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Germany

PHARMACEUTICAL ADVERTISING

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Germany.

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GERMANY
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

In Germany, the advertising of medicinal products is regulated by the German Act on Advertising of Medicinal Products ("*Heilmittelwerbegesetz – HWG*"). It applies to the advertising of (i) pharmaceuticals, (ii) medical devices, as well as (iii) other means, procedures, treatments and objects in case the advertising claims refer to the detection, elimination or alleviation of diseases, suffering, bodily harm or pathological disorders in humans or animals, as well as plastic surgery, insofar as the advertising refers to the alteration of the human body without medical necessity. It is applicable if the advertising in question is product-related and not a mere image advertising of the company.

The HWG is supplemented by the general rules of the German Act against Unfair Competition ("*Gesetz gegen den unlauteren Wettbewerb – UWG*").

In addition, the German Medicinal Product Act ("*Gesetz über den Verkehr mit Arzneimitteln – AMG*") also contains certain provisions regulating the advertisement of medicines and the cooperation with healthcare professionals and patient organisations.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

The German Association of Researching Pharmaceutical Manufacturers ["*Verband Forschender Arzneimittelhersteller e.V. – VFA*"] has founded the Association of Voluntary Self-Regulation for the Pharmaceutical Industry ["*Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. – FSA*"] which established the FSA codex also regulating the advertising on medicines.

a. If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The FSA codex only applies to member companies of the VFA and FSA.

b. What is the legal status of the self-regulatory codes?

The FSA Codex is binding only for member companies of the VFA and FSA. It is no law and does therefore not need to be observed by non-members. This has also been confirmed by the German Federal Court of Justice ("*Bundesgerichtshof – BGH*"). Still, in some instances, courts relied on the more detailed provisions of the FSA Codex in order to interpret the more general statutory requirements under the HWG, the UWG and the anti-bribery provisions in the German Criminal Code ("*Strafgesetzbuch – StGB*").

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

The HWG does not provide a legal definition of advertising. Art. 86(1) of the Community Code (Directive 2001/83/EC) defines the concept of advertising as "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products" and provides specific examples for such advertising. Under German law, advertising is generally understood in a very broad manner and captures any commercial activity which is intended/suited to promote the sale of

goods and services. Thus, most communication by companies is considered as advertising.

a. What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

As pointed out, the definition of advertising is very broad. It covers all product- or performance-related statements that are designed to promote the sale of the advertised medicinal product. It is not required that the promotion of sales is the only or main purpose of the communication. Instead, it is sufficient that the communication is *inter alia* suited to promote the sales. Against this background, also information provided in patient information leaflets, catalogues, correspondence or in case of disease aware campaigns are generally suited to qualify as advertising.

However, the mere provision of information in patient information leaflets, catalogues, correspondence is generally not subject to the restrictions of the HWG as long as such communication has no advertising purpose and the information contained in such communication is restricted to minimum necessary for fulfilling its respective purpose.

b. Does the definition apply equally to all target audiences?

Yes, the definition for advertising equally applies irrespective of the targeted audience.

However, the statutory requirements for such advertising can then be different depending on whether the advertising is made to the general public or healthcare professionals.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Press releases regarding medicines are generally allowed. Beyond the HWG (especially Sec. 3a HWG restricting advertising to the scope of the marketing authorization and Sec. 10 HWG which regulates the advertising on prescription and possibly addictive medicines) communication and advertising of medicines must comply with the principles of Press Law resulting from Constitutional Law and the Criminal Code.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Every pharmaceutical company putting finished medicinal products on the market has to employ a so-called information officer (*Informationsbeauftragter*) who – within the company – is *inter alia* responsible for assuring that the advertising is compliant with the contents of the marketing authorization or registration, Sec. 74a (1) AMG.

6. Do companies have to have material approved by regulatory bodies prior to release?

No.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Comparative advertising for medicinal products outside professional circles is restricted. Sec. 11 para. 2 HWG provides that:

"Medicines for human use shall not be advertised outside the medical profession with claims suggesting that the effect of the medicine is equivalent to, or superior to, another medicinal product or another treatment."

Other than that, the general principles of the UWG apply. As such, comparative advertising is generally admissible according to Sec. 6 UWG – both in a B2B as well as a B2C context. However, it needs to (i) relate to goods or services intended for the same purpose as well as (ii) objectively compare material, relevant, verifiable and representative properties of said goods or services or their price. It may not (iii) result in confusion in commerce between the advertiser and a competitor or its products or signs, (iv) unfairly exploit or impair the goodwill of a competitor's sign, (v) discredit or impair a competitor's goods, services, activities or personal or commercial circumstances, and (vi) present goods or services as imitations or replicas of goods or services being distributed under a protected sign.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or

unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

An off-label use can be well known to the pharmaceutical entrepreneur and accepted by him without him being held liable for it. However, it is not allowed to advertise the off-label use. According to Sec. 3a HWG, the advertising on a product that is subject to authorisation and does neither have any authorisation nor considered to be authorised is inadmissible. This restriction also applies where the advertising relates to therapeutic indications or dosage forms not covered by the marketing authorisation.

Due to the lacking intention for promoting sales, scientific presentations at, for example, specialist conferences organised and hosted by specialist societies (i.e. not pharmaceutical companies) are generally not considered advertising. Even the mentioning of product names can be irrelevant as long as the information is presented and discussed by the (independent) speaker on his own responsibility in a scientific way.

Something else applies if pharmaceutical companies include such scientific lectures and specialist publications on off-label use – which as such do not constitute advertising – in their product-related sales promotion. If, for example, a pharmaceutical company distributes a brochure containing short reports on scientific studies on the medicine in question, the company thereby adopts its content and could therefore be held liable for violating Sec. 3a HWG.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

According to Sec. 10 para. 1 HWG, advertising for prescription only medicines is exclusively allowed to doctors, dentists, veterinary surgeons, pharmacists and persons legally trading such medicines. Advertising for prescription only medicines to the general public is thus inadmissible.

Over the counter medicines may be advertised to the general public. Such advertising is inter alia subject to Sec. 4, 6, 7 and 11 HWG. Sections 4, 6, and 7 HWG equally apply to any advertising of medicines. Sec. 11 HWG only applies to advertising outside professional circles.

Sec. 4 sets out the mandatory information, such as the name or business name, the name of the medicine, the indications and the contraindications, etc for both, the general public and healthcare professionals.

Sec. 6 HWG sets out that advertising is also inadmissible if expert opinions or certificates are published, reference is made to scientific, technical or other publications and quotations etc. from the professional literature are not taken over verbatim.

Sec. 7 HWG prohibits granting benefits.

Sec. 11 HWG provides specific requirements for the advertising to the general public. Under this provision, it is inadmissible to publicly advertise medicines

- with statements or representations referring to a recommendation by scientists, health care professionals, animal health professionals or other persons who, because of their reputation, may encourage the use of medicinal products,
- with the reproduction of medical histories as well as with indications, if this takes place in abusive, repulsive or misleading way or can tempt by a detailed description or representation to a wrong self-diagnosis,
- with a pictorial representation which uses in an abusive, repulsive or misleading manner a changes in the human body caused by disease or injury or the action of a medicinal product in the human body or parts thereof,
- advertising claims suggesting that health could be impaired by the non-use or improve by the use of the medicinal product
- by means of advertising presentations involving the offering of goods for sale or the receipt of addresses,
- with publications whose advertising purpose is misleading or not clearly recognizable,
- with statements made by third parties, in particular with letters of thanks, recognition or recommendations, or with references to such statements if they are made in an abusive, repulsive or misleading manner,
- with advertising measures aimed exclusively or predominantly at children under the age of 14,
- by means of promotional contests, sweepstakes or other procedures the outcome of which depends on chance, provided that such measures or procedures encourage inappropriate or excessive use of medicinal products,

- by supplying medicinal products, their samples or specimens or vouchers therefor,
- by the unsolicited supply of samples or specimens of other products or articles or vouchers therefor.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

In principle, pharmaceutical companies are free to conclude contracts with patients and patient organisations in Germany as consultants or service providers, for example to generate disease awareness or obtain feedback on living with a disease. However, for prescription drugs you will need to make sure that any interaction with patient or patient organisation does not constitute advertising, which is only be allowed via-a-vis physicians, dentists, veterinarians, pharmacists and persons who legally trade in these drugs (cf. Q9).

In addition, if there is a contractual relationship with a patient or patient organisation and they engage in marketing activities on behalf of the pharmaceutical company, the company would likely also be liable for any legal violation incurred by such advertisements. Any such activities should thus rather closely be aligned on.

Further, certain kinds of marketing activities for pharmaceuticals are not legally permissible in Germany. Sec. 11 HWG inter alia introduces strict requirements on advertisements with patient testimonials or other statements by third parties, in particular with letters of thanks, recognition or recommendation, or with references to such statements, if they are made in an abusive, repulsive or misleading manner (cf. Q9).

Sponsoring is generally permissible, however in view of the restrictions laid out in Sec. 7 HWG and under Sec. 299a, 299b StGB regarding the granting of benefits ("*Zuwendungen*") and bribery such sponsorship should be reviewed closely before. Particular focus should be put on transparency and documentation.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

As explained in Q9, Sec. 4 (mandatory information), 6 (advertising with scientific publications), and 7 (prohibition of granting benefits) HWG equally apply to advertising directed at healthcare professionals.

Generally, advertising by using scientific publications or excerpts thereof is admissible unless (i) the publication originates from a person not being scientifically qualified and does not indicate the details of the author, (ii) the subject matter of the publication remains unclear, or (iii) citations are not made properly. In addition, the publications need to comply with scientific standards. For clinical studies, the German Federal Court of Justice ("*Bundesgerichtshof – BGH*") established the so-called 'gold standard' finding that normally a randomised, placebo-controlled, double-blinded study is required and expected by the addressed public.

Thus, if relying on studies not meeting these criteria, there is a higher risk that a court could find lack of sufficient scientific proof or consider the advertising as misleading. In any event, it should be disclosed in the advertising if a study does fall behind these requirements.

Further, providing information on clinical trials or copies of journals to healthcare professionals, the advertiser needs to ensure not to advertise any medicines outside the scope of their marketing authorisation (cf. Q8).

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

Sec. 7 HWG provides that it is generally not permitted to offer, announce or grant benefits or other advertising gifts (goods or services) while providing certain exemptions. Under these exemptions, granting benefits to healthcare professionals can be admissible in the following instances:

- the benefit is of low value (generally not above one Euro)
- the benefit is a small-value item (no notable economic value)
- rebates in kind or in cash only for over the counter medicines
- discounts in kind or cash for other medicines as long as they are not granted contrary to the price regulations applicable under the AMG
- customary accessories to the product or customary ancillary services
- providing information and advice
- customer magazines

If granted to healthcare professionals, in addition to the

above, the benefit needs to be for use in the medical, veterinary or pharmaceutical practice.

When offering gifts, the Criminal Code also must be taken into consideration as this can result in criminal liability under Sec. 299a StGB. This provision penalizes bribery of healthcare professionals.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

The value limit of Sec. 7 HWG does not apply to product samples. The provision of a sample within the limits of Sec. 47 (3), (4) AMG therefore remains permissible irrespective of the value of the sample. Therefore, pharmaceutical companies may supply or have supplied samples of a finished medicinal product – prescription-only or over the counter – to

- doctors, dentists and veterinarians
- other persons practising medicine or dentistry on a professional basis, except in the case of prescription-only medicinal products
- training centres for healing professions, only to an extent appropriate to the purpose of the training.

It must be noted that samples may only be provided upon express written or electronic request, cf. Sec. 47(4) AMG. The samples need to be supplied in the smallest packaging size available and may not be handed out to the same recipient more than twice a year. The samples need to be supplemented with the summary of product characteristics ("*Fachinformation*"). In addition, the company needs to record the recipient of the sample as well as the manner, scope, and date of the supply for each recipient.

Besides, samples may not contain any substances or preparations subject to the Narcotics Act or which may only be prescribes on a "special prescription" according to the AMG.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

According to Sec. 7(2) HWG, the sponsorship of scientific meetings is – as an exception for the prohibition of granting benefits in Sec. 7(1) HWG – permitted.

However, there are still some restrictions. Sec. 7(2) HWG shall only apply if the advertiser grants the benefit within the context of a scientific event, to the extent that this is exclusively related to the profession. Therefore, non-scientific events are not covered. In addition, the recipient may only be a healthcare professional and the benefit may not exceed a reasonable amount. For example, an accommodation of the participants in a luxury resort would most likely exceed this reasonable amount. In particular, the benefit granted must be of secondary importance compared to the scientific purpose of the event. Expenses for leisure activities or other persons accompanying the healthcare professional may not be covered.

In parallel to foregoing questions, violations of those requirements can also become relevant under criminal law aspects and could constitute bribery.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

As explained in Q14, expenses for non-scientific activities may not be covered. In addition, any leisure activities – even if paid for by the attendees on their own – may only accompany the main scientific event and must be of minor importance.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Yes, as long as the remuneration for such services does not constitute a hidden benefit within the meaning of Sec. 7 HWG. This means that service rendered by the healthcare professional and the agreed-upon remuneration should be proportionate to each other. In addition, any cooperation with healthcare professionals should be made transparent and only on basis of a written agreement.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

According to Sec. 7 HWG granting benefits is inadmissible. This does not only concern monetary

benefits but also benefits in form of goods and services. However, there are some exceptions to the prohibition of granting, cf. Question 12.

However, donations (no matter whether monetary or in kind) that are not provided in anticipation of any kind of consideration are admissible. Again, as with regard to interactions with patients / patient organisations, particular focus should be put on transparency and full documentation.

Just like offering advertising gifts, granting benefits can also result in criminal liability under Sec. 299a StGB, which penalizes bribery of healthcare professionals, i.e. the provision of benefits for gaining unfair advantage over competitors.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

There is no general statutory obligation for pharmaceutical companies to disclose details of transfers of value to healthcare professionals or healthcare institutions. However, all members of the FSA (c.f. Q2), undertake with the FSA Transparency Code to publish all direct and indirect cash benefits and asset benefits to members of professional circles and medical institutions. In that regard, also service and consulting fees to physicians, invitations to further training events or services in the field of research and development are made public.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

There is no requirement for an authority to get involved in authorising advertising. No specific regulations for advertising on the internet apply, either. The general requirements as outlined above of course need to be observed.

Lastly, it is recommendable for companies to restrict access on websites containing information/advertisements on prescription medications to healthcare professionals only. A common tool for that is i.e. http://www.doccheck.ag/home/.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

Secs. 299a and 299b StGB. prohibit granting “benefits” to health care professionals or, as a health care professional, accepting “benefits”, respectively, if those benefits are granted in consideration of an unfair preference over competitors in course of:

- the prescription of pharmaceuticals, aids and medical devices or
- ordering pharmaceuticals, aids and medical devices if they are intended to be used immediately by health care professionals
- the allocation of patients or examination material.

In many cases, it is difficult to determine whether a specific conduct falls under these provisions. In that respect, courts and public authorities work with the concept of social adequacy. Indications for social adequacy are, for example, a contractual exchange relationship with customary terms and conditions or compliance with statutory fee rates. Self-regulatory codes (see Q2) can also be taken into consideration when it necessary to assess whether a certain behaviour is social adequate.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

In general, there are three groups of rules that govern the offering of benefits or inducements to healthcare professionals:

Most importantly, the offering of benefits or inducements for health care professionals is governed by German criminal law (see Q20).

Further statutory provisions can be found in Sec. 7 HWG,

in several provisions of the AMG and in Sec. 128 of the German Social Code, Book V (SGB V), which is, however, only applicable for medical aids.

Self-regulatory codes (see Q2) do contain extensive regulations on the offering of benefits or inducements.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

The public prosecutor's offices are responsible for the enforcement of criminal law.

Regarding the other statutory rules mentioned in Q21, responsibility depends on the relevant legal framework: Provisions of AMG and HWG are enforced by the regional authorities on the level of the German Federal States (as example: The regional authority "*Regierung von Oberbayern*" is responsible for companies in Munich). Sec. 128 SGB V is enforced by the relevant statutory health insurance company.

Self-regulatory bodies sanction violations with fines and publish the offences.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

In Germany, there are multiple ways in which companies can proceed against unlawful advertising by competitors.

First and foremost, companies can initiate legal proceedings before the civil courts. Besides a main action, parties have the option of filing a motion for preliminary injunction ("*einstweiliges Verfügungsverfahren*"). The unique aspect of such PI-proceedings in Germany is that they are usually decided by the court within days after filing and in some cases even "ex parte", i.e. without involvement of the adverse party. For such preliminary injunction proceedings however, the urgency period within which any such motions will need to be filed has to be observed. This deadline is in general one month after having obtained knowledge of the infringement and the infringer. In such PI-proceedings, claims for cease and desist can be claimed.

Regular main action proceedings are also available, which do not require adherence to this urgency deadline but take roughly one year for a first instance decision to be reached, with appeal proceedings taking roughly one more year. In such proceedings, parties can also bring forward claims for information, damages, recall and destruction of marketing materials containing the advertorial claims in question.

In addition, any violations of the HWG are sanctionable offences or even punishable under criminal law. Competitors can thus also potentially file criminal complaints, leading to the prosecutor initiating investigations.

Lastly, if the competitor in question is a member of a self-regulatory organisation such as FSA, these organisations can initiate proceedings as laid out in their codices.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Depending on the violation in question, different sanctions or measures are possible:

In the event of a violation of criminal law, a financial penalty or even a prison sentence can be imposed by the court. This especially applies in context with a violation of Sec. 299a and 299b StGB.

Violating provisions of the HWG and AMG – if not subject to criminal law – may lead to an administrative fine.

If Sec. 128 SGB V is violated, this may result in a contractual penalty, imposed by the relevant statutory health insurance company: The background to this regulation are the contracts required for settlement with the health insurance fund.

In addition, competitors may be required to pay compensation for damages by a court ruling.

Health care professionals can also be punished according to the relevant professional law.

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

Measures taken by the self-regulatory body can only be imposed upon its members. They are unrelated to and independent of any other procedures in front courts/government competent authorities.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

Advertising for telemedicinal service / remote treatments – especially in cross border settings – continues to be the most hotly debated topic:

On 9 December 2021 (Case I ZR 146/20), the German Federal Court of Justice (*Bundesgerichtshof – BGH*) handed down its first judgment concerning the interpretation of Sec. 9 HWG. This provision restricts the advertising for remote treatments. It only exceptionally allows advertising of such treatments if, according to generally accepted professional standards, a personal contact between doctor and patient is not required. The BGH concluded that the general advertising for a digital doctor visit is inadmissible. It also found that even if the HCPs may be located abroad and therefore subject to different and more liberal professional rules, the restrictions under Sec. 9 HWG still apply to advertising directed towards the German public. However, in this case, the doctors were seated in Switzerland, whereas it remains to be seen whether the BGH would apply the same standards also to an intra-Community setup.

Further, German Pharmacists Associations are currently challenging business models for integrated telemedicine services, i.e., services that predominantly rely on online questionnaires for obtaining prescriptions that are, in turn, preferentially shipped by cooperating mail order pharmacies. On 10 June 2022, the Higher Regional Court of Cologne (*OLG Köln*) decided on such a case upon appeal (Case 6 U 204/21), essentially finding that the use of an online questionnaire does not comply with the generally accepted professional standards in Germany.

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