

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2008

A practical insight to cross-border Pharmaceutical Advertising work



Published by Global Legal Group with contributions from:

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 Žurić i Partneri

Austria

Barbara Kuchar



Max Mosing



Gassauer-Fleissner Rechtsanwälte GmbH

1 General - Medicinal Products

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

Special legal provisions regarding the advertising of medicinal products are stated in:

- Sec 50 to 56a of the Austrian Medicinal Products Act (“MPA”) (“Arzneimittelgesetz”, Austrian Federal Law Gazette 1983/185, as amended); and
- Sec 351g para 5 of the Austrian General Social Security Act (“Allgemeines Sozialversicherungsgesetz”, Austrian Federal Law Gazette 1955/189, as amended).

General legal provisions regarding the advertising in Austria are stated in:

- Austrian Unfair Competition Act (“UCA”) (“Gesetz gegen den unlauteren Wettbewerb”, Austrian Federal Law Gazette 1988/422, as amended).

Additionally, the Austrian Pharmaceutical Industries Association (Pharmig) and the Austrian Medical Chamber (“Ärztchamber”) established Industry Codes of Conduct regarding advertising of medicinal products in Austria. Under certain circumstances these Codes of Conduct can have factual legal effects in connection with the provisions of the UCA.

1.2 How is “advertising” defined?

Pursuant to Sec 50 MPA “advertising of medicinal products” shall include any form of information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

- advertising of medicinal products to the general public (business-to-layman advertising);
- advertising of medicinal products to persons qualified to prescribe or supply them (business-to-business advertising);
- visits by medical sales representatives to persons qualified to prescribe medicinal products;
- supply of samples;
- provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;
- sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and
- sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation

expenses in connection therewith.

However, the MPA states that the following cases are not covered by the restrictions regarding advertising of medicinal products:

- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- trade catalogues and price lists, provided they include no product claims;
- information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products; and
- approved summary of product characteristics, patient instructions for use and labelling.

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

Neither the Austrian laws nor the Codes of Conduct lay down any specific requirements for companies to ensure compliance. In Austria there exists no possibility to “sign off” promotional copies.

However, generally the companies ask for approval of the planned advertising of medicinal products from their attorneys at law respectively from their in-house lawyers. Nonetheless, an (incorrect) approval does not limit the liability of the companies for advertisement actually not complying with the Austrian laws.

Please note that pursuant to Sec 50a MPA advertising of medicinal products is only permitted for:

- medicinal products for which a marketing authorisation has been issued;
- registered traditional herbal medicinal products;
- registered traditional homeopathic medicinal products; and
- medicinal products for which a license for distribution via parallel import was issued.

The advertising of medicinal products shall present the properties of the medicinal product objectively and without exaggerating, and medicinal products advertising may not include either statements or pictorial representations, which:

- attribute an effect to the medicinal product that is not in keeping with its actual effect;
- wrongly create the impression that success may always be expected; or
- are not consistent with the labelling or with the instructions for use or with the summary of product characteristics (SPC) (see question 9.3 for case law).

Please note that pursuant to the (Pharmig members binding) Code of Conduct 7/2007 of Pharmig pharmaceutical companies are not permitted (*inter alia*): (i) to make reference to brands of competitors in their documentation or in their advertisement, unless permission has been granted to do so or this reference is admissible according to the provisions of the UCA; (ii) to imitate typical advertising features of competitors, the presentation, packaging or labelling of competitor products; (iii) to publish misleading or causing damage to reputation advertisement; (iv) to behave themselves in a blatant manner (as through exaggerated emphasis); (v) to assert in their statements that a product has no undesirable effects, side effects or toxic effects and/or addictive or habit-forming effects; (vi) to use the terms “safe” and “safety” without clearly defining them; (vii) to use the word “new” without any specification and/or definition so that it is not clear from the information provided to what the word “new” is actually referring; and (viii) to use the word “new” after one year has passed since the medicinal product, the respective indication, the respective pharmaceutical form, the respective application, the respective dosage or the respective package size was first put into circulation.

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

In Austria advertising of medicinal products must neither be approved by the competent authorities nor by the named associations in question 1.1.

In no case the authorities are competent to demand an approval of advertising of medicinal products in advance respectively to demand the supply of copies of advertising material prior to its publication.

However, if the compliance of the material is in dispute, the companies have to submit to the authorities (and in the Pharmig procedure) the material to establish whether it complies or not. It is worth mentioning that bodies of the Federal Agency for Safety in Health Care (department “PharmMed”) and the experts instructed by the Office are entitled to enter any premises and inspect any documentation and make copies as necessary for monitoring the compliance; inspections shall be carried out during operating hours unless danger is looming.

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

Pursuant to Sec 56a MPA the Federal Agency for Safety in Health Care - more concrete its department PharmMed - shall take all steps, which are necessary to restore a state conforming to the law, if an inspection (see question 1.4) shows or if the Federal Office for Safety in the Public Health System is otherwise informed that the MPA is violated in the context of advertising of medicinal products in Austria.

Therefore, the Federal Agency for Safety in Health Care (PharmMed) is entitled to order that the material is no longer distributed or must be recalled. However, the rules do not authorise the authority to require the issuing of a corrective statement.

Furthermore, violations of the advertising provisions of the MPA constitute an administrative offence (see question 1.6). The

Austrian General Procedural law on Administrative Offences applies and therefore, the right to appeal is provided by law.

Pursuant to the MPA in cases of advertisement not complying with the MPA a suit for a cease-and-desist order may be filed (see details in question 1.5). Furthermore, advertisements not complying with the MPA may also constitute a breach of the UCA and therefore, a suit for a cease-and-desist order may be filed by any competitor. On actions based on MPA respectively based on UCA the Austrian General Civil Procedural law applies and the right to appeal is provided by law.

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

Pursuant to Sec 84 MPA an administrative offence by violating the advertisement regulations of the MPA shall be punished with a fine amounting up to EUR 25,000 and a repeat offence shall be punished with a fine amounting up to EUR 50,000.

Furthermore, pursuant to Sec 85 MPA the Federal Office for Safety in the Public Health System may withdraw a marketing authorisation if a company was punished three times for violating the advertisement regulations of the MPA. In this context it is worth mentioning that repeated violation may also result in the withdrawal of the whole trade license of the company.

Pursuant to Sec 85a MPG in cases of advertisement not complying with the MPA a suit for a cease-and-desist order may be filed. The suit may be filed *inter alia* by the Federal Chamber of Labour, the Federal Economic Chamber, the Presidential Conference of the Austrian Chambers of Agriculture, the Main-Association of Social Security Insurances, the Austrian Trade Union Federation, the Austrian Patient Advocacies, the “Verein für Konsumenteninformation”, the Pharmig, the Austrian Medical Chamber or by the Austrian Chamber of Pharmaceuticals.

Please note that advertisement not complying with the MPA may also constitute a breach of the UCA and therefore, a suit for (*inter alia*) a cease-and-desist order may be filed by any competitor. This is the main field of legal conflicts: numerous cases are brought in front of the courts every year (see questions 1.7 and 9.3).

Additionally, the Pharmig has implemented an own procedure: The Pharmig Committees of Experts 1st and 2nd Instance are in charge of negotiating and deciding in the case of disputes relating to the violation of the Pharmig Code of Conduct vis-à-vis Pharmig members. The Pharmig Committee is entitled to impose the following sanctions in addition to the admonition and the cease-and-desist order: (i) in the case of a serious violation, a penalty of not less than EUR 5,000 up to a maximum of EUR 200,000 (the later in case of repeat violations); (ii) the violation may be publicly announced and the company concerned named in a Pharmig publication; (iii) the parent company of the company concerned will be notified accordingly; (iv) the Secretary General of EFPIA will be notified accordingly; and (v) exclusion from Pharmig or termination of the Pharmig Agreement. The Code provides the right of appeal against decisions of the Pharmig Committees of Experts 1st Instance.

Generally, there is a tendency that on all levels the rules have been enforced stricter over the last years - nevertheless, most cases are raised with the courts by competitors based on the UCA (in connection with the MPA).

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

The Austrian Pharmaceutical Industries Association (Pharmig), as the main self regulatory body regarding advertisement of medicinal Products in Austria, was established 1954 as a volunteer representation of interests of the Austrian pharmaceutical industry. Today Pharmig has more than 120 members. However, there is no “legal” relationship between the authorities and the Pharmig what so ever.

Neither the Federal Office for Safety in the Public Health System (PharmMed) nor the Pharmig Committees of Experts 1st and 2nd Instance are bound by any decision of the other body. Generally, they do not communicate (to the disadvantage of the companies) with each other and therefore, they investigate the possible violations on their own. The published findings of the Pharmig Committees of Experts 1st and 2nd Instance are made anonymous.

If any possible violation is drawn to the attention of the Federal Office for Safety in the Public Health System (PharmMed), they investigate *ex officio*.

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

The Austrian Unfair Competition Act (“UCA”) provides competitors with the right to file a suit:

- for a cease-and-desist order, including the right to apply for a temporary injunction;
- for removal of disturbance;
- for publication of sentence;
- for reimbursement of damages, including the claim for rendering of accounts; and/or
- for disclosure in connection with service providers,

(*inter alia*) when advertisements do not comply with the Austrian laws (= “marketing in breach of laws”). Advertisement for medicinal products not complying with the MPA may also constitute a breach of the UCA. There exists a lot of case law based on UCA in connection with advertisement for medicinal products (see question 9.3), whereas most of the cases relate to (illegal) business-to-layman advertising (especially regarding compliance-brochures); (unfair) advertising in connection with the Austrian General Social Security Act; (unfair) comparative advertising; borderline cases between food supplements, cosmetics, medical devices and medicinal products; and in connection with repackaging of foreign medicinal products.

2 Providing Information Prior to Authorisation of Medicinal Product

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

Information on non-authorised medicinal products can be made available in response to a documented request from specialist circles. Any kind of advertisement for non-authorised medicinal products is strictly prohibited with the exception of business-to-business advertising in connection with scientific events, if the participants come predominantly from abroad.

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

Apart from the publication of scientific articles in scientific journals, companies may distribute speeches or discussion contributions held at an event, or reports on these, provided they ensure that this information correctly express what was communicated at the event. The same applies if they commission other persons, media or companies to do this.

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

See question 2.2 above.

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

Information can either be made available in response to a documented request from a health professional or in the form of information regarding speeches etc. as described under question 2.2 above.

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

Apart from the correspondence with the authorities, as in the course of marketing authorisation, no other explicit exceptions regarding information on non-authorised products are available than the providing of information upon specialist request or as a summary of speeches and contributions.

Objective scientific information without any promotional character will however not contradict the legal restrictions.

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

According to the Pharmig Code of Conduct 7/2007 any service rendered by a physician for a pharmaceutical company of any kind (e.g. lectures, consulting, clinical trials, observational studies) must

be based on a written contract clearly indicating the service to be provided and the consideration received.

Such contractual service to be provided by a physician must be a scientific or technical activity performed for a company; this also includes educational purposes (prohibition of “sham contracts”).

Observational studies as well as all other studies or data survey may not be misused for the purpose of influencing therapy or procurement decisions or for mere advertising purposes.

Considerations may only consist of money and must be proportionate to the service provided. Among other options, the fee schedule for physicians can be used to assess the proportionality of a consideration. Appropriate hourly fees may also be agreed to compensate for the time spent in providing the service.

We are not aware of any further guidelines in this respect.

3 Advertisements to Health Professionals

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

Pursuant to Sec 54 MPA the advertising of a medicinal product to persons qualified to use or supply medicinal products shall contain, if such advertising appears in printed publications, via electronic media or by way of telecommunication, in a clearly legible form the essential information on the medicinal product consistent with the summary of product characteristics (SPC).

Furthermore, based on Sec 39 of the Austrian Regulation dealing with the Summary of Product Characteristics for Medicinal Products (“Verordnung über die Fachinformation (Zusammenfassung der Produkteigenschaften) für Arzneispezialitäten”, Austrian Federal Law Gazette 1998/3, as amended) advertising to professionals must include the following information: (i) name of the medicinal product; (ii) qualitative and quantitative composition; (iii) indications and contraindications; (iv) excipient; (v) whether the product is only available on prescription; (vi) whether such products shall only be distributed by pharmacies; (vii) whether such products can be disposed outside a pharmacy; (viii) pharmacodynamic properties; and (ix) to what extent the product is covered by the provisions on narcotics.

However, with respect to precautions, special warnings, interactions with other medicinal products, and undesirable and addictive effects of the product a reference in the publication to the SPC is sufficient.

Any advertisement to persons qualified to prescribe or supply medicinal products shall also state the date on which the information was drawn up or last revised.

See for further promotion material also question 3.4.

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

Comparative claims are not regulated in the MPA.

Generally, comparative claims in advertisement are subject to Sec 2a UCA (see question 3.3).

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

Comparator advertisements claims are not regulated in the MPA.

Generally, comparative claims in advertisement are subject to Sec 2a UCA: Comparative advertising shall be permissible, provided that it does not violate the fair competition, especially by discrediting the competitor and the advertisement does not create confusion in the market place.

The for Pharmig members binding Code of Conduct 7/2007 of Pharmig “specifies the environment” of comparative claims: Pharmaceutical companies are not permitted (*inter alia*):

- to make reference to brands of competitors in their documentation or in their advertisement, unless permission has been granted to do so or this reference is admissible according to the provisions of the UCA (see case law below);
- to imitate typical advertising features of competitors, the presentation, packaging or labelling of competitor products; and
- to publish misleading or causing damage to reputation advertisement.

The Austrian Supreme Court ruled on December 17, 2002 (4 Ob 241/02y) that a comparison between the prices of an original and generic product, where it is inevitable to name the brand name of the original product, is generally admissible.

Regarding the question if it would be possible to refer to a competitor’s product which had not yet been authorised in Austria, no case law has been issued yet. However, as long as such reference complies with the regulation above, it seems to be possible. However, pursuant to Sec 50a MPA advertising is only permitted for medicinal products for which a marketing authorisation has already been issued.

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

All documentation relating to a medicinal product which is transmitted as part of the promotion of that product to persons qualified to prescribe or supply it, have to meet the requirements named in question 3.1.

Furthermore, all such documentation shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in such documentation shall be faithfully reproduced and the precise sources indicated. Where such documentation refers to scientific literature, the essential content of the same shall be faithfully reproduced and the precise sources indicated.

Please note that the Code of Conduct 7/2007 states: if companies distribute speeches or discussion contributions held at an event, or reports on these, they must ensure that this information correctly express what was communicated at the event. The same applies if they commission other persons, media or companies to do this.

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

Neither the MPA nor the Code of Conduct 7/2007 of Pharmig refer to “teaser advertisements”. However, “teaser advertisements” must comply with the general requirements established by the MPA, the UCA and any other legal requirements.

Please note that regarding advertising to the general public of a medicinal product Sec 52 para 4 MPA states that advertising consisting exclusively of naming a medicinal product (“reminder advertising”) must not provide all information relevant for the

appropriate use of the medicinal product. However, if the “reminder advertising” appears on posters, printed advertisements or via acoustic or audiovisual media, a clearly visible reference to the fact that the medicinal product may cause undesirable as well as desirable effects and that the instructions for use must therefore be carefully observed or the advice of a physician or pharmacist followed, shall be included.

4 Gifts and Financial Incentives

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

According to Sec 58 MPA medical samples may be supplied only free of charge and shall be no larger than the smallest presentation on the market and must have a clearly legible and irremovable notice attached: “Unverkäufliches Ärztemuster” (free medical sample - not for sale). Delivery may be made only to physicians, dentists, veterinary surgeons upon their written request. Records must be kept of each medical sample delivered. Further restrictions are provided in the MPA as follows:

In the first year after first delivery as many medical samples of a proprietary medicinal product as may be necessary to assess the success of treatment of at most 10 patients; a maximum of 30 medical samples per recipient may be given, after one year at two medical samples per request, however, per recipient at most five medical samples per proprietary medicinal product per year is accepted.

The delivery of medical samples containing psychotropic or addictive substances generally is prohibited.

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

Sec 55 MPA prohibits the granting, offering or promising of gifts, pecuniary advantages or benefits in kind unless they are inexpensive and relevant to the practice of medicine or pharmacy.

The Pharmig Code of Conduct 7/2007 is even stricter by stating that in commerce, pharmaceutical companies and their employees shall not influence the buying, selling, prescribing or supplying behaviour by granting, offering or promising any gifts, whether in money or in kind.

The above mentioned rules do not prevent the provision of give-aways by pharmaceutical companies, provided they have only a small value commensurate with the occasion they are used for and have causal and direct connection to the addressee’s customary activity and serve the activity’s purpose. Give-aways may not contain any further reference or advertising messages than the company name, company logo or the company mark and/or the name of the medicinal product or the designation of the active substance its contains.

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

The sponsoring of institutions such as hospitals is not regulated by the MPA or the Pharmig Code of Conduct 7/2007 in general. It is not permitted to grant, offer or promise a premium, financial or material benefits to members of specialised circles for the

prescription or use of a medicinal product or the recommendation of a medicinal product to a patient.

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

By the general rule of the Pharmig Code of Conduct 7/2007 according to which pharmaceutical companies and their employees shall not influence the buying, selling, prescription or distribution behaviour by granting, offering or promising any gifts, whether in money or in kind, there is no possibility for legally providing medical or educational goods and services to doctors that could lead to changes in prescribing patterns.

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

According to Sec 55b of the MPA the granting, offering or promising of rebates in kind to persons qualified to prescribe or supply medicinal products is prohibited in the case of medicinal products included in the reimbursement code of the Board of the Austrian Social Insurance Institutions. It is prohibited for persons qualified to prescribe or supply medicinal products to solicit or accept rebates in kind described above.

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

Already under the general rules of the Austrian Unfair Competition Act (UCA) the granting of an extra benefit in connection with the purchase of a different product is considered unlawful. The more specific rules on medical advertising explicitly prohibit the acceptance respectively offering and/or granting of gifts and other benefits except for give-aways having a small value.

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

The offering of a refund scheme for a non-working product with regard to medicines most likely will be considered as “blatant” and in breach with the general rules of the UCA. Also with regard to an over-the-counter medicine such scheme could be considered “high risk”.

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

The sponsoring of continuing medical education is not regulated by the MPA or the Pharmig Code of Conduct in general provided the sponsoring is not connected with the prescription or use of a medicinal product or the recommendation of a medicinal product to a patient.

5 Hospitality and Related Payments

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

Pursuant to Sec 55a MPA no pecuniary advantages or benefits in kind may be supplied, offered or promised to health professionals unless these benefits are inexpensive and relevant to the practice of medicine or pharmacy. Additionally, hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than persons qualified to prescribe or supply medicinal products.

Please note that inappropriate provision to officials of public institutions/hospitals could be evaluated as bribery and could be prosecuted based on the Austrian Criminal Code.

Regarding the “cooperation with specialist circles or third parties” the Code of Conduct 7/2007 of Pharmig states that any service rendered by a physician for a pharmaceutical company of any kind (e.g. lectures, consulting, clinical trials, observational studies) must be based on a written contract clearly indicating the service to be provided and the consideration received. Considerations may only consist of money and must be proportionate to the service provided.

Furthermore, the Code of Conduct states that hospitality is only admissible in the course of events and business dinners for the purpose of an information exchange with members of specialist circles and only to a reasonable degree, not lavish, and to the extent that is considered socially appropriate. The occasion for extending hospitality is to be documented. Granting hospitality to accompanying persons the members of specialist circles is not permitted.

Regarding the rules on events see question 5.2.

Please note that pursuant to the MPA also persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited by the MPA.

The above does not change whether the hospitality is offered inside Austria or abroad.

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

The named provisions in question 5.1, that no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply them, shall pursuant to Sec 55a MPA not prevent direct or indirect payment of reasonable travel expenses and accommodation expenses and participant’s fees at events for purely professional and scientific purposes. Nevertheless, such hospitality shall always be strictly limited to the main scientific objective of the event. Furthermore, the payment of travel and accommodation expenses and participant’s fees as well as hospitality must not be extended to persons other than persons qualified to prescribe or supply medicinal products.

Please note that the MPA empowers the Federal Minister for Health and Women to issue an ordinance defining: (i) when the intrinsic value of bonuses or financial or material benefits is minimal; (ii) the permitted type and scope of hospitality in connection with events for the promotion of medicinal products including the choice of the conference site and hospitality; (iii) the criteria an event must meet to be considered a purely professional and scientific event; (iv) the

reasonableness of travel and accommodation expenses at events for professional and scientific purposes; and (v) the permitted type and scope of hospitality in connection with events for professional and scientific purposes including the choice of the conference site; it shall be carefully avoided to give the impression that persons qualified to prescribe or supply medicinal products are to be unduly influenced in their therapeutic decisions or recommendations. For whatever reason, such ordinance has not been issued since January 2, 2006.

Regarding “scientific events” the Code of Conduct 7/2007 of Pharmig states that the assumption of costs for these events shall be restricted to travel costs, room and board as well as the original admission fee. Social programmes (e.g. theatre, concerts, sports events) for participants may not be financed or organised. The invitation of any accompanying persons is not permitted. Therefore, pharmaceutical companies are not permitted to take care of the organisation nor assume the costs for travel, room and board or expenditures for recreational.

In any case, it is not possible to pay a doctor for his time “just attending” a scientific meeting.

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

Pharmaceutical companies might be held liable if they are organising an event contradicting the named provisions in questions 5.1 and 5.2.

Furthermore the Code of Conduct 7/2007 of Pharmig states that events must exclusively serve to provide scientific information and/or further specialisation. The venue must be appropriate for the purpose of the event, located in the home country and be chosen based on objective factors. The recreational value of a conference venue is no selection criterion. The organisation, implementation and/or support of international events or the assumption of costs for participation in these events is not admissible, if (i) the majority of participants come from a different country then the country in which the member company is based, or (ii) the necessary resources or specialised knowledge are available at the event venue, and in view of this there are appropriate logistical reasons for choosing a venue in a different country (in the case of recognised specialised congresses with international speakers or visits to the company’s own scientific or production facilities abroad).

The Code of Conduct also states that the invitation of persons as participants or speakers to events may not be made dependent on the recommendation, prescription or distribution of specific medicinal products. The speakers must inform the event organiser of any conflicts of interest and appropriately disclose their presentation to the participants of the event prior to the start of the event. The speaker’s fee must be adequate to the service rendered. In addition, their expenses, including travel costs, incurred through the participation in the event may be reimbursed appropriately.

In general, by just sponsoring an even without having any influence on the event as such a company cannot be held responsible for the breach of the laws by the organiser respectively by the speakers.

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

Generally, doctors can be paid by companies for expert services

services (e.g. participating in focus groups). However, the Code of Conduct 7/2007 of Pharmig states that in the cooperation with physicians, the generally recognised principles of the medical profession and the principles of the representation of interests of the pharmaceutical industry, which go beyond these, shall be observed.

Furthermore, the Code of Conduct 7/2007 of Pharmig states that any service rendered by a physician for a pharmaceutical company of any kind (e.g. lectures, consulting, clinical trials, observational studies) must be based on a written contract clearly indicating the service to be provided and the consideration received. Such contractual service to be provided by a physician must be a scientific or technical activity performed for a company; this also includes educational purposes (prohibition of “sham contracts”). Considerations may only consist of money and must be proportionate to the service provided.

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

In the following “post marketing surveillance study” is understood as a medical observational study after the medicinal product was launched.

For the general requirements see question 5.4. Furthermore, the Code of Conduct of the Austrian Medical Chamber (“Ärztlicher Verhaltenskodex der Österreichischen Ärztekammer”) states that a physician is not allowed to accept a performance-related fee, but the payment should correspond to the time and effort used in this project. For postmarketing surveillance studies, the Code of Conduct of the Austrian Medical Chamber states that the compensation for taking part shall follow the Guidance for Private Medical Fees of the Austrian Medical Association. It is worth mentioning that publications based on sponsored observational studies have to name the sponsor. Furthermore, the Code of Conduct of the Austrian Medical Chamber obliges physicians having shares in pharmaceutical companies to abstain from providing any services for such companies.

The Code of Conduct 7/2007 of Pharmig states that observational studies as well as all other studies or data survey may not be misused for the purpose of influencing therapy or procurement decisions or for mere advertising purposes. For the required documentation in the course of the observational study, a financial consideration that meets the local standard and appears appropriate for the service provided may be paid. In any case, the payment of a consideration for the services provided in the course of an observational study may not represent an incentive for the prescription of a medicinal product.

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

For the general requirements see questions 5.4 and 5.5.

Pursuant to Code of Conduct 7/2007 of Pharmig service to be provided by a physician must be a scientific or technical activity performed for a company. Furthermore, the Code of Conduct 7/2007 of Pharmig states that a physician or a third party shall not be granted, offered or promised any remuneration or benefit in kind to ensure that the physician agrees to receive a medical sales representative or accept information from members of other companies.

6 Advertising to the General Public

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

It is possible to advertise non-prescription medicines to the general public provided the following legal provisions of Sec 51 et seq MPA are met.

Advertising to the general public of a medicinal product shall be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product. Advertising and editorial contributions must be clearly identifiable as such.

The advertising of a medicinal product to the general public may include information about the marketing authorisation or registration, provided that it refers exclusively to the fact of the marketing authorisation or registration and this information is not apt to create a false impression in the consumers in terms of safety and effectiveness of the medicinal product concerned.

(i) Minimum Information

All advertising to the general public of a medicinal product shall include the following minimum information:

- name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;
- any information necessary for correct use of the medicinal product;
- a clearly visible reference to the fact that the medicinal product may cause undesirable as well as desirable effects and that the instructions for use must therefore be carefully observed or the advice of a physician or pharmacist followed. If the medicinal product is advertised in the acoustic or audio-visual media, this information must be made clearly evident acoustically; and
- advertising to the general public of a traditional herbal medicinal product shall additionally point out that it is a traditional herbal medicinal product for use for a specific therapeutic indication or for specific therapeutic indications exclusively on the basis of many years of use.

Advertising to the general public does not have to meet the requirements defined above if the advertising consists exclusively of naming a medicinal product (reminder advertising), unless it is a matter of advertising of medicinal products for performance enhancing in sports.

(ii) Prohibited Content

The advertising of a medicinal product to the general public shall not contain any material which:

- includes pictorial representations in conjunction with members of the healing professions or healthcare institutions;
- gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
- suggests that the effects of taking the medicine are guaranteed without adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;
- suggests that the health of the subject can be enhanced by taking the medicine;
- suggests that the health of the subject could be affected by not taking the medicine;
- is directed exclusively or principally at children;
- refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but

who, because of their celebrity, could encourage the consumption of medicinal products;

- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggests that the safety or efficacy of the medicinal product is due to the fact that it is “natural”;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refers, in improper, alarming or misleading terms, to claims of recovery;
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof; and
- is aimed at the procurement of medicinal products by mail order.

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

Pursuant to Sec 51 MPA advertising to the general public of a medicinal product is not permitted for medicinal products requiring prescription at all.

The only exception to the advertising prohibition regarding prescription-only products is vaccination campaigns carried out or sponsored by the competent authorities.

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

It is admissible to distribute issue-related information relating to diseases or human health, without any (even not indirect) reference to a medicinal product and information as part of the pharmacovigilance activities in coordination with the authorities.

Written documentation on prescription only medicines which are provided by the physician to the patient and serve to improve patient compliance and as special concomitant therapeutic measure must not contain any business-to-layman advertisement relating to preparations. The indication of the trade name of the preparation is permitted.

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

Pursuant to Sec 50 MPA the following is not considered falling under the legal term “advertisement for medicines”:

- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- trade catalogues and price lists, provided they include no product claims; and
- information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.

Additionally the Code of Conduct of Pharmig 7/2007 provides for the following shortlist of non-promotional information:

- correspondence and documents of a non-promotional nature needed to answer a specific question on a particular medicinal product;

- sales catalogues and price lists, provided they include no product information;
- issue-related information relating to diseases or human health, provided no reference is made - also no indirect reference - to a medicinal product;
- information as part of the pharmacovigilance activities in coordination with the authorities;
- company-related information, e.g. to investors or current or future employees, including financial data, reports on research and development programmes as well as information on regulatory developments concerning the company and its products;
- information on non-authorised medicinal products in response to a documented request from specialist circles;
- correspondence with the authorities, as in the course of marketing authorisation, pharmacovigilance or inspections; and
- texts approved by the authorities, e.g. summary of product characteristics or the patient information leaflet.

A press release as described above most likely will be considered unlawful advertising.

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

Information is considered lawful and non-promotional if it is company-related information including financial data, reports on research and development programmes as well as information on regulatory developments concerning the company and its products.

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

Regarding pharmaceutical advertising no specific rules exist with regard to funding of patient support groups and/or transparency requirements.

7 The Internet

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

The MPA does not state any specific regulations regarding advertising of medicinal products via the Internet.

However, the Code of Conduct 7/2007 of Pharmig regulates the Internet advertising rather concrete (*inter alia*):

- For information and advertisement on medicinal products made accessible by pharmaceutical companies, in their commission or with their approval in the Internet, the same requirements as “offline” have to be met.
- The presentation on the Internet must clearly specify the pharmaceutical company that is operating the website or directly or indirectly supporting it and which information on the website is addressed to specialist circles and/or to the general public.
- Information on the website must be updated on a regular basis and checked for its accuracy and should provide updated information.
- Regarding Information on the company: Websites may contain information of interest to investors, the media and

general public. Websites may contain financial data, descriptions of research and development programmes, information regarding regulatory matters which concern pharmaceutical companies and their products, information for future employees, etc.

- Regarding Information for patients and the general public via the Internet see question 7.4.
- Regarding information for specialist circles:
 - Information addressed to the specialist circles and containing advertisement must comply with the applicable provisions of the Pharmig Code of Conduct.
 - Information for specialist circles must be clearly indicated as such. It must be ensured that the access to this information is reserved exclusively to specialist circles.

Regarding the control of these requirements see questions 1.5 and 1.6.

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

As mentioned in question 7.1 the Code of Conduct 7/2007 of Pharmig states that Information for specialist circles must be clearly indicated as such. Furthermore, it must be ensured that the access to this information is reserved exclusively to specialist circles. However, the Code of Conduct 7/2007 of Pharmig does not stipulate any specific security requirements to ensure that members of the general public do not access this information.

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

The MPA does not stipulate any specific regulations regarding linking.

The Code of Conduct 7/2007 of Pharmig states that the website may contain a link to the complete, unmodified evaluation report as published by the CHMP (Committee for Human Medicinal Products) or a competent national authority. Furthermore, the website may contain links to other websites containing reliable information on medicinal products (websites of authorities, medical research institutions, patient organisations, etc.).

According to the Austrian doctrine generally there is no liability in case of "reverse linking".

Pursuant to Sec 17 of the Austrian E-Commerce Act ("E-Commerce-Gesetz", Austrian Federal Law Gazette I 2001/152) the company, which provides access to third-party information by means of an electronic link shall not be responsible for such information, provided the company: (i) does not have actual knowledge of illegal activity or information and, as regards claims for damages, is not aware of facts or circumstances from which the illegal activity or information is apparent; or (ii) upon obtaining such knowledge or awareness, acts expeditiously to remove the electronic link. However, this "privilege" shall not be applicable if the person from whom the information stems is subordinate to or supervised by the company or if the company presents the third-party information as its own.

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

For general information see question 7.1.

The MPA does not state any specific regulations regarding what information may a pharmaceutical company place on its website that may be accessed by members of the public. However, the general rules apply on such information, see question 1.3.

The Code of Conduct 7/2007 of Pharmig states that a pharmaceutical company may place on its website information addressed to the layman and containing advertisement, as long as the content complies with the applicable provisions of the MPA and the according provisions of the Pharmig Code of Conduct. Furthermore, the websites may contain non-promotional information on the medicinal products sold by the company for patients and the general public (incl. information regarding indication, side effects, interactions with other substances, application, reports on clinical research, etc.); conditionally, this information must be balanced, accurate and in harmony with the authorised summary of product characteristics (SPC).

The Code of Conduct 7/2007 of Pharmig states that apart from the brand name, the international non-proprietary name (INN) must also be mentioned on the website and the website must always contain a reference to a physician or pharmacist for further information.

8 General - Medical Devices

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

Sec 102 et seq. of the Medical Devices Act (MDA) ("Medizinproduktegesetz", Austrian Federal Law Gazette I 1996/657, as amended) govern the advertising of medical devices in Austria. Pursuant to the MDA different regulations apply on advertisement addressing consumers or health care professionals.

All advertisements for medical devices must clearly reveal the advertising character of the announcement and the product itself must be unambiguously presented as a medical device.

Generally, advertisements addressing consumers are not permissible for medical devices, which: (i) can only be obtained by prescription; (ii) can exclusively be administered by a health care professional; or (iii) can only be used under the supervision of a physician or a dentist. Furthermore, advertisements addressing consumers are not permitted when it: (a) suggests that the effect of the medical device is better than or equivalent to another treatment or a medical device; (b) is directed mainly at children; (c) gives the impression that consulting a physician is superfluous, in particular, by leading to an erroneous self diagnoses or suggesting treatment via mail; (d) refers in improper, alarming or misleading terms to claims of recovery; or (e) refers in improper, alarming or misleading terms to graphical descriptions of changes in the human or animal body resulting from diseases, etc.

Advertisements (legally) addressed to consumers must, at least, contain the following information:

- the name of the medical device;
- the intended purpose of the medical device;
- the necessary information for the appropriate use of the medical device; and
- an unambiguous warning if the medical device leads to unwanted effects or if for the use of the product specific precautionary measures must be taken; and
- a reference to the product information and state that the product information must be closely followed and if necessary that physicians, dentists, pharmacists, or other persons with an appropriate education should be consulted.

Advertisements addressed to health care professionals must be in compliance with the product information and all other approved information during the conformity assessment procedure.

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

The same regulations as for physicians prescribing medicinal products apply. Therefore, see questions in section 4 and 5.

9 Developments in Pharmaceutical Advertising

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

The Code of Conduct in its version 7/2007 by the Austrian Pharmaceutical Industries Association (Pharmig) brought more detailed regulations regarding the field of pharmaceutical advertising, especially advertisement via the Internet.

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

In the field of pharmaceutical advertising no significant developments are expected next year.

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

The Austrian Supreme Court ruled that a suit for a cease-and-desist order based on Sec 85a MPA (see question 1.6) does - contrary to the claim based on the UCA - not require any default by the "infringer"; the actual breach is sufficient for the suit (4 Ob 174/07b).

In another decision the Austrian Supreme Court ruled that pursuant to Sec 50a para 3 MPA the advertising of medicinal products may not include statements that are not consistent with the summary of product characteristics (SPC); therefore, advertisement referring to a higher dosing than in the SPC contradicts the law and therefore, violates the UCA (4 Ob 58/07v).

On the other hand, the Austrian Supreme Court ruled in other decisions that advertisements are only in breach of Sec 50a para 3 MPA in cases where the advertisements are contradictory to the SPC; therefore, advertisement with (correct) effects that are not mentioned in the SPC do not violate the UCA (4 Ob 78/07k and 4 Ob 174/07b).

Finally, the Austrian Supreme Court ruled that pursuant to the ECJ decision C-322/01 (Doc Morris) a national ban on (the advertisement for) long-distance-selling of medicinal products is only legally possible as far as the medicinal products requires a prescription; if a prescription is required has to be evaluated based on the laws of the state of residence of the purchaser, but not of the laws to which the seller is subject to (4 Ob 48/08z).

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

Neither the MPA nor the Code of Conduct 7/2007 by the Austrian Pharmaceutical Industries Association (Pharmig) has been amended in order to implement the current version of the EFPIA Code of October 2007. However, the differences between the Code of Conduct 7/2007 and the EFPIA Code of October 2007 seem to be minor.

**Mag. Barbara Kuchar**

Gassauer-Fleissner Rechtsanwälte GmbH
Wallnerstrasse 4
A-1010 Wien
Austria

Tel: +43 1 205 206 120
Fax: +43 1 205 206 207
Email: b.kuchar@gassauer.at
URL: www.gassauer.at

EDUCATION AND CAREER:

University of Vienna, Faculty of Law (Mag. iur. 1991).
Associate at Weis-Tessbach Rechtsanwälte OEG (1993-1996).
Management of the Weiss-Tessbach Budapest office (1996).
Foreign associate at A&L Goodbody Solicitors, Dublin (1996 - 1997).
Attorney at law in Vienna (since 1997).
Partner of Weiss-Tessbach Rechtsanwälte OEG (1997 - 2002).
Partner of Gassauer-Fleissner Rechtsanwälte GmbH (since 2002).
PRACTICE AREAS: Intellectual Property Law; Unfair Competition,
Advertising Law, Franchising and Licensing.

MEMBER OF: Austrian Association for Industrial Property and
Copyright, AIPPI, ECTA, LES, TIPLI, INTA.

LANGUAGES: German, English, French, Italian.

SUMMARY: Barbara Kuchar was admitted to the Austrian bar in
1997. She works primarily in the fields of intellectual property law
and unfair competition law, including trade libel. Barbara Kuchar
also assists clients in taking efficient action against counterfeiters
before courts and the customs authorities; further areas of
competence include licensing and franchising. She is a member of
the Austrian Association for Industrial Property and Copyright, and
also of AIPPI, ECTA, LES, INTA and TIPLI. Barbara Kuchar has
published on IP subjects in the Austrian legal journal ÖBI and
foreign publications, such as her contribution of the Austrian chapter
to the IP Enforcement Guide of the ICC Counterfeiting Intelligence
Bureau and the Austrian chapter in the first edition of Jurisdictional
comparisons "Trade Mark Litigation" (European Lawyer 2008).

**Dr. Max W. Mosing, LL.M., LL.M.**

Gassauer-Fleissner Rechtsanwälte GmbH
Wallnerstrasse 4
A-1010 Wien
Austria

Tel: +43 1 205 206 150
Fax: +43 1 205 206 207
Email: m.mosing@gassauer.at
URL: www.gassauer.at

EDUCATION AND CAREER:

University of Graz, Faculty of Law (Mag. iur. 2000; Dr. iur 2003).
Postgraduate studies in "Information Technology Law and Law
Information", University of Vienna (LL.M. 2001).
Associate at Schönherr Rechtsanwälte OEG, Vienna (2002).
Postgraduate studies in "Telecommunications Law", Strathclyde
University, UK (LL.M. 2003).
Associate at Rechtsanwalt Dr. Werner Mosing, Feldkirchen iK (2003).
Associate at Graf, Maxl & Pitkowitz Rechtsanwälte, Vienna (2004).
Lecturer at University of Applied Sciences for Information &
Knowledge Management, Eisenstadt (since 2004).
Associate at Gassauer-Fleissner Rechtsanwälte GmbH, Vienna
(2004 - 2007).
Attorney at law (since 2007).

PRACTICE AREAS: Information Technology Law; Data Protection
and e-Commerce Law; Industrial Property Law, esp Unfair
Competition Law, Trademark and Copyright Law; Pharmaceutical
Law and Liability of health professionals and veterinarians;
litigation.

MEMBER OF: Austrian society for Information Technology Law - IT-
LAW.AT; Society of Austrian Veterinarians Specialised in Horses -
VÖP; an.im.at - friends of veterinary anaesthesia, intensive care and
analgesia; TAT - Society for the Use of Animals in Therapies.

LANGUAGES: German, English.

SUMMARY: Max Mosing was admitted to the Austrian bar in 2007.
He works primarily in the fields of IT/IP law and unfair competition
law, including pharmaceutical marketing. Max Mosing is regularly
publishing on IT/IP subjects, such as his contribution to the
commentary on Austrian Copyright Law, several articles on
trademark issues, data protection, telecommunications and
copyright laws. Max Mosing is also active in the field of "medicine
law", especially pharmaceutical law and the liability of medical
doctors and veterinarians.



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