



The Legal 500 & The In-House Lawyer
Comparative Legal Guide
Austria: Pharmaceutical Advertising

This country-specific Q&A provides an overview of the legal framework and key issues surrounding pharmaceutical advertising law in the Austria.

This Q&A is part of the global guide to Pharmaceutical Advertising.

For a full list of jurisdictional Q&As visit <http://www.inhouselawyer.co.uk/index.php/practice-areas/pharmaceutical-advertising>

Greiter
Pegger
Kofler
Rechtsanwälte

Country Author: Greiter Pegger Kofler & Partner



**Dr. Georg Huber, LL.M.,
Attorney at Law**

georg.huber@lawfirm.at



**Mag. Simon Hellekalek,
Associate**

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

Primarily, the Austrian Medicines Act (AMG, implementing the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use) regulates advertising on medicines. Secondarily, mainly the Law on Unfair Competition (UWG) applies.

With regard to medical devices, the Austrian Medical Devices Act and its restrictions regarding advertising must be observed.

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?**

In 2007, the Austrian Pharmaceutical Industry Association (Pharmig) published its first code of conduct (Pharmig Code of Conduct), which is strongly oriented towards the AMG. All members who join Pharmig must comply with this code of conduct.

Non-members can voluntarily comply with the Pharmig Code of Conduct.

With regard to the Pharmig Code of Conduct, it is generally to be seen as a contractual self-regulation.

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 definition of Art 86 Directive 2001/83/EC was implemented in the AMG: Advertising of medicinal products shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.

This definition does not apply to labelling and package leaflets, to

correspondence needed to answer a specific question about a particular medicinal product (possibly accompanied by material of a non-promotional nature), trade catalogues and price lists (provided they do not contain information on medicinal products) and statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

This definition covers the advertising of medicinal products to the general public ('lay advertising') and to persons qualified to prescribe or supply them ('professional advertising').

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)?

A distinction must be made between the terms 'advertising' and 'information'. Advertising within the meaning of the AMG exists when the aim of the message is to promote the prescription, supply, sale or consumption of medicinal products.

If, on the other hand, the sole objective is to provide a purely informative indication without advertising intention, this would be admissible information. This must be assessed on a case-by-case basis.

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

Companies need to ascertain that advertising of medicines complies with the AMG and - for members of Pharmig - with the Pharmig Code of Conduct.

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

Advertising itself is not approved in advance, but advertising may only be made for a medicinal product if it has been authorised or registered for sale or supply by the authority.

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

Comparative advertising for medicines is allowed; however, a stricter standard must be applied compared to 'other advertising' that is regulated under the Law Against Unfair Competition (UWG).

Advertisements for medicinal products have to objectively and without exaggeration present the properties of the medicinal product and have to contain neither statements nor pictorial representations that attach an effect to the medicinal product which goes beyond its actual effect or falsely give the impression that success can be expected on a regular basis.

Furthermore, in general, information must be accurate, up-to-date, verifiable and complete enough to enable the recipient to personally assess the therapeutic value of the medicinal product.

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?

Advertising for medicinal products may be carried out only for authorised medicinal products, as well as certain other registered products.

This restriction does not apply to professional advertising within the framework of scientific events whose participants are predominantly from abroad.

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.

The advertised product must be clearly recognisable as a medicinal product. The following information must also be provided: the name of the medicinal product and the usual scientific name of the active substance if the medicinal product contains only one active substance, the information essential for the practical use of the medicinal product and a clearly perceptible indication that, in addition to effects, medicinal products may also have adverse effects and that the instructions for use must therefore be strictly observed or the advice of a doctor or pharmacist sought.

Advertising to the general public may not be carried out for prescription-only medicinal products, proprietary medicinal products which, although not available only on prescription, contain the same invented word or scientific expression as the name of a medicinal product available only on prescription, and registered homeopathic medicinal products.

Additionally, any advertising aimed at the general public must not give the

impression that a medical examination or surgical procedure is unnecessary or that a medicinal product has no side effects, that the patient's normal health is improved or, if the product is not taken, that it could be adversely affected. Furthermore, such advertising must not be aimed exclusively at children.

There are also restrictions with regard to the graphic presentation of advertising. No pictorial representations may be used in such a way that they are misused as the modification of the human body due to disease, injury or the impact of a medicinal product on the human body or parts of the human body. Furthermore, images relating to health professionals or health care institutions should not be included.

Finally, according to para 351g General Social Insurance Act it is prohibited to advertise medicinal products reimbursed by social security institutions.

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

With regard to consumers, any distribution of samples of medicinal products or vouchers for the free purchase of medicinal products is prohibited.

The collaboration between pharmaceutical companies and patient organisations is regulated under the Pharmig Code of Conduct. Accordingly, the patient organisations' right to self-determination is regarded as a fundamental principle, so that they must be independent of pharmaceutical companies. In addition, cooperation must take place on an ethical basis and must be transparent. The exclusive support of a patient organisation by a single pharmaceutical company is therefore inadmissible. Furthermore, a written agreement is required describing the purpose of the support. Finally, the patient organisations must give their consent for the donations to be published on the

homepage of the supporting company.

Services provided by the patient organisation to the pharmaceutical company may be provided exclusively for training, research or health support purposes or may only be provided within the framework of a scientific or technical activity.

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?

In principle, advertising directed at healthcare professionals may be carried out if it supplements the statements with regard to labelling, instructions for use or technical information.

All professional advertising has to contain the essential information reflected in the Summary of Product Characteristics (SmPC). In addition, all documents must show the date on which they were prepared. Furthermore, it must be disclosed on what occasion and in what context a certain statement was made.

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

In the context of the promotion of medicinal products, it is prohibited to grant, offer or promise any premium, financial or material advantage to any person entitled to prescribe or supply a medicinal product, except where such advantage is of negligible value and relevant to medical or pharmaceutical practice.

The payment of reasonable travel and subsistence expenses and the participation fees for exclusively occupation-related scientific events to any person entitled to prescribe or supply a medicinal product is not forbidden. However, only reasonable travel and subsistence expense may be covered.

In any case, the granting of advantages to other persons (e.g. spouse) is inadmissible.

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

It is generally permissible to supply healthcare professionals with unsaleable medicinal sample as part of a sales promotion. However, the healthcare professional is then also obliged to pass these on to his patients free of charge. However, these medicinal sample may not contain any psychotropic substances or addictive substances within the meaning of the Austrian Narcotic Substances Act.

The number of medicinal sample provided to one healthcare professional is limited. Furthermore, one year after the launch of a medicinal product, a specific request by the healthcare professional is a prerequisite.

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?

Sponsorship (e.g. sponsorship of sales promotion days as well as sponsorship of scientific congresses) and forms of direct marketing are subject to the general

restrictions of the AMG.

The AMG is only applicable in Austria, however, some restrictions do not apply to professional advertising within the framework of scientific events whose participants are predominantly from abroad (see point 8).

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

Sponsorship (e.g. sponsorship of sales promotion days as well as sponsorship of scientific congresses) and forms of direct marketing are subject to the general restrictions of the AMG.

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

The Pharmig Code of Conduct contains various restrictions regarding the cooperation between pharmaceutical companies and healthcare professionals.

Services provided by professionals for pharmaceutical companies (e.g. for lectures, consulting, clinical trials, non-interventional studies) may only be used for education/further training, research or support of the health care system or provided within the framework of scientific or professional activities. A written contract must be concluded, clearly stating the service, remuneration, type, scope and purpose of the service.

The provision of services by professionals must not be subject to a condition relating to the recommendation, prescription or supply of a medicinal product.

Furthermore, doctors working in public hospitals might be considered as 'public officials' within the meaning of the Austrian Criminal Code. A person/company commits a criminal offence if someone offers, promises or grants an advantage to a public official or a third party for the conduct or omission of an official act in breach of duty.

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?

In the context of the promotion of medicinal products, it is prohibited to grant, offer or promise any premium, financial or material advantage to any person entitled to prescribe or supply a medicinal product, except where such advantage is of negligible value and relevant to medical or pharmaceutical practice.

Under the Pharmig Code of Conduct, financial or material donations as well as grants to institutions consisting of professionals may only be made for the purpose of education/further training, research or support of the health care system or within the framework of scientific or professional activities.

Exact records must be kept of these donations or grants. Donations and grants to individual members of institutions consisting of professionals are not permitted.

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?

Under the Pharmig Code of Conduct, pharmaceutical companies must publish donations and grants to institutions, organisations or institutions that are predominantly composed of members of the professional community, unless these are of minor value. The institution that receives this donation must also agree to its publication. The donation may not be paid out without consent to publication.

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?

The AMG and the Pharmig Code of Conduct do not specifically regulate the presence of pharmaceutical companies in social media. However, the provisions for 'normal advertising' also apply to social media. Advertising in social media is therefore generally accepted.

With regard to websites, the Pharmig Code of Conduct obliges pharmaceutical companies to clearly indicate what information on the website is addressed to healthcare professionals or the general public. It must be ensured that only healthcare professionals have access to professional advertising (e.g. by means of access restrictions).

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

As mentioned above, in the context of the promotion of medicinal products, it is prohibited to grant, offer or promise any premium, financial or material advantage to any person entitled to prescribe or supply a medicinal product, except where such advantage is of negligible value and relevant to medical or pharmaceutical practice.

Furthermore, healthcare professionals may not demand or accept any premium, financial or material advantage as mentioned above.

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

In the context of the promotion of medicinal products the offering of benefits or inducements to healthcare professionals is governed by the AMG (see *inter alia* point 20).

Furthermore, under the Pharmig Code of Conduct, financial or material donations as well as grants to institutions consisting of professionals may only be made for certain purposes (see point 21).

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.

Penalties against a company or person can be imposed by administrative authorities or criminal courts (see point 24).

Civil claims (e.g. injunctive relief, damages) are asserted before civil courts. In addition to competitors, various associations can also be considered as plaintiff (see point 23).

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

Based on the UWG, any competitor or certain institutions (e.g. consumer protection association) may assert claims for injunctive relief, publication of judgements and damages before the general civil courts. This can lead to significant costs.

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?

Anyone who conducts advertising that does not comply with the provisions of the AMG commits an administrative offence, which is punishable by a fine of up to EUR 25,000, in the event of a repeat offence up to EUR 50,000. This does not apply if an ordinary court has jurisdiction.

Based on the UWG, anyone who knowingly uses aggressive or misleading business practices in the course of business for the purposes of competition in a

public announcement or in a medium (according to the Austrian Media Act) may be punished by the court with a fine of up to 180 daily rates.

The Pharmig Code of Conduct provides for a separate procedure in the event of a violation. Such a procedure is open to competitors as well as third parties. Penalties for the violation of the Pharmig Code of Conduct can range up to EUR 100,000 for the first violation and up to EUR 200,000 for the second violation.

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?

Only measures taken by courts/competent government authorities are binding. Self-regulatory measures are binding for members of Pharmig and non-members that voluntarily comply with the rules of the Pharmig Code of Conduct.

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.

There are no publicly available judgements by the Austrian Supreme Court (as far as can be seen) concerning violations of the advertisement provisions in the AMG in the last two years. Even the Association for Consumer Information (VKI), an Austrian consumer protection association which frequently asserts claims under the UWG, does not mention any claim in the last five years.