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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?

The advertising of medicines is regulated by the German Act on Healthcare Advertising (*Heilmittelwerbegesetz* ("HWG")). The HWG applies to advertising of

1. medicinal products,
2. medical devices and
3. other means, procedures, treatments and articles, insofar as the advertising claim relates to the detection, elimination or alleviation of diseases, ailments, physical injuries or pathological complaints in humans, as well as surgical plastic surgery procedures, insofar as the advertising claim relates to the modification of the human body without medical necessity.
4. procedures and treatments in animals, insofar as the advertising claim relates to the detection, elimination or alleviation of diseases, suffering, physical injury or pathological complaints.

Furthermore, the German Act against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb* ("UWG")) is applicable in parallel to the special provisions of the HWG.

Beyond that, the HWG is supplemented by the German Medicinal Product Act (*"Gesetz über den Verkehr mit Arzneimitteln* ("AMG")), the Regulation (EU) 2017/745 on medical devices, and the German Criminal Code (*Strafgesetzbuch* ("StGB")).

Changes in the legal landscape of pharmaceutical advertising are to be expected, once and insofar the directive 2023/0132 (COD) ("Draft Directive") of the EU Commission will be adopted.

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?

There are several self-regulatory associations that have set up codices of interactions between the pharmaceutical industry and healthcare professionals.

On European level, this is EFPIA (European Federation of Pharmaceutical Industries and Associations), on German level there is e.g. the *Arzneimittel und Kooperation im Gesundheitswesen e.V.* ("AKG"), or the the Association of voluntary self-regulation for the pharmaceutical industry (*Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.* ("FSA")). These associations each have issued far-reaching codes within its established framework of voluntary self-regulation. E.g., the FSA has passed the FSA Code of Conduct on the Interaction with Healthcare Professionals (*FSA-Kodex Fachkreise* ("FSA Code of Conduct"), which, among other topics, regulates the advertising of medicinal products.

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

In general, such codes only apply to members of the respective association. For example, the FSA Code of Conduct applies to the member companies of the FSA, their domestic subsidiaries and other affiliated companies, if these affiliated companies have acknowledged the binding nature of the Code of Conduct in a separate written agreement.

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

According to German Courts, Code of Conducts are not statutory provisions, but solely competition rules. Only members of the organizations are bound by their respective Code of Conduct. However, depending on the

case, German courts could and do use Code of Conducts as (although limited) means of interpretation for statutory provisions.

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 term “advertising” is not legally defined in the HWG. Art 86 (1) of the Directive 2001/83/EC (“Community Directive”) provides a definition for advertising of medicinal products as “any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products […]”.

In response to recent case law of the ECJ, Art. 175 (1) of the Draft Directive now aims to introduce a broader conception of advertising than Art. 86 (1) of the Community Directive, including advertising related to medicinal products, that does not refer to specific medicinal products (see Art. 175 (1) lit. h of the Draft Directive).

In German Law, advertising in means of the HWG is to be interpreted broadly as commercial practice intended to promote the sale of the goods and services within the material scope of the HWG.

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

Advertising can include any type of verifiable statement (verbal, written, literal, pictorial, acoustic, gestural, etc.) used by the advertiser to convey a certain impression to the recipient of this statement. An indirect reference to goods and services within the material scope of the HWG is sufficient. Therefore, patient information leaflets such as catalogues, disease awareness campaigns or correspondence could potentially qualify as advertising.

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

Yes, it does. Though, certain statutory requirements or provisions of the HWG can depend on the target audience.

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)?

In general, such press releases are allowed. However, the press release and its content may be subject to the HWG, UWG and other applicable law and statutory requirements, such as the StGB and general national press law. E.g., a press release providing information on a prescription only medicine is not permitted to be released to the general public, but only to a limited target audience, such as healthcare professionals.

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

Sec. 74a (1) AMG stipulates that every pharmaceutical company that places medicinal products on the market must appoint an information officer (*Informationsbeauftragter*). The information officer must, in particular, ensure that the advertising complies with the marketing authorisation or registration and the HWG.

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?

In general, comparative advertising for medicinal products is allowed, cf. sec. 6 (1) UWG. However, the HWG and UWG restrict certain comparative advertising.

According to sec. 11 (2) HWG, outside of healthcare professional circles, medicinal products for use in humans must not be advertised using information which suggests that the effect of the medicinal product corresponds to or is superior to that of another medicinal product or another treatment.

In addition, the general restrictions of sec. 6 para. 2 and sec. 5 para 3 UWG set out, which comparative advertisements are deemed to be an unfair commercial practice and therefore illegal. These general rules do not differentiate between specific target audiences.

In the future, Art. 176 of the Draft Directive could set

further restrictions for comparative advertising. Advertising that suggests that a medicinal product is safer or more effective than another medicinal product shall also be prohibited, unless demonstrated and supported by the summary of product characteristics.

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?

This depends on the information given to the target audience in the individual case. If information on unauthorised medicines or unauthorised indications qualifies as advertisement, it cannot be provided. Sec. 3a HWG sets out that advertising of medicines is inadmissible if the medicines require a market authorization, but do not have or are not considered to have such an authorization. The same applies in cases where the advertising refers to therapeutic indications or pharmaceutical forms which are not covered by the marketing authorizations.

Whether it is possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals depends on the individual case. Providing such information to promote sales of the medicine is inadmissible, cf. sec. 3a HWG. If the information however constitutes an academic contribution for a scientific conference and is aimed to inform on the status and progress of research or clinical trials, it may be used during scientific conferences.

The same principles apply to information sent to healthcare professionals. In addition, the general principles of the UWG must be adhered to. E.g., sending information, especially advertising, without prior consent by the recipient may be unlawful.

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.

Advertising for prescription only medicines to the general public is not permitted at all: Such medicines may only be advertised to persons who are authorized to market such medicines, cf. sec. 10 (1) HWG.

Same applies to medicines containing psychotropic active substances capable of causing dependency and intending to eliminate insomnia or mental disorders, or to influence the person's mood. These may only be advertised to healthcare professionals, cf. sec. 10 (2) HWG.

Over the counter medicines ("OTCs") may be advertised to the general public. However, subject to the rules and restrictions set out in the HWG, and the principals and stipulations of the UWG. E.g., misleading advertisement is inadmissible, cf. sec. 3 HWG. Mandatory information as provided for in sec. 4 HWG must be included in the advertising (*inter alia* contact information, name of the medicine, indications and contraindications, side-effects, indication 'prescription only'). Referencing specific information and/or using visual means for OTC advertising is not permitted, e.g. referencing third party opinions or certificates, and other publications, reproducing patient histories, all are subject to very strict restrictions (cf. sec. 11 HWG) if not unlawful at all, e.g., in case the advertising is improper, repulsive or misleading. Advertising by gifts or free samples is not allowed to the general public.

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 general, it is admissible for members of the pharmaceutical industry to engage in (contractual) relations with patients or patient organisations.

Pharmaceutical members of self-regulatory associations like the FSA are subject to their Code of Conducts, e.g. the FSA Code of Conduct on Interactions with patient organizations. The Code provides for a general rule that all advertising with patient organizations is subject to general advertising rules (see Question 9 above), sets rules for gifts (not permitted unless for certain exceptions acc. to the Code), as well as for sponsorship and interactions such as consultations.

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?

Generally, advertising of medicines is subject to specific rules and restrictions as set out in the HWG. In addition, the principals and stipulations of the UWG must be adhered to. In particular, misleading advertisement is inadmissible, cf. sec. 3 HWG.

Sec. 4 HWG specifies the mandatory information that must be included in advertising: – the name or the firm and registered place of business of the pharmaceutical entrepreneur, – the name of the medicinal product, – the composition of the medicinal product, – the therapeutic indication, – the contra-indications, – the side-effects, – warnings, where these are stipulated for the labelling of the containers and outer packaging, – the indication 'prescription-only' in the case of medicinal products which may only be dispensed upon prescription by a doctor, dentist or veterinarian, – the withdrawal period in the case of medicinal products which are intended for administration to food-producing animals. This information must correspond to the package insert, is set out separated form other advertising claims and easily legible.

If advertising refers to or uses scientific publications, the advertising must clarify whether the publication relates to the medicinal product or another product. It must further state the name of the author, the date of publication and the source. Quotes from publications must be given verbatim, sec. 6 no. 2, 3 HWG.

Referring or using clinical studies may be considered to be expert opinions or certificates and therefore regulated by sec. 6 No. 1 HWG: Advertising is only admissible, if the clinical studies have been issued by qualified persons and include the date on which the study was issued, as well as name, profession and place of residence of the persons that conducted the clinical trial.

Furthermore, the 'gold standard' case law must be considered when advertising with clinical studies. If studies are referenced, the target audiences expect randomized, placebo-controlled double-blind study with adequate statistical evaluation. If studies do not fulfil this standard, the advertising may be misleading and therefore unlawful.

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

German law is quite strict in this respect. In general, it is inadmissible to offer, announce or grant financial benefits or gifts of any kind or to accept as healthcare professional, sec. 7 (1) HWG.

However, benefits or gifts may be granted, if they are used in medical, veterinary or pharmaceutical practice and if – they are of low value and marked with the name or logo of the person advertising – they are a small-value item – rebates (with restrictions to over-the-counter medicines) – discounts (with certain restrictions with regard to pricing regulations set out in the AMG) – customary accessories or ancillary services – providing information and advice – customer magazines.

Criminal law also sets boundaries: Offering gifts could be considered bribery and therefore be prosecuted under sec. 299a StGB.

Furthermore, Codes of Conduct by self-regulatory associations like the FSA or EFPIA provide often for even stricter rules or prohibit gifts to healthcare professionals.

German courts may also consider the stricter FSA – Codes of Conduct and recommendations in their interpretation of sec. 7 HWG.

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

Samples of medicinal products are not covered by sec. 7 HWG. In general, pharmaceutical companies are allowed to provide samples of medicinal products to healthcare professional under certain limitations, cf. sec. 47 (3), (4) AMG.

Samples may be provided to

- physicians, dentists,
- other persons practicing medicine or dentistry as a profession, provided no prescription only medicinal products are involved,
- or training centers for health professions, to an extent required for the purpose of training,

if those samples do not contain substances or preparations that are regulated by the Narcotic Drugs Act (*Gesetz über den Verkehr mit Betäubungsmitteln*) or require a special prescription.

Furthermore, Codes of Conduct by self-regulatory associations like the FSA or EFPIA provide for rules on the provision of samples.

The same principles apply to veterinarians, see sec. 46 of the Veterinary Medicinal Products Act (*Gesetz über*

den Verkehr mit Tierarzneimitteln und zur Durchführung unionsrechtlicher Vorschriften betreffend Tierarzneimittel)

However, pharmaceutical companies require prior written or electronic consent. Samples may only be provided in the smallest package size and only twice a year. Additionally, the samples must be accompanied by a copy of the summary of product characteristics (SPC, *Fachinformationen*). Furthermore, the manufacturer is obliged to document certain information (recipients, samples, number, supply date) and must submit this information to the competent authority upon request.

The planned Draft Directive would expand the recipient group of free samples. According to Art. 185 (2) of the Draft Directive, free samples of OTF medicines may also be distributed to pharmacists on an exceptional basis.

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?

In general, pharmaceutical companies may sponsor scientific meetings as sec. 7 (2) HWG sets an exemption from the restriction on granting benefits (see also Questions 9 and 10).

Sponsoring such event as well as the attendance to such event by healthcare professionals, both are subject to rules that however are rather set by self-regulatory codes, such as e.g. the FSA Code of Conduct on Interactions with Healthcare Professionals or the EFPIA Code of Practice, than by statutory law.

The requirements as set out in such codes are detailed in terms of formal aspects as well as content of the sponsored event itself: This applies to the choice of location, of the venue, the permitted attendee list, the program and content of the event as well as other formal aspects, e.g. the reimbursement of costs of attendees. Also, no entertainment must be offered in connection with the event (e.g. theatre, concerts, sightseeing flights, sporting events, visits to amusement parks). Further, the codes require a professional relationship or reference between the event and the sponsor's business or research area, as well as between the attendee's professional expertise or specialization and the event's content. Neither scientific events that are not related to the attendees' profession or the sponsor's business nor non-academic events are permitted.

In case such (sponsored) events take place abroad, the codes also set rules, which are stricter than the ones applicable to local events, both for the sponsoring pharmaceutical industry as well as the attendees. E.g., it is important to evaluate whether the sponsoring company is based in said country of the event, whether most attendees in terms of their business are placed in the same country, whether the event is an established one organised by a recognised national or international medical or medical-scientific society or an association of such professional societies, and whether that event takes place at a location suitable for the organisation of such events in the country in which such a professional society is based.

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

Cultural, sports or non-scientific events in relation to scientific conferences organized or sponsored by pharmaceutical companies, whether offered directly or indirectly in connection with the event, are not permitted.

Those are neither covered by the exemption set out in sec. 7 (2) HWG nor by the codes of self-regulatory associations. For more details, see Question 14.

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

Yes, there are several possibilities, to engage with services provided by healthcare professionals, e.g. consultations, lecturing or training activities participating in trials, in non-interventional studies, or in market research activities.

Again, sec. 7 (1) HWG and further applicable relevant provisions such the ones of the German criminal code (StGB) apply.

Furthermore, rules set by self-regulatory codes, such the as e.g. the FSA Code of Conduct on Interactions with Healthcare Professionals or the EFPIA Code of Practice, provide for more details and requirements insofar as applicable to the pharmaceutical company engaging with a healthcare professional.

The general rule is that for any services there needs to be a justified interest in the execution of any such

services provided by the healthcare professional, e.g. a lack of expertise within the company which the respective healthcare professional is able to fill.

Also, the performance of the services and their compensation must be in reasonable proportion to each other and reflect the so called fair market value of the services

In general, in order to meet healthcare compliance requirements, there are four “golden rules” for the provision of services by a healthcare professional to the industry:

- Principle of separation: reimbursement must not be linked to procurement decisions
- Principle of transparency: all benefits and remuneration must be disclosed
- Principle of documentation: all services must be recorded in writing
- Principle of transparency equivalence: performance and consideration must be in an appropriate relationship.

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?

Providing grants is restricted (cf. sec. 7 (1) HWG), as they are considered benefits; see also Question 12.

Donations – both monetary or in kind – are generally permissible. Considering sec. 7 HWG and sec. 299a StGB, it should be ensured that donations are made independently of any sales transactions and do not constitute an inducement in this regard. They must not be transferred to private accounts. I.e., donations are permitted to healthcare organisations, however not to individual healthcare professionals.

Self-regulatory codes, such as e.g. the FSA Code of Conduct on Interactions with Healthcare Professionals or the EFPIA Code of Practice, and related documents, set out further details regarding donations and grants:

Donations and grants (in cash or in kind or otherwise) to healthcare organizations and/or patient organizations are only allowed if: (i) they are made for the purpose of supporting healthcare, research or education; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines. Donations and grants to individual healthcare professionals are not permitted.

One must differentiate donations and grants from the contribution to costs related to events (sponsoring). For this see Question 14 above.

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 are No statutory requirements for pharmaceutical companies to disclose details of transfers of value to healthcare professionals or healthcare organizations.

However, again, members of self-regulatory associations like the European EFPIA or the German FSA are bound by their respective codices, e.g. the FSA Transparency Code (*FSA – Kodex zur Transparenz bei der Zusammenarbeit mit den Angehörigen der Fachkreise und medizinischen Einrichtungen*). The FSA Transparency Code sets out documentation and disclosure obligations with regard to monetary benefits to be published on a regular basis (once a year, on a publicly available platform such as e.g. the company’s or on an affiliate’s website).

Overall, the companies must report the amount per year that was provided to healthcare professionals and healthcare institutions as fees or reimbursement for services and consultancies, as contributions to costs of healthcare professionals as attendees to events, for sponsorship activities, as donations and grants and for R&D activities. There are several options as to the form of disclosure (e.g. per affiliate, as aggregated form or per individual healthcare professional and organization). The codes provide for a template the companies may use for disclosure purposes.

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?

In Germany, advertising and related material does not have to be authorized by an authority.

Advertising medicinal products on the internet is subject to general healthcare advertising regulations, in particular the HWG. The rules and regulations set out in Question 1 et seq. apply therefore to advertising on the internet as well. In particular, focus should be placed on including mandatory information in online advertisement (see Question 9).

Advertising medicinal products on the internet is, in principle, considered to be advertising to the general public and thus restricted by sec. 10 and 11 HWG. Therefore, only OTCs may be advertised on the internet without access restrictions on the website (for details see Question 9). For advertising prescription only products, companies should include access restrictions (e.g. separate and restricted areas) on their websites that allow access only for healthcare professionals that need to verify themselves. A mere notice (e.g. in the form of a disclaimer or a pop-up) is insufficient.

In addition, influencer advertising bears potential risks as such advertising is restricted by sec. 10 and 11 (1) HWG:

Advertising prescription only medicinal products outside of the target audience of healthcare professionals is inadmissible.

In addition, even if it is advertising of OTCs, if advertised with statements and representations that refer to other persons who may encourage the use of medicinal products due to their reputation ('famous persons'), this is also not permitted. Depending on the case, influencers could be seen as such persons.

Influencer advertising further may be seen as surreptitious advertising which is also inadmissible with advertising to the general public, cf. sec. 11 (1) para. 1 no. 9 HWG and is further regulated by the UWG.

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

Yes, giving or taking bribes in the healthcare sector is a criminal offense, sec. 299a, 299b StGB: It is prohibited to grant, offer or promise benefits to healthcare professional or to a third party (and *vice versa* accepting such benefits) in return for unfair competitive advantages over competitors when

- prescribing medication, aids or medical devices,
- procuring medication or health aids or medical devices `that are intended for direct use by the healthcare professional, or
- supplying patients or samples and diagnostic data.

In general, the rules set by self-regulatory codes, such as e.g. the FSA Code of Conduct on Interactions with Healthcare Professionals or the EFPIA Code of Practice aim at preventing non-compliant activities between the industry and healthcare professionals and organizations, and explicitly apply to all types of communication, whether traditional or digital, including, but not limited to, oral and written promotional communications, journal and direct mail advertising, the activities of medical sales representatives, the use of digital communications and channels, such as websites and social media, the use of audio-visual systems such as films, video recordings, data storage services and the like. It also covers the provision of informational or educational materials.

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

Statutory criminal rules set that giving or taking bribes in the healthcare sector is a criminal offense (sec. 299a, 299b, 331 et seq. StGB). It is prohibited to grant, offer or promise benefits to healthcare professional or to a third party (and *vice versa* accepting such benefits) in return for unfair competitive advantages over competitors when

- prescribing medication, aids or medical devices,
- procuring medication or health aids or medical devices `that are intended for direct use by the healthcare professional, or
- supplying patients or samples and diagnostic data.

Also, other rules in this regard aim at the same goal of healthcare compliance regarding interactions of the industry with healthcare professionals: sec. 7 HWG, the AMG, sec. 128 of the Social Code, Book V (*Sozialgesetzbuch (SGB) Fünftes Buch (V)* ("SGB V")) and rules of professional practice govern the offering of benefits or inducements to healthcare professionals. For

details see Questions above.

In addition, self-regulatory codes, such as e.g. the FSA Code of Conduct on Interactions with Healthcare Professionals or the EFPIA Code of Practice aim at preventing non-compliant activities between the industry and healthcare professionals and organizations. Their purpose is to prevent any interaction that constitutes an inducement to healthcare professionals to e.g. prescribe, procure or otherwise trade a medicinal product in consideration for any benefit offered or received by or from the industry.

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.

There is not the one authority responsible for enforcing the rules on advertising and the rules on inducement.

In principle, Germany relies on self-regulation through competitors and authorized associations, e.g. consumer associations, by filing civil actions out of court and in court.

Also, for criminal cases, the public prosecutor's office investigates relevant activities and brings indictments against accused persons.

Local authorities enforce provisions laid out in the HWG and AMG. They monitor advertising and report possible breaches to above-mentioned prosecution authorities. Administrative offenses (*Ordnungswidrigkeiten*) may be enforced by the respective local authority designated by the respective federal state government.

Self-regulatory associations like the German FSA have set up arbitration boards that can enforce infringements of applicable codes by their members, including any infringement of rules regarding advertising and on inducement.

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

Companies have various options: They may file civil actions out of court and/or a civil lawsuit, report possible criminal offences or – if member of an self-regulatory association like the German FSA– file complaints with the self-regulatory association as set out in its respective rules of procedure.

Civil actions may be instigated by competitors, who can, *inter alia*, issue a warning letter, apply for an injunction or claim damages based on the UWG against companies breaching regulations set forth in the HWG. Claimants can file a motion for preliminary injunctions or initiate main proceedings. Preliminary relief may be granted within weeks and sometimes even *ex parte*. Main proceedings are more lengthy and costly.

Companies can also inform authorized bodies (e.g. Centre for Protection against Unfair Competition, "*Wettbewerbszentrale*") that can also initiate civil proceedings and apply for preliminary or permanent injunctions.

Criminal offences may be reported to the public prosecution office. If investigations provide sufficient grounds to bring a public prosecution, the public prosecutor's office submit an indictment with the competent court.

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?

In civil proceedings, claimants may ask for and courts may order injunctions, e.g. to cease and desist a certain form or content of advertising, to provide information, to pay damages and to surrender profits.

If sec. 229a, b StGB or penal provisions of the HWG or AMG are breached, criminal courts can impose fines and in worst cases prison sentences, confiscate benefits or order an occupational ban. Fines and prison sentences can only be imposed on natural persons (such as managers or directors of companies).

Self-regulatory associations may impose sanctions based on their rules of procedure.

Violations of sec. 128 SGB V are subject to contractual penalties that are stipulated in contracts between pharmaceutical companies and the relevant statutory health insurance funds.

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?

In principle, procedures before self-regulatory authorities and procedures before state courts are independent procedures.

As self-regulatory boards are not considered arbitration tribunals in terms of the German Code of Civil Procedure (*Zivilprozessordnung*), parallel civil proceedings cannot be stayed. However, rules of procedure set out by self-regulatory authorities may have an option to stay procedures before self-regulatory boards (cf. sec. 28 FSA rules of procedure).

As case law shows, German courts may, within their discretion, rely on rules or principles as set out by codes issued by self-regulatory associations, insofar reasonable.

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 of telemedicine services has become a widely discussed topic in Germany. Sec. 9 HWG was amended in order to lift restrictions on advertising for remote treatments. Such advertising meanwhile is allowed if, according to generally recognised professional standards, personal medical contact with the person to be treated is not necessary.

Recent court decisions shed light on the prerequisites of sec. 9 HWG. In a decision handed down in December 2021 (Case no. I ZR 146/20), the German Federal Court of Justice (*Bundesgerichtshof (*"*BGH*") has clarified that the exemption set out in sec. 9 HWG has to be interpreted with recourse to the corresponding term and developed legal principles set out in contractual law. As such, professional standards represent the current state of scientific knowledge and medical experience that is required to achieve the medical treatment objective and has proven itself in practice. When determining the recognised professional standards, both the guidelines of medical associations and the guidelines of the Federal Joint Committee (*Gemeinsamer Bundesausschuss)* can be taken into account.

In practice, however, this approach may prove difficult. If no guidelines for remote treatments of a specific illness exist, telemedicine providers may risk violating Sec. 9 HWG when advertising telemedicine services, as they bear the burden of proof that the remote treatment meets general professional standards (cf. Higher Regional Court (*Oberlandesgericht* ("*OLG*")) Karlsruhe, judgment of 22.12.2022, case. no 4 U 262/22).

In this respect, the OLG Köln has decided that a simple online questionnaire does not fulfil generally recognized professional standards as the patient's health may be at risk (Case no. 6 U 204/21): A questionnaire cannot be compared to a video consultation. A doctor cannot examine the patient, ask further questions and therefore asses the credibility of the information provided in the online questionnaire.

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