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The International Comparative Legal Guide to:

# Pharmaceutical Advertising 2012

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A practical cross-border insight into pharmaceutical advertising

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## Preface:



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# Austria


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## 1 General - Medicinal Products

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

- The Medicinal Products Act, "*Arzneimittelgesetz*" (in the following referred to as "AMG"), BGBl No 195/1983, as last amended by Federal Law Gazette (in the following referred to as "BGBl") No I 146/2009, sections 6 and 50-56a.
- Section 351g paragraph 5 of the General Social Security Act ("*Allgemeines Sozialversicherungsgesetz*" - ASVG, BGBl No 1955/189, as last amended by BGBl No I 101/2007).
- The Unfair Competition Act ("*Gesetz gegen den unlauteren Wettbewerb*" – in the following referred to as "UWG", BGBl No 1984/448, as last amended by BGBl No I 2007/79).
- The Austrian Pharmaceutical Industries Association's (Pharmig) Code of Conduct, in its current version of July 1, 2009 (in the following referred to as "CoC 2009").

### 1.2 How is "advertising" defined?

Section 50 AMG defines "advertising" and mainly reflects the wording of section 86 of Directive 2001/83/EC (as amended).

According to section 50 paragraph 1 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; it shall include in particular:

- the advertising of medicinal products to consumers (lay advertising);
- advertising of medicinal products to persons qualified to prescribe or supply them (expert advertising);
- visits by medical sales representatives to persons qualified to prescribe or supply medicinal products;
- the supply of samples;
- the provision of inducements to persons qualified 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
- payment of travelling and accommodation expenses, as well as attendance fees in the context of occupation-related scientific events for persons qualified to prescribe or supply medicinal products.

Section 50 paragraph 2 AMG explicitly excludes the following cases from the rules restricting advertising:

- correspondence, possibly accompanied by material of a non-promotional nature, which is 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.

Finally, section 50 paragraph 3 AMG provides that the advertising restrictions shall not apply to the approved summary of product characteristics, labelling and patient instructions for use if these are used in line with AMG.

### 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?

There is no explicit requirement to provide for specific compliance arrangements neither in the AMG nor in the Pharmig Code of Conduct.

However, section 56 AMG obliges the authorisation holder to ensure:

- that any promotion for its products complies with sections 50 – 56a AMG;
- that its medical sales representatives comply with the qualification requirements (section 72 AMG) and their obligations laid down in section 73 *et seq.* AMG; and
- all distributed promotional material is available and a register of all addressees and distribution ways is maintained.

Further, the authorisation holder has to nominate a person within the company who is responsible for the scientific information about the medicinal products distributed by the respective authorisation holder ("*Informationsbeauftragter*"). This person needs to be equipped with the necessary powers of such position. In practice, all promotional material will need "sign-off" by the qualified person (section 56 AMG).

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

There are no explicit requirements for companies to have SOPs on advertising activities in place. However, as there is a number of requirements to be fulfilled (see answers to the questions in sections 3 and 6 below), it seems advisable (and is common in industry) to establish such SOPs (see question 1.6).

**1.5 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, no prior approval by any authority is needed for the advertising of medicinal products, neither in general, nor in any specific situation. The law further does not provide the authority with a specific right to require the companies to have their promotional material approved in advance by the authority; however, such right could eventually be deducted from the authority's rights mentioned in section 56a AMG.

**1.6 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?**

The Austrian Federal Office for Safety in Health Care ("*Bundesamt für Sicherheit im Gesundheitswesen*", in the following referred to as "BASG") is entitled to take all necessary measures to restore a situation conforming to the law in case it finds, during an audit according to section 56a paragraph AMG or otherwise gets to know, that the advertising restrictions are violated; i.e. the BASG is also entitled to stop further publication of the advertisement in question. However, the law does not entitle the BASG to ask for a corrective statement. Against such measures which would usually be taken in the form of a decision ("*Bescheid*"), an appeal is admissible.

Violations of the advertising restrictions further constitute an administrative offence (administrative penalty of up to €50,000 in case of a repeated offence). Against decisions in this context, an appeal is admissible.

**1.7 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?**

A violation of the advertising restrictions contained in sections 50 to 55b AMG constitutes an administrative offence and penalties amounting to €25,000 or €50,000 (the latter in case of a repeated offence) can be imposed. Please note that the responsible authority for the imposition of such penalties is not the Federal Office for Safety in Health Care, but the respective regional administrative authority ("*Bezirksverwaltungsbehörde*").

Moreover, according to section 85 AMG, the BASG may withdraw a marketing authorisation if a company was punished three times for violating the advertising restrictions of the AMG.

The repeated violation of these regulations may also result in the withdrawal of the whole trade licence of the company.

However, in Austria, the predominant amount of cases of violations of the advertising restrictions are challenged by competitors and brought before the civil (commercial) courts. Any violation of the advertising restrictions constitutes a violation of section 1 UWG and the competitors can claim forbearance, (eventually, as the case may be) payment of damages and publication of judgment. Usually, the respective action is filed together with the application for rendering a preliminary injunction.

Furthermore, a number of institutions, *inter alia*, the Federal Economic Chamber, the Federal Chamber of Labour, the Main Association of Austrian Social Security Institutions, the Austrian Patient Advocacies, the Association for Consumer Information ("*Verein für Konsumenteninformation*"), the Pharmig, the Austrian Medical Association and the Austrian Pharmacists Association are entitled to sue undertakings for violation of the advertising restrictions based on section 85a AMG.

Finally, the industry association Pharmig has implemented its own procedure: The Pharmig Committees of Experts of the 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 as far as Pharmig Members are concerned. The Pharmig Committee of Experts of the 1st Instance is entitled to impose the following sanctions in addition to the admonition and the cease and-desist order: (a) in the case of a serious violation, a penalty of not less than €5,000 up to a maximum of €100,000 (and €200,000 in case of repeated violations); (b) the violation may be publicly announced and the company concerned named in a Pharmig publication; (c) the parent company of the company concerned will be notified accordingly; (d) the Secretary General of EFPIA will be notified accordingly; and (e) exclusion from Pharmig or termination of the Pharmig Agreement.

The Code provides for a right of appeal against decisions of the Pharmig Committee of Experts of the 1st Instance.

Please note that the predominant amount of cases are raised with the courts by competitors based on the UWG (in connection with the AMG) or by institutions (the Association for Consumer Information continues to be particularly active in this field) based on section 85a AMG.

**1.8 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?**

There is no legal relationship between the self-regulatory body of the Austrian pharmaceutical industry (Pharmig) and the authorities competent for supervision and enforcement of the advertising regulations, i.e. any decisions of Pharmig are neither binding nor otherwise relevant for the authorities. The competent authorities – namely the BASG and, in case any administrative offence procedure is opened, the respective *Bezirksverwaltungsbehörde* – will in any case investigate matters drawn to their attention on their own. Please note in this context that according to article 6.2.c of the *Pharmig Code of Procedure of the CoC Committees of Experts of the 1st and 2nd Instance* (forming an integral part of the CoC), a complaint with Pharmig is inadmissible if the object of the complaint is also the object of pending court proceedings.

**1.9 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?**

As mentioned in question 1.7 above, violations of the advertising restrictions can be challenged by competitors and brought before the civil (commercial) courts. Any violation of the advertising restrictions constitutes a violation of section 1 UWG and the competitors may claim forbearance, (eventually, as the case may

be) payment of damages and publication of judgment. Usually, the respective action is filed together with the application for rendering a preliminary injunction.

The plaintiff needs to be a competitor regarding the respective medicine for which unlawful advertising has been made.

## 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? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product's variants not authorised)?**

In principle, any promotion for non-authorised medicines is prohibited (section 50a paragraph 1 AMG), except in case of promotion to experts during scientific events if the majority of participants come from outside Austria (section 50b paragraph 2 AMG). There is no exception corresponding to section 50b paragraph 2 AMG in place for off-label information; one could in this case, however, argue with an *argumentum a maiore ad minus* as according to section 50b paragraph 2 AMG; even promotion for non-authorised medicines is permitted and therefore promotion for a non-authorised indication of an authorised medicine or for another product variant should be allowed under the same conditions, too. Please note that the above view has neither been confirmed, nor refused by case law so far, as the question has for the time being not been the object of a Supreme Court decision.

Further, it is possible to make available non-promotional information as a response to a (documented) specific question on the respective medicine. Likewise, the discussion of such unauthorised products during scientific meetings (even if sponsored by a company) is possible as long as the provided information is not promotional and a genuine exchange of scientific information takes place.

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

It is obviously possible to publish scientific articles on such medicines in scientific journals, but as any promotion for unauthorised medicines is prohibited, no publications of a promotional nature are allowed. However, it is possible to provide promotional material on such medicines during scientific events if the majority of participants come from outside Austria (section 50b paragraph 2 AMG, see above answer to question 2.1).

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

Such press releases will in general be covered by the broad definition of "advertising" in section 50 paragraph 1 AMG. As none of the exceptions in section 50 paragraph 2 AMG applies, the issuance of a press release on an unauthorised medicine will most likely violate section 50a paragraph 1 AMG.

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

It is possible to make available non-promotional information as a response to a specific question on the respective medicine. Otherwise, the prohibition to promote unauthorised medicines would be violated.

**2.5 How has the ECJ judgment in the Ludwigs case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in Austria?**

The Ludwigs case has not (yet) been reflected in the Austrian legislation or practical guidance.

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

There are no specific rules in Austria with respect to that situation; however, such information would most likely have to be regarded as promotion of the unauthorised medicine as it is obviously intended to enhance the sales of such product, and therefore such information is not admissible.

**2.7 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?**

First of all, it would be necessary to clarify if such involvement of health professionals would not as such already violate the prohibition to promote unauthorised medicines (which will most likely be the case). In case the involvement is not already inadmissible as such, the general rules regarding the cooperation with specialist circles and third parties laid down in section 8 CoC apply, as no more specific guidelines exist in this respect.

Section 8.2 CoC states the following rules for the cooperation with physicians that would be relevant for such market research:

- Any service rendered by a physician for a pharmaceutical company of any kind (e.g. lectures, consulting, clinical trials, non-interventional 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").
- Non-interventional 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. Please note in this context that the regulation on non-interventional studies (*Verordnung über die Meldepflicht von nicht-interventionellen Studien,* BGBl II 180/2010) applicable to non-interventional studies as of September 1, 2010 needs to be observed (see question 5.5 below).

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.

## 3 Advertisements to Health Professionals

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

Section 54 AMG requires that any advertising of a medicinal product directed to persons authorised to prescribe or supply medicinal products shall contain, if such advertising appears in printed publications, via electronic media or by way of telecommunication, the essential information about the medicinal product in line with the Summary of Product Characteristics (SPC) in a clearly legible form.

Moreover, based on section 42 of the Austrian Regulation dealing with the Summary of Product Characteristics for Medicinal Products ["*Verordnung über die Fachinformation (Zusammenfassung der Produkteigenschaften - SPC) für Arzneispezialitäten*", BGBl II 175/2008], advertising to professionals must include the following information:

- name, pharmaceutical form and dosage of the medicinal product;
- qualitative and quantitative composition;
- indications and contraindications;
- information on excipients;
- name and address of the authorisation holder;
- whether the product is only available on prescription;
- whether the product may only be distributed by pharmacies;
- whether the product can be disposed outside a pharmacy;
- information on the pharmaco-dynamic properties (active substance) of the product; and
- to what extent the product is covered by the provisions on narcotics.

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

Moreover, according to section 55 paragraph 2 to 4 AMG, all information contained in promotional material 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 scientific publications for use in such material shall be faithfully reproduced and the precise sources indicated. In case of references to scientific publications, the essential content of the same shall be impartially described and the precise sources indicated.

Finally, paragraph 50a section 3 No 1 to 3 AMG needs to be observed, which requires that pharmaceutical advertising describes the property of the pharmaceutical product objectively and without exaggeration and that it does not contain information (in writing or figuratively) that:

- implies a property of the product exceeding its actual property;
- gives the misleading impression that a result can be expected regularly; or
- is not in accordance with the labelling, the user information or the SPC or goes beyond these.

It is currently unclear and discussed among experts whether the last part of the third requirement ("…or goes beyond these") is still fully valid due to the ECJ's decision C-249/09 (*Novo Nordisk AS vs Ravimiamet*). So far, the Supreme Court has not rendered a decision reflecting the impact of the above-mentioned ECJ legislation on paragraph 50a section 3 No 3 AMG.

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not in the SmPC?

Paragraph 50a section 3 No 3 AMG was amended in 2009. The provisions for pharmaceutical advertising are stricter than before as no statements going beyond the SmPC (i.e. which are not explicitly mentioned in the SPC) may be added. As a result, it is not permitted to use studies not mentioned in the SPC in advertisements. However, as mentioned before in question 3.1, it is currently unclear and discussed among experts whether paragraph 50a section 3 No 3 AMG is still fully valid due to the ECJ's decision C-249/09 (*Novo Nordisk AS vs Ravimiamet*). It seems arguable that promotional claims compatible with and confirming or clarifying the SPC (even if not explicitly mentioned therein) are (again) possible.

Paragraph 50a AMG applies both to promotion to health professionals and lays.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

There are no restrictions in place relating specifically to such endorsements; however, according to paragraph 50a section 3 No 3 AMG, pharmaceutical advertisements must not contain information that is not in accordance with the labelling, the user information or the SPC or goes beyond these (see above answers to questions 3.1 and 3.2). Endorsements by healthcare professionals in promotional materials would therefore only be allowed if they do not go beyond this permitted information (see also answers to questions 3.1 and 3.2 regarding the possible impact of ECJ's decision C-249/09 on paragraph 50a section 3 No 3 AMG).

### 3.4 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?

The AMG does not contain any rules with respect to comparative advertising. However, any comparative claims need to be in line with the provisions of the UWG (see below question 3.5).

Comparative advertising, as it was common before the amendment of paragraph 50a section 3 No 3 AMG in 2009 (often using the outcomes of head-to-head trials as a basis), is not admissible anymore, as the comparison may in principle only be based on information which is contained in the SPC and does not go beyond that information, i.e. any studies quoted need to be contained in the SPC. However, ECJ's decision C-249/09 could change that situation in so far as comparative advertising claims compatible with and confirming or clarifying the SPC might (again) be possible (see above answer to question 3.1).

**3.5 What rules govern comparative 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 AMG. However, according to section 5.7.1. CoC 2009, pharmaceutical companies are not permitted to make reference to brands of competitors in their promotion, unless the reference is admissible according to UWG. As a consequence, comparative claims in advertisements are subject to section 2a UWG: comparative advertising is permissible, provided that it does not violate the rules on fair competition, especially by discrediting the competitor or by misguidance of the addressed public.

Regarding the question whether it would be possible to refer to a competitor's product which had not yet been authorised in Austria, we can hold that no case law has been issued yet, but it seems possible if the reference complies with section 2a UWG; in particular the fact that competitor's product has not yet been authorised needs to be clearly and visibly mentioned in order to avoid any misguidance of the addressed public. Finally, please also consider the answer to question 3.4.

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

Section 7.8 CoC 2009 specifically refers to this question and holds that if companies distribute speeches or discussion contributions held at an event, or reports on these, they must ensure that this information correctly expresses what was communicated at the event. The same applies if they commission other persons, media or companies to do this.

Further, in case any such material has to be regarded as promotional, the requirements mentioned in the answer to question 3.1 above have to be met.

**3.7 Are "teaser" advertisements permitted that alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?**

Neither the AMG nor the CoC 2009 contain specific rules on "teaser advertisements".

However, such advertisements must comply with the general requirements laid down (above all) in the AMG and the UWG if they already refer to a specific medicine.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide health professionals with samples of products? If so, what restrictions apply?**

Section 58 AMG allows the provision of medical samples to physicians, dentists and veterinary surgeons if the following requirements are observed:

1. Samples may be supplied:
   - only free of charge;
   - in a package not larger than the smallest package on the market and including a clearly legible and irremovable reference that the package is a free medical sample - not for sale ("*Unverkäufliches Ärztemuster*"); and
   - to physicians, dentists or veterinary surgeons upon their written request.
2. During a period of one year after first delivery, as many medical samples of a medicinal product as may be necessary to assess the treatment success of at most 10 patients may be provided, however not exceeding a maximum of 30 medical samples per recipient. After the first year, two medical samples per request may be provided, however, not exceeding an amount of five medical samples per proprietary medicinal product per year and per recipient.

Records must be kept of each medical sample delivered. Finally, please note that the delivery of medical samples containing psychotropic or addictive substances is generally prohibited.

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

Section 55a paragraph 1 AMG prohibits the granting, offering or promising of gifts, pecuniary advantages or benefits in kind unless they are inexpensive and relevant to the medical or pharmaceutical practice.

The above-mentioned rules do not prevent the provision of giveaways by pharmaceutical companies, provided they have only a small value and are relevant to the medical or pharmaceutical practice of the recipient. Unfortunately, no case law or other guidelines exist that would clarify the amount of such "small value".

Section 8.6.2 CoC 2009 provides that 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 product logo of the medicinal product or the designation of the active agent it 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?**

Austrian law does not contain regulations on the provision of gifts or donations of pharmaceutical companies to institutions or bodies.

In principle, gifts or donations to institutions or bodies are permitted if the gift or donation is provided for a specific purpose and it is not conditional upon the purchase or prescription of any of the company's medicinal products. The same is valid for the donation of equipment and funding of costs of medical or technical services. About any such provision of a gift or donation, a written contract should be concluded.

Please note that it has to be carefully checked in each individual case – in particular in case of a public hospital being the recipient – whether the respective gift or donation could violate the Austrian anti-corruption regulations, in particular sections 307 *et seq.* Austrian Penal Code ("*Strafgesetzbuch*", BGBl 60/1974, as latest amended by BGBl I 98/2009 with regard to anti-corruption regulations).

**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?**

In principle yes, but such practice would only be possible if such medical or educational goods or services comply with section 55a

paragraph 1 AMG, i.e. they are of a small value and relevant to the medical or pharmaceutical practice.

**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?**

Volume-related (cash) discounts to institutions (hospitals) are permitted by the AMG and the UWG. However, the general competition (antitrust) rules need to be observed.

When it comes to rebates in kind, please note that section 55b AMG prohibits the provision, the offering and the promise of such rebates to persons entitled to prescribe or supply medicinal products as far as medicinal products contained in the Code of Reimbursement ("*Erstattungskodex*") are concerned. However, according to the legislative materials, this prohibition shall not be valid for hospitals (i.e. for the legal entities standing behind those).

**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?**

No. Such offer would violate the provisions of the AMG and the CoC 2009 if addressed to persons entitled to prescribe or supply medicinal products; furthermore, it could also violate the more general rules of the UWG and of the Cartel Act.

**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?**

Austrian law and the CoC 2009 do not contain any specific rules referring to such situation. However, offering of a refund scheme would most likely involve the statement that a treatment success can be expected for sure or that no adverse effects arise and would therefore likely to be violating sections 6 and 50a paragraph 3 AMG (misguidance).

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

As mentioned above, the granting, offering or promising of gifts, pecuniary advantages or benefits in kind are prohibited by section 55a paragraph 1 AMG. The sponsoring of continuing medical education is likely to be covered by that prohibition as it would not qualify as inexpensive.

However, it might be that the exception in section 55a paragraph 3 AMG applies to the respective "sponsoring". That provision allows that pharmaceutical companies bear reasonable travel and accommodation costs, as well as participation fees for persons entitled to prescribe or supply medicinal products regarding scientific events related to the participants' profession; the applicability of the exception has to be determined in each individual case. Article 7 CoC 2009 contains more detailed rules regarding this issue (see below, answer to question 5.1).

## 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?**

Section 55a paragraph 3 AMG allows that pharmaceutical companies bear reasonable travel and accommodation costs, as well as participation fees for scientific events related to the participants' profession. These costs can only be paid for the HCPs (speakers and attendees), but not for an accompanying person.

Section 7 CoC 2009 contains more detailed rules regarding this issue. Section 7.2 CoC 2009 states that leisure time activities and/or social programmes (e.g. theatre, concerts, sports events) for participants may not be financed or organised and that pharmaceutical companies are not permitted to take care of the organisation nor assume the costs for travel, room and board or expenditures for recreational activities.

Section 7.3 CoC 2009 requires that the attendance of the participants, the programme and the scientific and/or technical content of the event implemented must be documented.

With respect to the venue of the event, section 7.4 CoC 2009 holds that it 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 has no selection criterion.

The question of whether hospitality may be offered for an event taking place in another country is regulated in section 7.5 CoC 2009:

Section 7.5 CoC 2009 defines *international events* as events at which the company organising and implementing the event or supporting the event or its participants has its registered office outside of the country in which the event venue is located. The organisation, implementation and/or support of international events or the assumption of costs for participation in these events is only admissible if:

- the majority of participants come from a different country than the country in which the member company is based; or
- 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).

Please note that section 7.5.2 CoC 2009 holds that in such case, both the code of the country in which the company organising, implementing or supporting the international event is based and the code of the country in which the international event is taking place, shall apply.

**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?**

See the answer to question 5.1 above – pharmaceutical companies may bear reasonable travel and accommodation costs, as well as admission fees for scientific events related to the participants' profession. The participant is not allowed to be paid for his time. 7.6 CoC 2009 explicitly states that the invitation of persons as participants or speakers to such scientific events may not be made dependent on the recommendation, prescription or distribution of specific medicinal products.

**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?**

A pharmaceutical company will not be held responsible for the contents of and the general hospitality arrangements of independent meetings where they just provide sponsorships to individual doctors to attend (but they are in any case responsible for individual sponsoring provided by them).

If the contents and hospitality arrangements of an event directly sponsored and organised by the company violate the advertising restrictions of the AMG, the company will most likely be held responsible by competitors and can of course be held responsible by the authorities.

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

It is possible to pay doctors for the provision of expert services under the following conditions (section 8.2 CoC 2009):

- Conclusion of a written contract clearly indicating the services to be rendered and the compensation to be paid.
- The service must be a scientific or technical activity, including for educational purposes.

Considerations may only consist in 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.

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

Yes, if the requirements mentioned in the answer to question 5.4 above are met; the AMG does not contain specific legal rules governing such studies except for the definition of such "non-interventional studies" contained in section 2a paragraph 3 AMG.

Further, section 8.2.5 CoC 2009 clarifies that non-interventional studies (as well as all other studies or data surveys) may not be misused for the purpose of influencing therapy or procurement decisions or for mere advertising purposes.

Pharmig adopted an ordinance on non-interventional studies in March 2010 which contains more detailed requirements regarding such studies (regarding their content and documentation). As of September 2010, non-interventional studies also need to be notified with the BASG in accordance with the requirements described in the regulation on non-interventional studies (*Verordnung über die Meldepflicht von nicht-interventionellen Studien*, BGBl II 180/2010). Among others, the names of the doctors taking part in the study, as well as a template of the contract to be concluded with these physicians, including the intended payments need to be notified with the authority (section 5.2 of the regulation on non-interventional studies). The BASG has to keep an electronic register about all non-interventional studies notified. The company responsible for a non-interventional study has to provide the BASG with an executive summary report of the study which will be provided to the general public on the Internet (sections 4 and 7 of the regulation on non-interventional studies).

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

It would at first have to be determined if such service could qualify as scientific, technical or educational activity, according to section 8.2.4 CoC 2009. If this can be answered in the affirmative, it would be necessary to determine whether the other requirements of section 8.2. CoC 2009 are met (see above answers to questions 5.4 and 5.5).

**5.7 Is there a requirement in law and/or self-regulatory code for companies to make publicly available information about donations, grants, benefits in kind or any other support provided by them to health professionals, patient groups or other institutions? If so, what information should be disclosed, from what date and how?**

The AMG does not contain any such requirement. However, the Pharmig CoC requires that if publications by third parties on medicinal products are entirely or partly financed by a pharmaceutical company, it must be ensured that these publications contain a clear reference to the financing by the company (section 5.6 CoC 2009).

Further, the CoC 2009 contains detailed provisions regarding transparency concerning any support granted to patient organisations. Following these provisions, pharmaceutical companies need to detail on their publicly accessible homepage on the Internet all the patients' organisations they support. This publication shall contain information about the nature and scope, as well as a description of the support involved, and shall be updated at least once a year (not later than 31.3. for the preceding calendar year).

Moreover, pharmaceutical companies are obliged to ensure contractually in a written agreement that patients' organisations disclose to the public the relevant support provided by pharmaceutical companies transparently at all times and clearly from the outset (section 8a.4 CoC 2009).

It is not permitted for pharmaceutical companies to demand the exclusive support of patients' organisations and/or their programmes (section 8a.5 CoC 2009).

## 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?**

Yes. Sections 50a, 52 and 53 AMG contain the requirements which need to be followed.

The general rule to follow is that any pharmaceutical advertising has to describe the property of the medicinal product objectively and without exaggeration (section 50a paragraph 3 AMG). It must not contain information (in writing or figuratively) that:

- implies a property of the product exceeding its actual property;
- gives the misleading impression that a result can be expected regularly; or
- is not in accordance with the labelling, the user information or the SPC or goes beyond these (see question 3.1).

Section 52 paragraph 1 AMG requires that lay advertising must 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.

Lay advertising may refer to the marketing authorisation or

registration if such reference is not apt to create a false impression among the consumers regarding the safety and efficacy of the respective medicine.

The provision of samples is prohibited, as well as sweepstakes in connection with the supply of medicines.

Advertising directed to lays needs to contain the following minimum information (section 52 paragraph 2 AMG):

- the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;
- the information indispensable for correct use of the medicinal product; and
- an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.

Regarding "reminder advertising" (advertising exclusively consisting of the name of a medicinal product) to the general public, section 52 paragraph 4 AMG states that such does not need to contain all information relevant for the appropriate use of the medicinal product as required for "normal" advertising. If the "reminder advertising" appears on posters, printed advertisements or via acoustic or audio-visual media, a clearly perceivable reference to the fact that the medicinal product may also cause undesirable effects and that the instructions for use must therefore be carefully observed or the advice of a physician or pharmacist followed, shall be included.

Lay advertising shall not contain any elements which (section 53 paragraph 1 AMG):

- contain pictorial representations in connection with healthcare professionals or institutions of public healthcare;
- give the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
- suggest that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;
- suggest that the normal good health of the patient can be enhanced by taking the medicine;
- suggest that the health of the patient could be affected by not taking the medicine;
- is directed exclusively or principally at children;
- refer to a recommendation by scientists, healthcare professionals or persons who because of their celebrity could encourage the consumption of medicinal products;
- suggest that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggest that the safety or efficacy of the medicinal product is due to the fact that it is a "natural product";
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refer, 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
- indicate that the medicinal product is available by mail order.

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

No. Section 51 paragraph 1 AMG prohibits advertising prescription-only medicines to the general public with the only exception of vaccination campaigns organised or supported by the state, a province or a municipality.

### 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?

Section 50 paragraph 2 No 3 AMG exempts information about the health or diseases of human beings and animals from the definition of promotion, provided that no reference is made, whether direct or indirect, to a specific medicinal product.

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

No. Such press releases will generally have to be regarded as unlawful promotion.

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

Article 4.1.5 CoC 2009 exempts 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.

The AMG does not contain any rules on that question and there is no case law available in this respect. However, in case the respective provision of information is required by other legal provisions, such provision of information will not violate the AMG, as long as any promotional tone is avoided.

### 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?

The AMG does not contain any specific provisions in this respect; however, such rules have been implemented in Article 8a CoC 2009.

Patients' organisations are defined as "*non-profit organisations which solely represent the interests of patients and/or their families and exist or were founded out of their interests*". Support is deemed to be any direct and/or indirect financial or non-financial contribution to patients' organisations. Article 8a CoC 2009 does not apply where the support in an individual case is of small value (without such small value being defined in the CoC 2009).

Section 8a paragraphs 1 to 5 CoC 2009 require that:

- any support of patients' organisations shall serve solely the interests of the patients and/or their families;
- any support of patients' organisations may only be provided on the basis of a written agreement (containing the nature, scope and further description of the support);
- pharmaceutical companies must not influence the editorial work of the publications of patients' organisations supported by them without a justifiable factual reason (such as a correction of inaccuracies of content or correction from scientific aspects);

- pharmaceutical companies shall detail on their publicly accessible homepage on the internet all the patients' organisations they support (containing the nature, scope and further description of the support);
- pharmaceutical companies shall ensure contractually that patients' organisations disclose to the public the relevant support provided by pharmaceutical companies transparently at all times and clearly from the outset; and
- no exclusive support of a patients' organisations and/or their programmes may be agreed upon.

Further, article 8a paragraph 6 CoC 2009 contains specific rules concerning the invitation of members of patients' organisations to scientific events.

## 7 The Internet

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

Austrian law does not contain any provisions specifically regulating advertising over the Internet, i.e. the normal rules apply accordingly.

In addition, the CoC 2009 contains specific provisions regarding information and advertising via the Internet in its article 6. According to these provisions, the companies are required, *inter alia*, to regularly check the website for its accuracy and update it and to clearly specify the name of the pharmaceutical company operating or supporting the website and which information on the website is addressed to expert circles and which to the general public.

Section 6.2. CoC 2009 refers to information about the company provided on websites and states that websites may contain:

- information of interest to investors, the media and general public; and
- financial data, descriptions of research and development programmes, information regarding regulatory matters which concern pharmaceutical companies and their products, information for future employees, etc.

Section 6.3 CoC 2009 contains provisions on the information for patients and the general public:

- Information addressed to the general public and containing advertisement must comply with the applicable provisions of the AMG and of the Pharmig Code of Conduct.
- 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.), provided that this information is balanced, accurate and in harmony with the authorised SPC.
- 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.
- The website may contain links to other websites containing reliable information on medicinal products (websites of authorities, medical research institutions, patient organisations, etc.).
- Apart from the brand name, the International Non-proprietary Name (INN) must also be mentioned.
- The website must always contain a reference to a physician or pharmacist for further information.

Finally, section 6.4 CoC 2009 specifically requires that information for specialist circles is clearly indicated as such. Further, the companies need to ensure that the access to this information is reserved exclusively to specialist circles.

The control of Internet advertising mainly happens through competitors. We are not aware that the authorities have been specifically active in controlling information provided over the Internet so far.

### 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?

There are no specific legal requirements in place. However, in order to comply with the specific Internet provisions of the CoC 2009, as well as with the general advertising restrictions of the AMG, a company must establish a reasonable "safe access system" for the pages directed to healthcare professionals. Mostly, systems like those offered, e.g. by "DocCheck", are used.

### 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?

In the absence of specific regulations on the responsibility for links in the AMG or the CoC 2009, the general rules apply.

The company is not responsible for the content of a website connected to its own by way of reverse linking.

Regarding links to other websites from a company-sponsored site, section 17 of the Austrian Act on E-Commerce (*E-Commerce-Gesetz*, BGBl I 152/2001) states that the company which provides access to third-party information by means of an electronic link shall not be responsible for such information, if 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 becomes apparent; or (ii) upon obtaining such knowledge or awareness, acts expeditiously to remove the electronic link. However, this "privilege" shall not apply if the person from whom the information originates 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?

Any information available for the general public (lays) needs to comply with the general advertising restrictions (see above answers to section 6). Most companies provide restricted access to information on medicinal products to healthcare professionals on their website, as the information and advertisement to the general public (lays) is strictly limited with regard to content and appearance (see question 6.1).

However, according to ECJ's decision C-316/09 (*MSD Sharp & Dohme v Merckle*), the dissemination of information on medicinal products available on prescription only on (generally accessible, i.e. including for lays) websites of a pharmaceutical undertaking is permitted if the dissemination:

- consists solely in the faithful reproduction of the packaging of the medicinal product, and in the literal and complete

reproduction of the package leaflet or the SPC, as approved by the competent authorities; and

- is accessible on the website only to someone who seeks to obtain it.

On the other hand, any information on such websites relating to a medicinal product which has been selected or rewritten by the pharmaceutical undertaking, which can be explained only by an advertising purpose, is prohibited.

## 8 Developments in Pharmaceutical Advertising

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

Neither the AMG nor the CoC 2009 has been amended in 2010. No significant Supreme Court decisions have been rendered in the field of pharmaceutical advertising. The most significant developments have therefore probably been the ECJ judgments in the Novo Nordisk case, Case C-249/09, and in the MSD case, Case C-316/09.

In particular, the ECJ's decision in Case C-249/09 (*Novo Nordisk AS vs Ravimiamet*), according to which Article 87(2) of Directive 2001/83 cannot be interpreted as requiring that all claims in advertisements for medicinal products directed at persons qualified to prescribe or supply them should be included in that summary of product characteristics or be derivable from information in that summary has been broadly discussed in professional Austrian literature. Some opinions tend to see the amendment of paragraph 50a section 3 No 3 AMG as of 2009 (no statements going beyond the SPC, i.e. which are not explicitly mentioned in the SPC) may be added – see question 3.2) as inconsistent with the legislation of the ECJ and therefore as inapplicable. Others argue that the provision can be interpreted in line with the ECJ judgment, as only claims compatible with and confirming or clarifying the SPC are allowed. So far, the Supreme Court has not yet had a chance to provide a final assessment of the impact of the Novo Nordisk case on the application of paragraph 50a section 3 No 3 AMG and the professional literature is still undetermined.

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

It will be interesting to learn the Austrian Supreme Court's assessment of the possible impact of the Novo Nordisk case on paragraph 50a section 3 No 3 AMG, however, obviously, such assessment can only be made in the form of a decision on a case that has been brought to its attention. We are currently not aware that any such case is pending.

No other significant developments are expected.

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

The Austrian civil courts continue to be the most important "controlling authority" with respect to the advertising restrictions of the AMG. Enforcement is therefore mostly driven by competitors and by one of the institutions entitled to sue companies for unlawful advertising in accordance with section 85a AMG, namely the "Consumers' Information Association" ("*Verein für Konsumenteninformation*"), whose main focus is on combating unlawful promotion to lays.

### 8.4 Has your national code been amended in order to implement the 2011 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and the 2011 EFPIA Code on relationships between the pharmaceutical industry and patient organisations 2011 and, if so, does the change go beyond the requirements of the EFPIA Codes or simply implement them without variation?

The national CoC has not been amended (yet); currently, no amendment with regard to the 2011 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and the 2011 EFPIA Code on relationships between the pharmaceutical industry and patient organisations 2011 is conceivable.


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