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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2006

A practical insight to cross-border Pharmaceutical Advertising work

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1 General - Medicinal Products

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

In Austria, the advertising of medicinal products is currently regulated by the Medicines Act ("Arzneimittelgesetz", BGBl No 195/1983, as amended, Secs 50-56a) and by the General Social Security Act ("Allgemeines Sozialversicherungsgesetz", BGBl No 189/1955, as amended, Sec 351g). The legal regime is supplemented by an industry code of conduct (Code of Conduct or Code) established by the Austrian Pharmaceutical Industries Association (Pharmig) and a Physician's code of conduct (Physician's Code) established by the Austrian Medical Association.

In addition, competitors can rely on the Unfair Competition Act ("Gesetz gegen den unlauteren Wettbewerb", BGBl No 448/1984, as amended).

1.2 How is "advertising" defined?

Since 2005, the Medicines Act (AMG) defines "advertising" as all measures with respect to information, market investigation and market development and all inducement measures aimed at enhancing the prescription, the supply, the sale or the consumption of a medicinal product. The list covering advertising measures corresponds to the list included in article 86 of the amended Human Use Directive. The provision of the summary of products characteristics as well as of the package leaflet is no longer considered as an advertisement.

The rules do not prevent a company from providing general information with respect to the treatment of certain diseases as long as the information does not relate to a specific medicinal product and is not intended to enhance the distribution of a product.

1.3 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?

Advertising must neither be approved by the competent authorities nor by the Austrian Pharmaceutical Industries Association. Under the AMG, the competent authority does not have competence to issue a notice requiring a marketing authorisation holder to supply copies of advertising material prior to the publication. However, they can require that such material is submitted to establish whether it complies with the advertising rules. They also have the authority to enter the premises and to make copies of the relevant material.

The Code of Conduct requires that persons drafting advertising materials must be familiar with all provisions of the Code and its amendments and that such materials must be approved, prior to distribution, by a physician or a pharmacist.

1.4 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 competent authorities can order a company to abstain from any behaviour violating the advertising rules. Thus, the authorities are entitled to take all appropriate measures forcing a company to comply with the advertising provisions. This, of course, means that they can order that the material is no longer distributed or must be recalled. However, this does not authorise the competent authority to require the issuing of a corrective statement. Violations of the advertising provisions constitute an administrative offence and, therefore, an appeal is possible.

1.5 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?

Violation of the AMG advertising provisions constitutes an administrative offence, provided the offence is not punishable under criminal law. Fines can amount to EUR 25,000 for a single infringement and up to EUR 50,000 in the case of repeated offences. Moreover, the Federal Institute for Safety in the Health Field can withdraw a marketing authorisation if a company was punished three times for the violation of advertising rules (Sec 85 para 1 AMG). In addition, repeated violation of applicable laws or rules could result in the withdrawal of the trade license.

Under specific circumstances, namely if a medicinal product

was unlawfully advertised as a food supplement, the "Landeshauptmann" (leader of a province government) is competent to enforce advertising rules. There are numerous cases where such proceedings were initiated.

Under the Code of Conduct, fines of up to EUR 100,000 can be imposed. In addition, the name of the infringing company can be (i) published in the relevant Pharmig publication; and (ii) revealed to the mother company as well as to the Secretary General's Office of Efpia.

Competitors may base claims for cessation, damages and publication of an advantageous judgment on violation of "unfair practices" according to the Unfair Competition Act ("UWG") due to the breach of law, namely of the AMG. According to Sec 85a AMG certain associations, such as the Association for Consumer Information or the Pharmig, are also entitled to file complaints with the civil courts.

1.6 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?

Competitors can base their claims on Sec 1 UWG (*action contra bonos mores*). Violations of the advertising rules are generally considered to be in violation of Sec 1 UWG and therefore any competitor can initiate such proceedings. There is numerous case law available where competitors specifically relied on the UWG to "indirectly" enforce compliance with the advertising rules. Most of the cases initiated by competitors relate to:

- violation of the provision that no advertisement to the general public is permissible for "prescription-only" products;
- food supplements, for which disease-related claims were made, and should, therefore, have been authorised according to the medicines rules; or
- products, which were already authorised in another country, but not in Austria.

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?

Sec 50a para 1 AMG prohibits advertising for products which are not approved in Austria, other than at scientific events if the participants are mainly from outside Austria. The restriction also applies to the advertisement of an indication not approved within Austria.

Furthermore, the Code of Conduct states that advertising of non-approved products is in general inadmissible except if such information was requested by a physician. However, this prohibition shall neither restrict (i) the exchange of medical and scientific information during a clinical trial; nor (ii) the information about the results as long as the protection of personal data is given.

It is possible to discuss, as mentioned above, an unauthorised medicinal product in such meetings, even if such a meeting is sponsored by a company, as long as the information provided is not promotional and there is a genuine exchange of scientific information.

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

Scientific information with respect to an unauthorised medicine is not considered to be promotional and can be published in scientific journals. However, it is always advisable to only state the INN in such a publication and not the product name. It is common practice in Austria that, if a study was sponsored by a company, the publication mentions the sponsor's name. This is also now specifically required by the Physician's Code.

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

It is, in general, possible to issue press releases to health care professionals as long as they are of a scientific nature and are not intended to promote an unauthorised product. However, if a specific product name is mentioned, it can easily be argued that such materials are intended to enhance the distribution of an unauthorised product.

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

It is, in general, possible to issue press releases to health care professionals as long as they are of a scientific nature and are not intended to promote an unauthorised product. However, if a specific product name is mentioned, it can easily be argued that such materials are intended to enhance the distribution of an unauthorised product.

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?

There are no specific rules with respect to informing institutions about a product, which will be authorised in the near future. However, it is likely that such information would be considered an advertisement of an unauthorised product as the focus appears to be on the enhancement of the distribution of the product

3 Advertisements to Health Professionals

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

The AMG requires that all advertising must comply with the information provided in the package leaflet, the Summary of Product Characteristics ("SmPC") or on the labelling. In addition, advertising for medicinal products, for which a SmPC must be published, must include certain information as stated in the SmPC. The Federal Minister for Health and Women can issue a regulation describing in detail which

information must be provided. This issue is regulated in the Regulation dealing with the Summary of Product Characteristics for Medicinal Products ("Verordnung über die Fachinformation (Zusammenfassung der Produkteigenschaften) für Arzneispezialitäten", BGBl II No 3/1998 as amended, Sec 39).

According to the Regulation, advertising to professionals must include the following information:

- name of the medicinal product;
- qualitative and quantitative composition;
- indications and contraindications;
- excipients;
- whether the product is only available on prescription;
- whether such products shall only be distributed by pharmacies;
- whether such products can be disposed outside a pharmacy;
- pharmaco-dynamic properties; and
- to what extent the product is covered by the provisions on narcotics.

A reference to the SmPC is sufficient with respect to precautions and special warnings, interactions with other medicinal products and undesirable effects and "addictive" effects of the product.

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?

The AMG does not regulate when a comparative claim is admissible. In general, comparative claims are allowed if they comply with the criteria established by Sec 2 UWG, namely that such claims are not misleading, refer to the same goods and services, do not discredit or denigrate the trademark, trade names etc. of the competitor and do not create confusion in the market place between the advertiser and the competitor.

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 your country?

Comparative advertisement is generally permitted in Austria and must be in compliance with the Misleading Advertising Directive, as amended by 97/55/EC and implemented by Sec 2 UWG. This was recently confirmed by a decision of the Austrian Supreme Court. It ruled that a comparison between the prices of an original and generic product, where it is inevitable to name the original product, is admissible, if in compliance with the EC rules.

However, the Code of Conduct takes a stricter approach. The Supreme Court ruled that this provision must be interpreted in light of the Misleading Advertising Directive as a prohibition to use a reference to a trademark of a competitor only if it is done to exploit the goodwill of the trademark owner.

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

If scientific information is provided, such information must be accurate, up-to-date, checkable and sufficiently complete to enable the recipient of the information to evaluate the therapeutic effect of the product. In addition, if quotes are used in such information, excerpts, tables and other presentations, they must be quoted verbatim and their sources must be accurately revealed. If the distributed scientific papers comply with these principles, there is no restriction to distribute such papers.

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)?

Teaser advertisements are not specifically regulated in the AMG nor in the Code of Conduct. Therefore, they must comply with the rules established by the AMG, and of course, with the principles established under the UWG. Printed advertisements consisting exclusively of the name of a medicine and intended for consumers (reminder advertising) are less heavily regulated and such advertising, for instance, must not provide all information relevant for the appropriate use of the medicinal product.

4 Gifts and Financial Incentives

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

The AMG specifically allows the provision of free samples to the physicians in the following amount:

- within the first year after obtaining marketing authorisation: as many packages as needed for the treatment of ten patients, but not exceeding thirty samples; and
- after the first year of marketing authorisation: per request not more than two samples and not more than five samples per year of each medicinal product.

The provided sample must (i) be labelled with "physician sample - not for sale"; and (ii) be the smallest available package on the market. The provision of free physician samples is prohibited for narcotic or psychotropic substances. The company must keep a register listing the amount of samples provided, to whom and when. The register can be inspected by the Federal Institute for Safety in the Health Field.

The Code of Conduct, in addition, stipulates that during congresses companies are also entitled to provide to physicians a maximum of two samples of only one medicinal product.

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

The AMG makes it illegal to offer, grant, or promise gifts or any other inducement, whether they are in kind or of a monetary nature, to health professionals for prescribing a medicinal product. Not only is the offering prohibited, but

also the acceptance by a physician. Exempted from this prohibition are only gifts of little value that are relevant to the medical or pharmaceutical practice. The Federal Minister for Health and Women is entitled to regulate this area in more detail. So far, and to our best knowledge, no such regulation was adopted.

Since 2005, it is prohibited to offer persons, who prescribe or dispense medicinal products, rebates in kind of products that are reimbursed by the social security system.

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?

Donations to institutions such as hospitals, universities etc. are neither regulated by the AMG nor by the Code of Conduct. However, also here the general principle applies namely that such gifts or donations must not be given to induce the prescription of any medicinal product.

If such donations or gifts are provided to physicians, who are also public officials, the official as well as the employees of a pharmaceutical company can face criminal prosecution, if such a donation can be classified as a bribe under the Criminal Code. Furthermore, the UWG provides for a similar prohibition in the private sector. Each competitor, but not an association such as Pharmig, can initiate private criminal proceedings, so called "Privatanklagedelikt".

4.4 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 9a UWG, rebates in kind as well as financial rebates are permissible (except to persons prescribing or dispensing medicinal products being reimbursed by the social security system). The rebate in kind must be of the same nature as the main product. This means that if, for instance, a company purchases product A five times, the rebate in kind can only be, for instance, one additional package of product A. This was recently confirmed by a Supreme Court decision, where a competitor initiated proceedings (and was successful), because the rebate in kind was not exactly the same as the main product.

4.5 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?

The UWG prohibits generally the provision of free services and free equipment as long as such provision cannot be considered a general trade custom (usual in trade). In addition, the provision of such extra services/equipment must be based on a reasonable commercial assessment. Furthermore, the granting of such services/equipment at an unreasonably low price will generally be considered as a violation of the UWG.

No specific case law exists with respect to the pharmaceutical sector, but "usual in trade" is normally interpreted very restrictively. For instance, the free provision of a rented car for the actual car repair time period was not considered as usual in trade.

4.6 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?

We are not aware that such a refund ever happened on the Austrian market. Neither the AMG nor the Code of Conduct regulates such a situation. Therefore, this could only be admissible if the general principles of the UWG were respected.

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

Nothing in the AMG or of the Code of Conduct prohibits a pharmaceutical company to sponsor continuing medical education as long as the information provided therein is not aimed at enhancing the prescription of a specific medicinal product and complies with the general principles established in the UWG.

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?

According to Sec 55a AMG, hospitality can be provided by pharmaceutical companies as long as such hospitality is strictly limited to its main purpose and is not extended to persons other than persons prescribing or dispensing medicinal products. Inappropriate provision of hospitality to officials could be considered as bribery and would therefore be punishable under the Criminal Code.

The rules do not differentiate whether hospitality is provided to physicians within or outside of Austria.

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?

Sec 55a AMG allows pharmaceutical companies to pay for appropriate travel and accommodation costs as well as the participation fee. However, such cost can only be paid if they are strictly related to an "occupational" scientific event. The hospitality must be strictly limited to its main purpose.

The Code contains the principle that physicians should only be paid if they provide an appropriate consideration in exchange. Under the Code, it would not be possible to pay a physician for his attendance at the meeting. If the physician is also a speaker, a reasonable honorarium can, however, be paid. The Physician's Code, in addition, requires that the payment must be revealed to the organiser.

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

Physicians can be paid for expert services. Such expert services can only be provided after a written contract has been concluded, stipulating specifically which services have to be provided by the physician. In addition, the service must be of a scientific nature. Therefore, each presentation given in such an expert group meeting is not allowed to be promotional. Moreover, it must also be clear from the contract that the services were not rendered for enhancing the prescription of a specific medicinal product.

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

As stated under question 5.3, a written contract must be concluded if a physician shall take part in a post-marketing surveillance study. According to the Physician's Code, 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 post-marketing surveillance studies, the Physician's Code specifically regulates that the compensation for taking part shall follow the Guidance for Private Medical Fees of the Austrian Medical Association. Moreover, the Physician's Code encourages physicians having shares in pharmaceutical companies to abstain from providing any services for such companies.

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

The Code of Conduct provides that pharmaceutical companies should only hire services from physicians if they are related to scientific or medical services for the company. This should prevent companies from concluding so-called shame contracts. It is doubtful whether market research involving promotional materials qualifies as "scientific or medical service".

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?

Non-prescription medicinal products can be freely advertised to the general public as long as the following conditions are fulfilled:

- the advertisement does not contain graphic elements connected with members of the medical professions or medical facilities;
- the advertisement does not give the impression that a consultation or a surgical intervention is not necessary;
- the advertisement does not suggest that the effect of a medicinal product is guaranteed and without any side effect or better than or equivalent to the effect of another medicinal product;
- the advertisement does not suggest that by taking the medicinal product health will be enhanced or by not taking such a medicinal product health may be adversely effected;
- the advertisement is not directed exclusively or mainly to children;
- the advertisement does not refer to recommendations given by scientists, health care professionals, if this could encourage the consumption of a medicinal product;
- the advertisement does not suggest that the medicinal product is a food, cosmetic or a general consumer product;
- the advertisement does not suggest that the safety or efficacy of the medicinal product is attributed to the fact that it is a "natural product";
- the advertisement does not lead to an erroneous diagnosis by providing a detailed description of the anamnesis;
- the advertisement does not refer in improper, alarming or misleading terms to testimonials;
- the advertisement does not use improper, alarming or misleading monographic description of changes to the human or animal body resulting from a disease, etc.; or
- the advertisement does not suggest that the medicinal product can be obtained by mail order.

The advertisement must at least contain:

- the name of the product;
- the information necessary for the appropriate use;
- a clear warning that the product can have adverse effects and the package leaflet must therefore be adhered to; and
- a note to consult a physician or a pharmacist.

However, an advertisement to the general public for non-prescription products is prohibited if the product in question is reimbursed by the social security system. Restrictions also apply to homeopathic products.

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

It is prohibited to advertise prescription-only medicinal products to the general public.

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?

Vaccination campaigns as well as disease awareness programmes are normally initiated either by the competent authorities or by non-profit organisations such as the Krebshilfe (Cancer Society). However, such campaigns are often financially supported by pharmaceutical companies.

If neither the product is mentioned nor a promotional tone is used, no restrictions should generally apply.

The Code of Conduct specifically regulates brochures enhancing patient compliance or accompanying therapies and states that such kind of brochures are not allowed to contain any advertisement for consumers. According to the

Code of Conduct, the reference to the name of the product is normally acceptable. However, such brochures must be drafted carefully, because the slightest promotional tone in the brochures could be considered to be an advertisement to the general public.

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

No. This would be considered to be an advertisement. However, it is permissible to provide information to a journalist upon request.

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

Neither the AMG nor both of the Codes specifically regulate this issue. Therefore, information provided in corporate brochures, annual reports etc., is not considered as an advertisement for the enhancement of prescribing medicinal products as long as it is neutral information, for instance the turnover.

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?

No specific rules apply either to the funding of patient support groups or to the recording of such funds and other support in corporate reports. General report requirements are laid down, among others, in the Commercial Code.

7 The Internet

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

Advertisements on the internet are not specifically regulated and therefore the general rules of the AMG as well as the rules provided in the Code of Conduct are applicable. According to a circular provided by the Federal Minister for Health and Women, the inclusion of the internet address in the package leaflet or the SmPC is acceptable, as long as the inclusion of such an internet address is not used to advertise the product.

According to this circular, the display of the SmPC as well as the product information on the internet is acceptable. In addition, all other information must be of general scientific content and all products approved for an indication must be named and a specific product may not be highlighted. Such displayed information is not even allowed to indirectly enhance the prescription of the distribution of a specific product.

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?

No guidance is currently available on whether a totally restricted access is necessary or whether a pop-up window, stating that this area is restricted and should only be accessed by health professional, would be sufficient. Therefore, companies use different methods to indicate that such a section is restricted to health care professionals. The safest method appears to be the use of the so-called Doc.check-password system, which requires prior approval by an independent organisation, before such restricted areas can by accessed. It is very unlikely that pop-up boxes, where you have to identify yourself as a health professional, will be sufficient, because such a system can easily be circumvented.

8 General - Medical Devices

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

The advertisement of medical devices is regulated in Sec 102 et seq. of the Medical Devices Act ("Medizin-produktegesetz" BGBl No 657/1996, as amended). The Medical Devices Act (MPG) differentiates between advertisement for consumers and for health care professionals.

In general, advertisements directed to consumers are not permissible for medical devices which:

- can only be obtained by prescription;
- can exclusively be administered by a health care professional; or
- can only be used under the supervision of a physician or a dentist.

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.

Advertisements directed at consumers are not permitted when it:

- suggests that the effect of the medical device is better than or equivalent to another treatment or a medical device;
- is directed mainly at children;
- gives the impression that consulting a physician is superfluous, in particular, by leading to an erroneous self diagnoses or suggesting treatment via mail;
- refers in improper, alarming or misleading terms to claims of recovery; or
- refers in improper, alarming or misleading terms to graphical descriptions of changes in the human or animal body resulting from diseases, etc.

Advertisements directed at 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.

The advertisement must also specifically refer 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.

Advertisement directed at health care professional 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 restrictions as for physicians prescribing medicinal products apply. Therefore, the offering as well as the acceptance of financial benefits and benefits in kind is prohibited as long as such inducement is not of minor value.

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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 significant developments in relation with respect to pharmaceutical advertising relate to the implementation of the provisions as laid down in the amended Human Use Directive. In addition, due to some "scandals", also the rules with respect to benefits in kind were tightened.

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

No significant developments are expected in the next year because the implementation of the amended Human Use Directive is now completed. It could be, however, that the Minister for Health and Women issues a regulation dealing with issues such as, what classify as items of small value, extent of hospitality, appropriate travel expenses etc. as provided for in Sec 55a (5) AMG.

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