and pharmacies will be introduced.

DRGs. Each DRG is calculated to cover the costs of the hospital, namely the physicians' services, inpatient care and the necessary medicinal products. If the costs for a medicine are not sufficiently covered by the respective DRG, the hospital may agree with the relevant bodies in the SHI on a supplementary benefit, on a national or regional level, to ensure that the actual incurred costs for an inpatient treatment are covered. The responsible body for calculating DRGs in Germany is the Institute for the Hospital Financing System, and the respective DRG catalogue is enacted each year upon the collaboration of the SpiBu, the Private Health Insurance Association and the German Hospital Federation.

Finally, the medicines must be incorporated in the Lauer-Taxe, regardless of whether the medicines will be reimbursed in the outpatient or the hospital sector. The Lauer-Taxe is an official databank that contains information of authorised finished medicinal products that are reported to the Information Centre for Proprietary Medicinal Products. After the inclusion in the Lauer-Taxe, the medicine receives a central pharmaceutical number (PZN), a nationwide identification key for products distributed by pharmacies. Beside the PZN, the Lauer-Taxe also includes information regarding the respective medicine such as product characteristics, form of administration, package size and package price. It is legally ruled that the PZN serves as an identification key for the reimbursement of medicines within the SHI, (section 300 SGB V), and the PZN is, for this purpose, also listed on the prescription.

24 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

As mentioned in question 22, the new pricing requirements, which introduced (further) requirements for the pricing and reimbursement of medicinal products, have applied since 1 January 2011. After a marketing authorisation has been granted, the G-BA reviews, in an 'early assessment procedure', whether a new medicinal product has any additional benefit regarding the existing therapies. The 'early assessment procedure' is carried out by the G-BA on the basis of a

dossier submitted by the marketing authorisation holder. Provided that no dossier will be submitted by the marketing authorisation holder, the G-BA is under no obligation to become active and the additional is deemed to be not proven.

25 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

Pharmaceutical manufacturers are legally obliged to grant a discount of 16 per cent on their finished medicinal products, based on the manufacturer price listed in the Lauer-Taxe. This has recently been increased from 6 to 16 per cent with effect from 1 August 2010 until 31 December 2010, and applies to medicinal products that are dispensed by community hospitals for the outpatient sector and by hospital pharmacies for the outpatient care. The increase to the manufacturers' discount has been introduced jointly with a price moratorium, which considers the official price listed in the Lauer-Taxe on 1 August 2009. This was supposed to have the effect that pharmaceutical manufacturers would not compensate for the increase in the manufacturers' discount by rising the price before the discount applied.

Medicine quality and access to information

26 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

According to section 8(1a) AMG, it is prohibited to manufacture or to market medicinal products that are incorrectly labelled with regard to their identity or origin (counterfeit medicinal products, counterfeit active substances). An infringement is penalised by a fine or imprisonment of up to 10 years (section 95(1) No. 3a and (3) AMG). In addition to respective rules laid down in the StGB, the VfA issued a position paper titled 'Counterfeit Medicinal Products' in January 2009. Meanwhile, the European Commission has passed the respective proposal within the Pharmaceutical Package amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of counterfeit medicines (falsified medicinal products) in relation to their identity, history or source. Although the number of counterfeit medicines placed on the market in Germany is very low (approximately 1 per cent), the relevance for pharmaceutical manufacturers is expected to be very high. Presumably all medicinal products available on prescription-only (Rx products, except listed in a white-list; 'opt-out solution') and specific OTC products (listed in a white-list, 'opt-in solution') are obliged to add a unique identifier and a tamper-proof feature on the outer package, allowing a complete tracing of the product within the distribution chain (ie, manufacturer, wholesalers and pharmacies).

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27 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

For the time being, the HWG does not contain detailed rules on information for the general public on medicines available for prescription only. As mentioned, section 10 HWG prohibits advertisements regarding medicines available on prescription only whereas the provision of information to a non-health-care professional is allowed, given that such information is provided within correspondence of a non-promotional nature and needed to answer a specific question about a particular medicine (section 1(5) HWG). However, the restrictive approach stipulated in section 10 HWG will be subject to legal amendments in the near future (caused by the Pharmaceutical Package and the ECJ judgment on 5 May 2011 C-316/09 regarding MSD Sharp & Dohme GmbH/Merckle GmbH) and the availability of high-quality information addressed to the general public regarding medicines available on prescription only will be liberalised.

28 Outline major developments to the regime relating to safety monitoring of medicines.

In Germany, the AMG sets out that the marketing authorisation holder shall keep detailed records of all cases of suspected adverse effects. Furthermore, the marketing authorisation holder shall record every case of serious suspected adverse effects and every case of serious suspected unexpected adverse effects. Such adverse effects must be reported to the competent higher federal authority no later than 15 days after it comes to his or her knowledge. The 15th Amendment to the AMG, recently enacted by the German Federal Assembly, has now clarified that the documentation and notification obligations do not apply to investigational medicinal products (section 63b(9) AMG). Adverse effects occurring when conducting a clinical trial must be reported under the requirements of good clinical practice.

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