Germany

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1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in Germany?

Advertising of medicinal products is governed by the Law on Advertising in the Field of Healthcare (*Heilmittelwerbegesetz - HWG*), last amended on 26 April 2006. With regard to advertising to health professionals, a large part of the industry agreed to comply with the FSA Code of Conduct on the Collaboration with Healthcare Professionals (FSA-Code of Conduct Healthcare Professionals) of the Organisation "Voluntary Self-regulation of the Pharmaceutical Industry" (*Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V - FSA*) which has been amended recently (FSA-Code of Conduct Healthcare Professionals). The FSA-Code of Conduct Healthcare Professionals takes into account, in particular, the "Common Position of the Assessment in Criminal Law of the Cooperation between Industry, Medical Institutions, and their Employees" (Common Position) which was published in October 2000 by the major trade associations and other organisations in the healthcare sector, as well as the Professional Rules for German Physicians issued by the German Federal Chamber Physicians. The FSA-Code of Conduct has been revised recently in order to reflect the recent requirements of the EFPIA Code of Practice on the Promotion of Prescription-only Medicines to, and Interactions with Healthcare Professionals issued by the European Federation of Pharmaceutical Industries' Associations (EFPIA) as of October 2007 (EFPIA-Code of Conduct). The revised version of the FSA-Code of Conduct Healthcare Professionals entered into force on 1 July 2008. In addition, the provisions of the Law against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb*) of 3 July 2004 must be observed.

In November 2007 the new self-regulatory organisation "Pharmaceuticals and cooperation in the health care sector" (Arzneimittel und Kooperation im Gesundheitswesen e.V. (AKG)) was founded and became active as of 1 January 2008. The AKG implemented the AKG-Code of Conduct (*AKG-Verhaltenskodex*) which is binding for its member companies. The fourth chapter of the AKG-Code of Conduct, which covers the cooperation between the member companies and health professionals, is supervised by a mediation and arbitration body of the AKG. This mediation and arbitration body can enforce the rules of the fourth chapter of the AKG-Code of Conduct within a formalised proceeding vis-à-vis the member companies.

As to the provisions relating to the collaboration between the industry and physicians, the content of the FSA-Code of Conduct Healthcare Professionals and the AKG-Code of Conduct are also based on the Recommendations of the collaboration of physicians issued by the German Association of Research-based Pharmaceutical Companies (VFA), the German Federal Association of Pharmaceutical Manufacturers (BAH) and the German Association of the Pharmaceutical Industry (BPI) in July 2003. While the Recommendations have no legal force, the conduct requirements of the FSA-Code of Conduct Healthcare Professionals are binding on member companies of the FSA and monitored and sanctioned by the FSA. The same applies to the AKG-Code of Conduct, which is monitored and sanctioned by the AKG.

1.2 How is "advertising" defined?

The HWG provides no definition of "advertising". According to the case law of the German civil courts, the term "advertising" implies any kind of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of a specific pharmaceutical product. Therefore, almost all information, which is published by a pharmaceutical company to the general public or to third parties, is very likely to be classified as "advertising".

However, German law differentiates between so-called "product advertising" and "image advertising". Product advertising means advertising of a specific product, while image advertising is characterised by advertising with the name of the pharmaceutical company or the entire range of products without any reference to a specific product. "Image advertising" is not subject to the rules of the HWG.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and Codes of Practice on advertising, such as "sign off" of promotional copy requirements?

There is no direct requirement regarding arrangements companies are required to have in place. However, the creation of internal arrangements stipulating a "sign-off" of promotional campaigns and/or documents can be helpful with regard to the control of documents and material published by the company. In this regard it should be taken into account that a company is also liable for the activities and conduct of its employees, agents, etc. even where the company did not have knowledge of the individual activity or conduct of the employee, agent, etc. Against this background the control and supervision of advertising material prior to publication may be reasonable to avoid liability for violating content published by employees, agents, etc.

1.4 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Advertising for medicinal products need not be approved, neither in general nor in specific circumstances. Furthermore, there is no obligation in Germany to provide competent authorities with advertising material.

1.5 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

If a competent authority considers an advertisement to be unlawful, it has the power to stop further publication of that advertisement. However, they have no legal power to force a pharmaceutical company to publish a corrective statement. A pharmaceutical company which has been subject to such administrative measures by the competent authorities have various rights of appeal. They can file an objection to the ruling since such rulings by competent authorities are considered to be administrative acts. If the objection has not been successful, a company can file a law suit at the competent administrative courts.

However, prohibition of advertisements by competent authorities is very rare in practice. Usually, competitors take action directly through the civil courts and seek to obtain injunctive relief against unlawful advertisements (see question 1.6).

1.6 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

The intentional breach of the regulations of the HWG on misleading advertising constitutes a criminal offence with a punishment of up to one year imprisonment. The negligent breach of these regulations may be punished by an administrative fine of up to EUR 20,000.00. All other intentional or negligent breaches of the HWG may result in fines of up to EUR 50,000.00. However, infringements of the regulations of the HWG are only prosecuted in exceptional cases. Furthermore, administrative fines are only imposed in rare cases where infringements have a severe impact on patients or public health.

The public prosecution authorities investigate criminal offences and bring them before a criminal court. The responsibility of imposing and enforcing regulatory fines lies with the relevant competent authorities who are responsible for the administrative supervision of the pharmaceutical company in question. Both bodies have the option to refrain from investigation or punishment in the case of minor infringements.

Competitors may take action directly through the civil courts. They generally seek injunctive relief to stop advertisements violating their rights on the basis of the German Law against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb - UWG*). In addition competitors may claim further remedies substantive proceedings.

Apart from the judicial sanctions noted above, a breach of the regulations of the HWG on misleading advertising may, provided that a member company of the VS Pharmaceutical Industry Organisation (FSA) committed the infringement, also result in a sanction by this organisation. The monitoring and sanctioning of the conduct requirements is the responsibility of the FSA's arbitrators, who can impose fines of EUR 5,000.00 to EUR 250,000.00.

1.7 What is the relationship between any self regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self- regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

In principle, the decisions or other measures of self-regulatory bodies (e.g., the arbitration body of the FSA in Germany) do not have any legal impact on the potential actions of German competent authorities. Consequently, a German competent authority may investigate matters that require interpretation of both the law and the relevant code, even though the arbitration body of the FSA has previously assessed such matters and has issued a decision. Due to the young practice of the arbitration body of the FSA, there are currently no reported instances of where the competent authorities have in practice investigated such matters.

1.8 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

In cases where the violation of the provisions of the HWG also constitutes unfair competition, it is possible to take action directly through the civil courts. A breach of a rule within HWG is automatically considered unlawful under the German Act against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb - UWB*) as the HWG does not provide for a right to an injunction.

Action can be taken in order to seek injunctive relief as well as to seize the illegal advertising material. However, such actions may be taken only by direct competitors, associations promoting commercial interests (*Wettbewerbsvereine*), and consumer associations. Industry and Commercial Chambers are also entitled to such claims. A claimant can request a corrective statement or the communication or publication of the judgment to third parties. Apart from this, a claimant can also sue for damages and compensation, and can request an account of any profit made.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product?

The HWG is applicable to the advertising of a specific medicinal product (product related advertising), but does not cover the provision of general information. Pursuant to the HWG, any

advertising activity concerning a specific medicinal product is permissible only if it has obtained the relevant marketing authorisation or registration. Any advertising of unauthorised or unregistered products during development is generally considered to be unlawful. Such pre-marketing sales promotion activities constitute an infringement of the HWG. The same applies to indications or pharmaceutical forms which are not covered by the marketing authorisation.

However, the exchange of medical and scientific information during the development or marketing authorisation phases of a medicinal product are permissible, provided that such activities are not considered to be part of product-related advertising. Therefore, scientific information material such as copies of reports on the outcome of clinical studies, or scientific speeches and publications, may be made available at scientific meetings or conferences by mentioning the non-proprietary name of the active ingredient(s) (INN), provided that the anticipated new product name is not mentioned or otherwise identified.

Consequently, the risk of infringement of the HWG is higher the more such scientific information relates to a specific product or product trademark, or is used in relation to the advertising activities for an unauthorised product.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Publications relating to unauthorised medicines must not be of promotional nature (see question 2.1). Articles in scientific journals which comply with the conditions outlined in question 2.1 above are permissible.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

It is permissible to inform the media about medicinal products which have not yet been authorised or registered, provided that the conditions noted in question 2.1 above are followed. However, press releases are most likely to be considered promotional (and therefore unlawful) where the anticipated new product name is mentioned. An exemption is made where such information is not intended to promote the medicinal product itself but where such information is necessary to understand the financial position of the corporation. The press release must therefore be drafted in a way that it cannot be considered as an advertising tool. The cumulative effect of using marketing materials or advertising slogans, or making exaggerated, ambiguous or incomplete claims may lead to the press release being characterised as promotional. It is, in any case, not permissible to pay or grant incentives for the publication of a press release or an article written on the basis of such press release.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

Unsolicited information as well as material sent upon request will be considered (prohibited) advertisement if the company distributed the information within its product promotion. Such communication may be lawfully performed only if the active substance itself is mentioned and the brand-name of the product is not mentioned in or not easily deductible from the information provided.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

Institutions may be provided with such information so long as the rules noted in question 2.1 (above) are met. However, it may be difficult in practice to avoid unlawfully promoting such information.

2.6 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Health professionals may be involved in market research exercises relating to such marketing materials if it is ensured that the involvement cannot be deemed to circumvent of the prohibition against promoting unauthorised medicinal products. Consequently, the involvement of health professionals should not be misused to promote the unauthorised medicinal product. Furthermore, the rules for the contractual cooperation with health professionals as set forth in question 5.4 and 5.6 must be met. No guidelines on market research have been published to date.

3 Advertisements to Health Professionals

3.1 What information must appear in advertisements directed to health professionals?

Advertising to health professionals, including claims for use of a medicinal product, must contain the following mandatory information:

a) name or company and permanent address of the pharmaceutical company;

b) name of the medicinal product;

c) the composition of the medicinal product;

d) the therapeutic indication;

e) contra-indications;

f) side effects;

g) specific precautions for use insofar as these are required for the labelling of containers and outer packaging; and

h) for medicinal products that can be obtained only on prescription, the marking "prescription only" (*verschreibungspflichtig*).

In addition, the FSA-Code of Conduct Healthcare Professionals requires that the member companies of the FSA must also specify the date on which such information was granted or last revised.

3.2 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?

There is no such requirement under German law.

3.3 What rules govern comparator advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in Germany?

Comparisons with the medicinal products of competitors are only

permissible with respect to advertisements to health professionals; such comparator advertising is not allowed to the general public. Comparator advertising to health professionals must not be misleading and the compared products must be similar. However, such comparisons have to compare relevant, verifiable and typical characteristics of the products concerned, such as their prices and active ingredients. Otherwise the comparison may be misleading, and, therefore, unfair under the rules of the German Act against Unfair Competition.

To the extent that the provisions of the German Act against Unfair Competition are considered, the competitor's brand name or trademark may be used as part of the comparison, provided that the comparison does not constitute any unobjective or disparaging statements about the competitor.

3.4 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

There are no specific rules for the distribution of scientific papers and/ or proceedings of congresses to doctors.

According to the general rules, such material relating to pharmaceuticals which have already obtained marketing authorisation may be provided to physicians who attend a medical conference, for example, as part of the conference documentation.

Apart from participation in further education events, such materials may be given to doctors if they satisfy the limited number of exceptional rules for gifts (see question 4.2). If the scientific papers and/or proceeding of congresses relate to a non-authorised pharmaceutical, the rules set out in question 2.1 apply.

3.5 Are "teaser" advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

German law on advertising medicinal products does not provide for any specific regulation relating to "teaser" advertisements. Therefore, such advertisements should be permissible if they are in compliance with the general principles regarding the advertising of medicinal products mentioned previously.

However, according to these general principles, each advertisement for medicinal products that is to be considered "product advertising" within the meaning of the HWG (see question 1.2 above) has to provide certain information on the medicinal product: section 4 HWG (see question 3.1). As the nature of "teaser" advertising suggests, if neither the name of the medicinal product nor the name of the pharmaceutical company is mentioned in order to arouse the reader's curiosity, such "teaser" advertisements are impermissible under the HWG.

If such "teaser" advertising is considered "image advertising" within the meaning of the HWG (see question 1.2), information related to the medicinal product (see question 3.1) need not be provided as such "image advertising" is not subject to the rules of the HWG (see question 1.2). Such "teaser" advertisements are, therefore, permissible if the general provisions for all advertisements are met, including that the advertisement may not be misleading.

4 Gifts and Financial Incentives

4.1 It is possible to provide health professionals with samples of products? If so, what restrictions apply?

The provision of samples of medicinal products is limited according to section 47 para. 3 and 4 of the German Drug Act (*Arzneimittelgesetz - AMG*). Health professionals may be provided with samples of medicinal products, but only in small numbers and upon their written request. The supply of such samples must be recorded by the company. Samples may be provided to health professionals and to healthcare training institutions with a maximum amount of two packages per year. The packages must be of the smallest commercially available size or may be specially manufactured sample packages with even smaller content. Furthermore, they must be labelled as samples, i.e., the labelling must indicate that they are not for sale. In addition, samples may only be provided accompanied by a professional information sheet according to section 11a AMG.

4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

The HWG does not allow the offer or supply of gifts or other benefits, or the acceptance of such gifts or benefits. In addition, the Professional Rules for German Physicians prohibit the acceptance of any gifts or benefits which might influence their prescribing or therapeutic decisions, or which could be considered as a reward for such previous decisions. Furthermore, the FSA-Code of Conduct Healthcare Professionals and German penal law generally prohibit the provision and acceptance of any kind of benefits with respect to hospital physicians which are granted in the context of their work, especially as consideration for carrying out purchasing or prescription decisions (see question 4.3).

However, the HWG foresees a limited number of exceptional rules, e.g., with regard to promotional gifts of minor value or to volume rebates in kind or money (see question 4.4). Furthermore, benefits may only be granted, offered or provided to health professionals if they are relevant for the professional activity of the health care professional, e.g. they can be used for the practice.

The question whether or not the provision of gifts or other benefits is permissible, therefore, depends on the circumstances of the individual case, taking the different regulations and rules into consideration.

4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

In principle, the above rules with respect to the offering and granting of gifts and other benefits to health professionals apply also to medical institutions. Therefore, the pure funding of a nurse or the costs of a laboratory nurse by a company might also become critical with respect to a medical institution, provided that this is not part of a proper contractual relationship.

It is, however, recognised that a company may grant donations to medical institutions if these donations are made:

a) to medical institutions which are recognised as non-profit organisations being able to issue donation certificates under the relevant tax law;

b) for the purpose of research and teaching, to improve health and patient care, or to realise advanced and further training or charitable purposes;

c) to official bank accounts held by the medical institution and supervised by their administration; and

d) dependent on the prior approval of the hospital administration.

In addition, it must be ensured that donations are made independently of sales transactions and are not intended to influence procurement decisions. Therefore, the potential involvement of hospital physicians in the solicitation of the donation has to be disclosed to the hospital administration and approved by the administration.

The FSA-Code of Conduct Healthcare Professionals (see question 1.1) provides for additional rules as regards donations. In addition to the aforementioned rules, the documentation relating to a donation must be retained for at least five years. Furthermore, the member companies of the FSA must publish annually donations exceeding EUR 10,000.00 per donation per year as of 1 January 2008. In each case, donations may give rise to a suspicion that they might influence health professionals in prescribing or applying specific medicinal products. Therefore, the rules of the German Penal Code against corruption, which apply to employees of public as well as private hospitals, are to be observed and considered on a case-by-case basis.

4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

As a general rule, the Professional Rules for German Physicians prohibit the acceptance of any gifts or benefits by physicians that might influence their prescribing, or therapeutic decisions, or which could be considered as a reward for such previous decisions. Furthermore, the FSA-Code of Conduct Healthcare Professionals and German penal law generally prohibit the provision and acceptance of any kind of benefits with respect to hospital physicians that are granted in the context of their work, especially as consideration for carrying out purchasing or prescription decisions. However, it is permissible to provide educational services (e.g., scientific education or meetings) so long as the services are not intended to influence the prescribing or therapeutic decisions of the physicians, and provided that other conditions are satisfied as appropriate. For example, in some cases it will be necessary for a physician to obtain supervisory approval. In other cases, there may be regulatory limitations that also must be satisfied such as the FSA-Code of Conduct as described above.

4.5 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

In principle, the rules noted in question 4.2 above with respect to the offering and granting of gifts and other benefits to health professionals apply here. A volume-related discount is - as a general rule - considered to be a benefit within the meaning of section 7 HWG, and therefore not permissible.

The exemptions to this general prohibition in section 7 HWG allow a company to grant a volume-related discount in kind or in money only in the following cases:

a) Rebates in kind are prohibited for all kinds of pharmacy-only pharmaceuticals (*apothekenpflichtige Arzneimittel*). Rebates in kind will then be allowed only for medical devices and pharmaceuticals which may be sold outside pharmacies.

b) Rebates in money are prohibited if they are granted against the Ordinance on Pharmaceutical Prices (*Arzneimittelpreisverordnung - AMPreisVO*). This leads to the following rules:

- rebates in money between wholesalers and pharmacies are only permissible within the limits of the wholesale margin according to the AMPreisVO;
- rebates in money for OTC products are permitted, since OTC products are excluded from the scope of AMPreisVO;
- rebates in money to hospitals or hospital pharmacies are still permissible; and
- rebates in money between pharmaceutical companies and wholesalers/pharmacies: not absolutely clear whether permissible or not. The wording of the AMPreisVO does not directly regulate these relationships. At the same time it should be argued that such rebates would be granted against the purpose of the AMPreisVO (view of the Federal Ministry of Health). It has to be awaited in which direction the relevant courts will interpret the new legislation in that regard.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

Subject to the very few exceptions contained in section 7 of the HWG, it is not permissible to grant, offer or provide health professionals with any material benefits if these benefits are contingent on the purchase of medicinal products.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

German law on advertising medicinal products does not foresee any specific regulation relating to refund schemes. However, there is a risk that the advertising for such a refund scheme might be considered as misleading advertising within the meaning of section 3 of the HWG, and that a German court could classify such an advertisement as impermissible. A court might argue that such advertising may lead consumers to believe that the success of the product is assured, as no pharmaceutical company would offer such a refund scheme if the company was not certain that the product's success was assured.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

The HWG does not provide any specific regulation concerning the sponsoring of continued medical education ("CME"). Pharmaceutical companies may support CME through a reasonable financial contribution. The subject of the supported CME must stand in close relation to the application and/or research areas of the products, resp. of the pharmaceutical company. In return, image-promoting advertising activities in connection with the educational material shall or may be developed, e.g. by marking the educational material with the logo of the pharmaceutical company. Furthermore, such financial support may only be provided based on a written agreement with the publisher of such CME material. The FSA-Code of Conduct Healthcare Professionals requires that the member companies of the FSA disclose such sponsorships.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

The offering of hospitality to health professionals is governed by various German legal provisions, e.g., the HWG, the German Penal Code, the Professional Rules for German Physicians as well as the recommendations and codes of conduct of the relevant trade associations (see question 1.1), irrespective of whether the hospitality is offered in Germany or abroad.

According to these various rules, hospitality must not be offered to health professionals or their associates to influence their prescribing and purchasing decisions or to renew products that have already been prescribed or purchased. Hospitality is only allowed as part of training and further educational events organised by a pharmaceutical company. Work-related meals are also permissible. However, a meal is not considered as being "work-related" if accompanying persons (e.g., the physicians' spouse) participate. Hospitality must - as a general rule - not exceed reasonable limits beyond the requirements of politeness and courtesy (generally EUR 40-50).

5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

The applicable legal provisions of the Professional Rules for German Physicians as well as the relevant recommendations and codes of conduct differentiate between "active" and "passive" participation in scientific meetings.

a) "Active" participation exists when the participant gives a presentation, moderates an event, or renders another reasonable service for the pharmaceutical company. A compensation for the active participation may only be paid on a contractual basis and may only be made if the active participation deals with products of the company or associated treatment forms. There must be a reasonable need for the active participation and the remuneration must be appropriate with regard to the services rendered. In addition, hospital physicians are required to obtain the prior written approval of their superior/administration.

b) Physicians who are attending scientific meetings without giving a presentation or acting as speakers ("passive participants") must not be remunerated. It is, however, acknowledged that a pharmaceutical company may reimburse conference fees, reasonable travel and accommodation costs. A pharmaceutical company should not bear additional costs. As with active participants, the remuneration must be appropriate with regard to the services rendered and hospital physicians need the prior written approval of their superior/administration. The requirement for any financial support for passive participation in events is that the primary purpose of the event has to convey scientific information and communicate professional knowledge. Furthermore, an objective connection to the field of activity of the participating physicians must exist. Holding events in typical resort destinations or in particularly luxurious settings must be avoided, since otherwise doubts could arise as to the professional relevance of the event. The organisation of tours or programmes for spouses or other accompanying persons is not permissible for the same reasons. Such conference travel support must, in each case, not be made dependent on any prescription or purchase decision.

The FSA-Code of Conduct Healthcare Professionals (see question 1.1) provides for additional rules as regards so-called international events. International events within the meaning of the FSA-Code of Conduct Healthcare Professionals are internal or external training events in a country in which the company organising, holding or supporting the event or supporting its participants is not domiciled.

Member companies may only provide assistance for the participation in such international events, provided that (i) the majority of participants are not from the company's home country; or (ii) the relevant resources or expertise is available at the location of the event (e.g. recognised medical congresses with international lecturers). In addition to the abovementioned alternative prerequisites (i) or (ii) it must make more logistic sense to hold the event in another country.

The organisation, holding and/or sponsoring of international events are subject to both the German FSA-Code of Conduct Healthcare Professionals as well as the applicable local code at the place of the event, interpreting the EFPIA-Code of Ethics (see question 1.1). In the event of a conflict of the applicable codes, the more restrictive code will apply. Furthermore, the member company of the FSA must notify any assistance in an international event in advance to its affiliated companies in the country where the event takes place.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

In principle, the organiser of a scientific meeting is fully responsible for the content and the other elements of the meeting, such as hospitality granted to the participants. In the event a pharmaceutical company organises a scientific meeting with the help of an independent third party (e.g., an event organiser), the company remains responsible for the content and the hospitality.

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

Doctors can be paid for offering expert services to pharmaceutical or medical device companies. However, such payments may only be made under a contractual relationship between the doctor and the company, e.g. a research and development or a consulting agreement. In any case such agreements may only be considered if there is a real need for consulting services, which must be carefully examined and documented in each individual case. In addition, the decision to enter into an agreement with a specific physician must be justified by the physician's particular specialised expertise. The stipulated compensation must be reasonable with respect to the services to be rendered. Hospital physicians need prior written approval of their superior/hospital administration. Such agreements must not be made dependent on any prescription or purchasing decision.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

Doctors may be paid for participating in post marketing surveillance

studies ("PMS-Studies"). PMS-Studies may only be conducted if the pharmaceutical company has a legitimate and objective interest in obtaining the data and a written agreement has been concluded with the doctor. In addition, the physician performing the PMS-Study must possess the appropriate professional skills and knowledge. Furthermore, a German court recently decided that PMS-Studies are only permissible provided that pharmaceutical companies perform such studies in strict compliance with the principle of non-intervention, i.e. that they must not make any study specific guidelines with respect to the therapeutic decisions of the physicians.

The compensation for the involved physicians must be calculated in the style provided by the Fee Ordinance for Physicians (*Gebührenordnung für Ärzte - GOÄ*). As long as the documentation effort for the particular physician remains within a timeframe of 15 to 20 minutes, a lump sum (currently EUR 17.49 according to the normal compensation rate) shall be granted. A higher lump sum (currently EUR 29.14 according to the normal rate, number 87 GOÄ) may be granted, if the documentation effort exceeds the "ordinary dimension" of the usual effort (i.e. a time exposure of more than 15 to 20 minutes). The aforementioned lump sums can be multiplied by up to 2.3 of the compensation rate depending on the degree of difficulty. Exceeding the rate by more than 2.3 is generally only permitted if the particular documentation shows a special degree of difficulty or requires extraordinary time exposure. According to the GOÄ, typing fees are also billable at EUR 3.50 per commenced A 4 page, as are postage and packaging expenses.

The FSA-Code of Conduct Healthcare Professionals (see question 1.1) provides additional rules for Non-interventional Studies (NIS). Following the respective rules of the FSA-Code of Conduct, the planning, performance, analysis and quality assurance of NIS must be made within the responsibility of the head of the medical department of the member company. Apart from this, the FSA-Code of Conduct Healthcare Professionals recommends obtaining a positive opinion of the ethics committee. Furthermore, the FSA-Code of Conduct recommends obtaining a declaration of consent for the participation. Such information and consent shall be mandatory where this is required under data protection laws. The results of NIS need to be retained for 10 years and must be made available to those health professionals involved in the study twelve months after the finalisation of the study at the latest.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

Payments to doctors for their participation in market researches or the development of product brochures are permissible provided that the conditions outlined in question 5.4 (concerning the payments) and question 3.1 (concerning promotional material) above are met.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Apart from some restrictions, non-prescription medicines may be advertised to the general public. As a general rule, such advertisements relating to non-prescription products have to comply with the general provisions for advertising, i.e., they must not be misleading.

Furthermore, advertisements for medicinal products - whether for non-prescription or prescription-only products - have to provide certain basic information relating to the product (see question 3.1). The information must be set apart and clearly distinguished from the other promotional information and be clearly legible. An advertisement for medicinal products in the print media or on television must be clearly separated and distinct from the editorial parts of these media. Advertisements that are directed to the general public must provide an invitation to seek the advice of a health professional and to read the packaging leaflet, as follows: "For risks and side effects read the package leaflet or ask your doctor or pharmacist".

However, advertising to the general public must not contain any advertising statements relating to (mostly severe) diseases explicitly mentioned in the HWG, including epidemics, tumour diseases, diseases of the metabolic system and internal secretion, diseases of the blood and blood-forming organs, organic diseases. Furthermore, such advertisements to the general public must not contain expert opinions, statements that the product is recommended, tested or used by health professionals, or certain pictorial representations.

However, should an advertisement serve only as a reminder of the medicinal product (*Erinnerungswerbung*) the advertisement need not contain the basic information on the medicinal product mentioned above or the invitation to seek the advice of a health professional.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

No, prescription-only medicines must not be advertised to the general public.

6.3 If it is not possible to advertise prescription only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

In accordance with the definition of advertising (see question 1.2) a disease awareness campaign, i.e., a campaign providing only factual information about a disease but not mentioning the name of a specific product, would not be considered as being product advertising within the meaning of the HWG. Consequently, such campaigns would not be subject to the strict regulations of the HWG. Therefore, such campaigns only have to be in compliance with the general rules of the German Act against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb*), i.e., they must not be misleading and must comply with the rules relating to comparative advertising (see question 3.2 above).

However, such disease awareness campaigns might become critical in cases where only a specific medicinal product exists for the treatment of the described disease. In such cases a court might argue that it is obvious for the end-consumer that only this specific medicinal product on the market can treat the disease and that, therefore, this disease awareness campaign is non-permissible as it circumvents the general prohibition on advertising for prescription-only medicines to the general public.

6.4 Is it possible to issue press releases concerning prescription only medicines to non-scientific journals? If so, what conditions apply?

There are no specific provisions in Germany which prohibit the issuing of information relating to medicinal products to the press. Therefore, pharmaceutical companies - as a general rule - are entitled to inform the press about the company and its marketing of authorised products by the means of press conferences, press

releases or press portfolios. In each case, providing information to the readers should be the main purpose of such press releases and any advertising would only be considered as an unavoidable side effect of the publication. Furthermore, problems could arise if information given to the press is used to publish disguised advertising or editorially designed advertising (*Schleichwerbung*), which is prohibited by the HWG.

However, a pharmaceutical company should act carefully when providing information on prescription-only medicinal products to the press, any information to the press about prescription-only products should contain only objective information relating to the product and any advertising effect of the press information should be avoided.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

The description of medicinal products and research initiatives in corporate brochures or Annual Reports must comply with the aforementioned rules for advertising medicinal products to the general public (see questions 6.1 and 6.2). In general, such descriptions are permissible as far as they are necessary to provide for the relevant information to, e.g. investors, current or future employees etc., and are not misused to circumvent the relevant advertising restrictions.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

There are no specific provisions in Germany which govern the cooperation between companies from the pharmaceutical industry and patient support groups. However, it is to be considered that prescription-only medicinal products must not be promoted vis-à-vis the general public (see question 6.2).

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

There are no particular provisions regarding the advertising of medicinal products on the Internet. Therefore, the same rules as for other types of advertising apply.

Apart from the legal provisions relating to the health care sector, German websites have to meet the relevant regulations of the German Telecommunication Services Act (*Teledienstegesetz*). This requires the set-up of specific information about the company responsible for the content of the site (i.e. name and address of the company, domicile, register number, etc.). In addition, the website must meet the general legal requirements (i.e. no infringement of copyright, no criminal content, etc.). Germany does not require a preview of a new website by any official supervisory body.

Competitors may take action directly through the civil courts. They usually seek to obtain injunctive relief to stop advertisements violating their rights on the basis of the German Law against Unfair Competition. In addition, competitors may seek relief in substantive proceedings.

7.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for health professionals?

There are no specific provisions in Germany regulating the level of security required with regard to the restriction of "health professionals only" websites. However, a mere statement on a website that the details of prescription-only pharmaceuticals are only directed to healthcare professionals, or a simple unverified question asking whether the corresponding person is a health professional, is not sufficient. A company must instead establish a reasonably "safe access system" for accessing the pages directed to health care professionals only.

The safest and least complex solution is the installation of a password system, in which a service-rendering company such as DocCheck (www.doccheck.com) carries out registration.

7.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

As a matter of course companies are completely liable for the content published on their websites. Therefore, content published on a company's website must not violate any law, e.g. German Criminal Code (*Strafgesetzbuch - StGB*), UWG, HWG, etc., or any third party rights, e.g. intellectual property rights, personal rights, etc. In the case of a violation the company is liable for omission as well as for damages.

Additionally, companies may also be liable for content which is linked to the companies' website. In particular, companies are liable for linked content if such content appears from the user's point of view as the content of the company.

Moreover, companies may also be liable for content which is linked to the site and which does not appear as its own content but as third party content. If the company is aware that the content which is linked to the sites violates any law or third party rights, the company is obliged to remove the link. Otherwise, the company may be liable for such content. In addition, companies are also obliged to monitor and control on a regular base the content of the sites that may be accessed by links. Such monitoring and control obligation exists prior to establishing the link as well as after the link is established. The scope and frequency of the obligation depends on the circumstances of the individual case.

If, on the other hand, a third party site links to the company's website, the company is generally not liable for the content of the linking site. However, even in such case the company might be liable for unlawful content of the linking website in cases where the company has knowledge of such content and has the ability to remove the link or to block visitors following the link. The automatic blockage must be possible from a technical and reasonable from an economic point of view.

Notwithstanding the above, it must be considered that a company may also be liable for third party content which is published on the company's sites by third parties within forums or online portals. To that extent, the company is also obliged to remove illegal content after receiving notice. In addition, the company is obliged to monitor and review on a regular basis content which is published by third parties within forums, portals or other interactive parts of the sites. The scope and frequency of the monitoring obligation depend on the particular circumstances of the individual case, e.g. violations in the past, the company's financial power, etc.

7.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

The general rules as mentioned in questions 6.1 and 6.2 also apply to information on websites.

Moreover, as with any company that maintains a website, pharmaceutical companies are also obliged to publish on the website contact information regarding the company. Required contact information includes the name of the company, domicile, address, legal form, representatives, an e-mail address which enables the user to contact the company quickly and easily, commercial register, registration number of the commercial register, competent regulatory authority, sales tax identification number, etc. Such contact information must be legible and easily obtainable for each user of the website when browsing on any page of the site. Usually such information is called the "imprint" or "contact" and can be accessed by a link on the page's bottom line or navigation bar.

If editorial content is published on the website, special press related obligations are applicable, e.g. the name of a person responsible for the editorial content must be made available on the website.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in Germany?

The advertising of medical devices is governed predominately by the HWG and - to a certain extent - the Medical Devices Act (*Medizinproduktegesetz - MPG*). Apart from these legal provisions, a large part of the medical devices industry agreed to comply with the Code of Conduct for "Medical Devices" in 1997.

Most of the provisions of the HWG have been designed to take into consideration the particularities of medicinal products, in particular the high risks caused by self-medication without the prior involvement of health professionals. Therefore, only certain provisions of the HWG are applicable to medical devices. Provisions in the HWG relating to medicinal products, e.g., the prohibition on advertising of medicinal products without a marketing authorisation and the prohibition of advertising for prescription-only medicines, are not applicable to medical devices.

However, some of the restrictions of the HWG also apply to medical devices, e.g. the prohibition on misleading advertising, the limited possibility to refer to expert opinions as well as the limitations relating to advertising gifts.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

The rules that apply to the promotion of medicinal products also apply to medical devices (see questions 5.1 and 5.2 above).

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The FSA (see question 1.1) has implemented the provisions of the revised EFPIA Code of Conduct into its national Code of Conduct. The revised EFPIA Code of Conduct has significantly increased in the scope of coverage. With the increasing number of published decisions by the FSA, accompanied by a corresponding increase in the number of specific guidelines to be applied it is increasingly important for business compliance functions within pharmaceutical companies to carefully review the decisions in order to integrate appropriate processes into proper standardised company procedures, guidelines and training and education measures.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

There is increasing concern in the general public media that pharmaceutical companies are moving too close to patient support organisations, allowing the companies to advertise directly to the organisations' members (i.e., patients). As there are no specific details contained within statutory law to govern or prohibit such activities (other than the prohibition against direct to patient advertising of prescription medicines), the EFPIA has developed self-regulating guidelines in order to provide a transparent mechanism for appropriate conduct, which provide the pharmaceutical industry with a set of ethical guidelines for governing the relationship with patient support organisations. The "*EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations*" also makes clear to the general public that such relationships will not be used in a manner to circumvent the laws prohibiting direct advertising. This Code of Practise is currently being implemented into a national Code of Practice by the *FSA* and will likely enter into force on 1 July 2008.

9.3 Are there any general practice or enforcement trends that have become apparent in Germany over the last year or so?

An area of continued concern for pharmaceutical companies remains how they report on their research and development pipelines. Many stakeholders receive and interpret such reports differently, from patient consumers, physicians and hospitals (the presumed targets of specific advertising campaigns) to investors and regulatory bodies. Pharmaceutical companies are sometimes accused of attempting to disguise advertising messages within the pretext of issuing a "report" on their pipeline products. Companies should thus draft such reports with great care in order to avoid challenges as prohibited direct to patient advertising, as more of these cases have headed to decision in German courts.

9.4 Has your national code been amended in order to implement the EFPIA Code of October 2007?

The FSA-Code of Conduct has recently been amended according to the EFPIA-Code of Practice of October 2007. The assembly of the FSA has adopted the amended code of conduct on 18 January 2008. The revised FSA-Code of Conduct Healthcare Professionals will enter into force on 1 July 2008.

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