

<b>PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES</b>
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<b>GENERAL</b>
<b>1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.</b>
<p>In Germany, advertising for medicinal products and medical devices is primarily regulated by the Therapeutic Products Advertising Act (Heilmittelwerbeengesetz or HWG). Advertising is essentially harmonised by Directive 2001/83/EC. There are also general laws, such as the Unfair Competition Act (Gesetz gegen den unlauteren Wettbewerb or UWG), which mainly applies to the advertising of medicinal products and medical devices when it comes to comparative advertising, which is not permitted to consumers under the HWG.</p> <p>There are also the codes of the pharmaceutical associations (Freiwillige Selbstkontrolle für die Arzneimittelindustrie eV (FSA) Code of Conduct and Arzneimittel und Kooperation im Gesundheitswesen eV (AKG) Code of Conduct), to which only member companies are subject. They also contain advertising regulations. However, the most relevant part is made up of regulations on cooperation between doctors and the industry in the area of prescription-only (Rx) drugs, which are primarily intended to ensure compliance and thus avoid corruption. In addition, a significant proportion of the industry only offers over-the-counter (OTC) medicines that are not subject to a code.</p>
<b>2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?</b>
<p>The term 'advertising' itself is not legally defined. According to national case law, however, it includes everything that serves to promote the sale of medicinal products or medical devices.</p>
<b>3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?</b>
<p>The competent authorities of the federal states are responsible for monitoring and enforcing the statutory regulations (unlike the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte or BfArM), which is responsible for the approval of medicinal products). There is certainly coordination between the federal and state authorities. In cases of doubt, the state authorities have the option of consulting the BfArM for a final assessment.</p> <p>A special feature in Germany is the so-called competition associations. These have the authority to protect competition and consumer interests. To this end, they are entitled to issue warning letters against pharmaceutical entrepreneurs for the unlawful advertising of medicinal products and medical devices. If the advertising company does not sign a cease-and-desist declaration with a penalty clause, these associations apply to the civil courts for interim injunctions. The procedure is quite fast: in two to four weeks, unauthorised advertising can be prohibited in this way. This instrument is usually more effective than an official complaint, which can take months or even years to obtain an enforceable title. Ultimately, these associations take on some of the tasks of the state.</p>
<b>4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, for example, food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?</b>
<p>Advertising regulations under the HWG also apply to cosmetics only if they are advertised with disease-preventing or disease-treatment claims. This is permitted from a regulatory point of view, provided the main purpose remains that of care. However, the HWG does not apply to foodstuffs, food supplements or foodstuffs for special medical purposes. A separate (European) legal framework applies to these categories.</p>

<b>CONSUMER MARKETING</b>
<b>5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?</b>
<p>Consumer marketing is subject to further restrictions, in particular, Rx medicines may not be advertised to consumers. In addition, there is a whole catalogue of prohibitions with which the legislator wishes to protect consumers from advertising methods that would overburden them. These consumer advertising bans are based on Directive 2001/83/EC. One example is the prohibition of advertising with medical or other professional recommendations because consumers cannot check the accuracy of the content.</p> <p>Misleading advertising bans apply in their various forms to both professionals and end consumers.</p>
<b>6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?</b>
<p>In principle, the HWG also applies to the advertising of medicinal products and medical devices on the internet and social media. Certain formal requirements are specifically regulated, but these are not specific to medicinal products and medical devices. In addition, there is extensive competition law case law in Germany that helps to apply the legal framework to these new technologies.</p>
<b>7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?</b>
<p>The aforementioned case law is all the more important because there is no prior control or approval of advertising by the authorities. Companies are subject to their internal responsibility. Ultimately, effective post-market control is carried out with the help of the authorities and warning associations (as mentioned above). Companies are aware of this and think twice before investing in expensive campaigns that are inadmissible from the outset if they expect their advertising to be 'closed' within a few weeks.</p>
<b>8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?</b>
<p>Advertising for unapproved medicines, such as nutritional supplements, which are positioned on the market for the treatment of illnesses, is fundamentally inadmissible and misleading. This also applies to off-label use or information. Ultimately, there is no marketing authorisation for either, which means that the advertised effects have not been verified. For this reason, they also fall under a special misleading offence (section 3a of the HWG).</p> <p>As mentioned, there are certain forms of advertising to consumers that are prohibited, regardless of whether they are misleading, because they are intended to protect consumers. It is interesting to note, but difficult to understand, that not all of these apply to medical devices. Medicinal products may not be advertised to consumers:</p> <ul style="list-style-type: none"><li>• with information or representations that refer to a recommendation by scientists, persons working in the health sector, persons working in the field of animal health or other persons who may encourage the use of medicinal products due to their reputation;</li><li>• with the reproduction of medical histories, as well as with references to such histories if they are abusive, repulsive or misleading, or may lead to a false self-diagnosis due to a detailed description or presentation;</li><li>• with a pictorial representation that uses, in an abusive, repulsive or misleading manner, changes in the human body due to illness, or damage or the effect of a medicinal product in the human body or parts of the body;</li><li>• with advertising claims suggesting that health could be impaired by not using the medicinal product or improved by using it (this also applies to medical devices);</li><li>• by advertising presentations that are associated with offering items for sale or receiving addresses (this also applies to medical devices);</li><li>• with publications whose advertising purpose is misleading or not clearly recognisable (this also applies to medical devices);</li><li>• with statements by third parties, in particular with letters of thanks, recognition or recommendation, or with references to such statements, if these are made in an abusive, repulsive or misleading manner (this also applies to medical devices);</li></ul>

- with advertising measures aimed exclusively or predominantly at children under the age of 14 (this also applies to medical devices);
- with competitions, prize draws or other procedures whose outcome is dependent on chance, insofar as these measures or procedures encourage the inappropriate or excessive use of medicinal products;
- by the distribution of medicinal products, their samples or specimens, or by vouchers for them; and
- by the unsolicited supply of samples or specimens of other substances or objects, or by vouchers for them.

**9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?**

Comparative advertising to consumers is prohibited (section 11 paragraph 2 of the HWG). This is because consumers must be protected from information whose substance they cannot verify or even understand.

Comparative advertising to professional circles is permitted, provided that the requirements of section 6 of the UWG are met. This means that only products that are substitutable (from a medical point of view) may be compared with each other. This is the case, for example, if the approved indications are largely congruent. In addition, potencies and other parameters must be comparable, and the comparison must not be misleading overall. Superiority in terms of efficacy or safety may only be claimed if direct comparative studies are available (ie, the comparison of results from separate studies is not sufficient).

In line with European Court of Justice (ECJ) case law (judgment of 8 April 2003, C-44/01 – Pippig Augenoptik), brands and product names of competitors may be mentioned in comparative advertising, although this is rarely the case in practice.

**DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS**

**10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?**

There are two definitions of healthcare professionals:

The broad and narrow definitions are as follows:

According to section 2 of the HWG, healthcare professionals within the meaning of this act are members of the medical professions or medical trade, institutions that serve human or animal health, or other persons, insofar as they legally trade in medicinal products, medical devices, procedures, treatments, objects or other means, or use them in the exercise of their profession.

There is a narrower definition of healthcare professionals in the context of section 10 paragraph 1 of the HWG when it comes to advertising for prescription-only medicinal products. This provision states that prescription-only medicinal products may only be advertised to doctors, dentists, veterinarians, pharmacists and persons who trade in these medicinal products in a lawful manner.

Conversely, however, there are no restrictions to the effect that communication to healthcare professionals is not permitted, which is permitted for consumers.

**11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?**

Surprisingly, there are no specific rules in Germany governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings, and participation in virtual congresses and symposia. Specific rules only exist for medical treatment, that is, in the doctor-patient relationship, which is still very restrictive.

**12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?**

As mentioned above (Question 8) medicinal products may not be advertised to consumers with information or representations that refer to a recommendation by scientists, persons working in the health sector (healthcare professionals) or other persons who may encourage the use of medicinal products due to their reputation. This does not apply in purely promotional (advertising) materials for (other) healthcare professionals.

**13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

The dispensing of samples of medicinal products is permitted, but only within very narrow limits, which are taken very seriously and strictly controlled by the authorities.

Pharmaceutical entrepreneurs may only supply samples of a (prescription-only) medicinal product to doctors, dentists and training centres for human medical professions:

- on a respective written or electronic request;
- in the smallest pack size; and
- not more than two samples of a finished medicinal product may be dispensed or supplied in any one year.

A summary of product characteristics (SPC) shall be sent with the samples. The sample serves in particular to inform the doctor about the subject of the medicinal product. Separate records shall be kept for each recipient regarding the recipients of samples, as well as the type, scope and time of supply of samples, and shall be submitted to the competent authority on request.

There are no comparably strict regulations for medical devices. The general prohibition on the provision of benefits under section 7 of the HWG applies here and is applied to samples of OTC medicinal products to pharmacies. Section 7 is a complicated system with several exceptions to the rule. It essentially stipulates the following:

Offering, announcing or granting benefits and other promotional gifts (goods or services), or accepting them as a healthcare professional, is not permitted, unless the gratuities or promotional gifts are items of low value that are identified by a permanent and clearly visible designation of the advertiser or the advertised product or both, or are small items of low value. According to established German case law of the Federal Court of Justice, 'low value' means approximately €1.

There are also other exceptions to the ban on donations. According to these, donations or promotional gifts are permitted in the form of:

1. a certain amount of money or an amount to be calculated in a certain way; or
2. a certain quantity of the same goods or a quantity to be calculated in a certain way.

This refers to discounts for which the following further restrictions apply:

Benefits or promotional gifts pursuant to item 1 above are not permitted for medicinal products if they are granted contrary to the price regulations that apply on the basis of the German Medicinal Products Act or the Fifth Book of the German Social Code (especially for prescription-only medicines); item 2 above does not apply to medicinal products whose dispensing is reserved for pharmacies.

For the sake of completeness, the following should also be mentioned with regard to section 7 of the HWG (even if it is more relevant for consumers):

- Benefits or promotional gifts are expressly permitted in advertising for medicinal products or medical devices if they consist only of customary accessories to the goods or customary ancillary services; in particular, a partial or full reimbursement, or the assumption of travel costs for local public transport that is reasonable in view of the value of the goods or services and may be incurred in connection with a visit to the business premises or the place where the service is provided is deemed customary.
- Benefits or promotional gifts consisting of the provision of information or advice are also permitted.
- The same applies if they are magazines to be distributed free of charge to consumers, which,

by their design and layout, serve as customer advertising and serve the interests of the person distributing them. Their purpose should be recognisable by an appropriate imprint on the cover page and they should be of low value in terms of their production costs (customer magazines).

Returning to the sample topic, briefly, I quote the summary from the final decision of the Higher Regional Court of Frankfurt of 10.02.2022 (6 U 161/15) on samples of OTC medicinal products to pharmacies after two referrals to the Federal Court of Justice and one even to the ECJ (11.06.2020, C- 786/18 – ratiopharm):

In the free distribution of 100 gram tubes of a painkiller to pharmacists with the label 'For demonstration purposes', this cannot be considered a violation of section 7 paragraph 1 no 1 of the HWG if it was a gift of low value, there was no risk of the pack being passed on to the end consumer and only one free pack was given to each pharmacist for self-testing (affirmed here).

Notwithstanding the above, promotional gifts for healthcare professionals are only permitted if they are intended for use in medical or pharmaceutical practice.

The regulation in section 7 paragraph 2 of the HWG is somewhat more generous for gifts in the context of exclusive profession-related scientific events, provided these do not exceed a justifiable scope; are of secondary importance, in particular with regard to the scientific purpose of the event; and do not extend to persons other than those working in the healthcare sector.

There are several undefined legal terms here, and there is virtually no published case law on their interpretation. This has ultimately been taken over by the industry codes mentioned at the beginning under 'General', which contain numerous detailed regulations that are widely accepted as industry standards.

**14. What rules govern the offering of hospitality to healthcare professionals?**

The aforementioned industry codes also contain specifications for the hospitality and hotel accommodation that pharmaceutical companies may provide to physicians when they invite them to scientific training events. Accordingly, a maximum of a four-star hotel is generally appropriate, but only if an overnight stay is necessary according to the programme of the event and the accessibility of the location. No supporting or entertainment programme may take place, not even during lunch or dinner.

**15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?**

As far as donations to healthcare institutions are concerned, there is no specific regulation in the area of healthcare law, only in tax law. The tax deductibility of donations is only permitted to certain non-profit healthcare institutions and is very restrictive. In addition, the industry codes provide for transparency provisions that require the publication of donations, albeit not in great detail, but rather cumulative; therefore, quite general information is sufficient.

Reporting transfers of value made by permit/authorisation holders to healthcare professionals is a 'shall' regulation only; it is not mandatory in Germany.

**16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?**

The above comments on hospitality and hotel accommodation are in connection with scientific training events. This means that, in principle, pharmaceutical laboratories, or medical device manufacturers or their licensees may organise and/or support scientific or educational meetings, as long as they are related to the indication of their products. There is no significant difference between these two sectors from the perspective of rules on the promotion of products.

**17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.**

The same approach as mentioned previously (Question 16) applies to relationships with patient organisations, where donations are also permitted. In addition, there are (only code) regulations regarding sponsoring. This applies to the transparency requirement to publish the names of sponsors. Sponsoring is also permitted, provided the sponsoring pharmaceutical company receives appropriate consideration in the form of advertising opportunities in printed publications or trade fair stands at events.

**18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if**

<b>so, how?</b>
<p>Of course, pharmaceutical companies do not have to organise scientific training events themselves, but can make use of third parties, such as specialised agencies. They can also support external scientific training events with financial contributions or pay the participation fees for the doctors they invite (eg, at international congresses). The prerequisite is always that the content of the scientific event is related to the indications of the inviting company's products.</p> <p>In any case, the pharmaceutical company remains legally responsible for whether it was allowed to support the doctors, that is, whether the scientific events were permitted under section 7 of the HWG and/or the industry codes. This is because, if the scientific events do not meet the requirements, it is not permissible to invite doctors to them.</p>
<b>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</b>
No.
<b>ENFORCEMENT</b>
<b>20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?</b>
<p>Regarding penalties, anyone who contravenes the ban on misleading advertising (section 3 of the HWG) is liable to a custodial sentence of up to one year or a fine.</p> <p>All other advertising violations as of the HWG, whether committed intentionally or negligently, are administrative offences. These administrative offences can be punished with a fine of up to €50,000.</p> <p>A negligent breach of the aforementioned prohibition on misleading advertising (section 3) is an administrative offence punishable by a fine of up to €20,000.</p> <p>In practice, however, advertising violations are not usually prosecuted by the authorities. They are more concerned with the quality and safety of medicinal products and medical devices. In most cases, the competition associations mentioned at the beginning are much more effective in prosecuting advertising violations.</p> <p>As a rule, no judgments or other decisions on advertising violations are published. There are more frequent denunciations in cases of code violations, such as cases of an unfair influence on doctors, but not in cases of simple advertising for medicinal products or medical devices.</p>
<b>21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?</b>
<p>In addition to the competition associations mentioned at the beginning, competitors issue warning letters and injunctions to each other in order to stop their competitors' illegal advertising. These measures are aimed at the future. They are usually very fair and transparent, that is, competitors generally fight 'with an open face'. It is virtually unheard of for a pharmaceutical company to file criminal charges against its competitor.</p>
<b>FUTURE DEVELOPMENTS</b>
<b>22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?</b>
<p>As we have extensive (almost daily) case law on the enforcement of advertising bans in Germany, no significant developments in the field of pharmaceutical or medical device promotion (advertising) are expected in the next year or so. The same applies to any general practice or enforcement trends. No change has become apparent in the German jurisdiction over the last year.</p>