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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2017

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A practical cross-border insight into pharmaceutical advertising

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General Chapter:

Country Question and Answer Chapters:

EDITORIAL

Welcome to the fourteenth edition of *The International Comparative Legal Guide to: Pharmaceutical Advertising*.

This guide provides the international practitioner and in-house counsel with a comprehensive worldwide legal analysis of the laws and regulations of pharmaceutical advertising.

It is divided into two main sections:

One general chapter. This chapter provides an overview of off-label use in the EU and U.S.

Country question and answer chapters. These provide a broad overview of common issues in pharmaceutical advertising laws and regulations in 29 jurisdictions.

All chapters are written by leading pharmaceutical lawyers and industry specialists and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editor Ian Dodds-Smith of Arnold & Porter Kaye Scholer LLP, for his invaluable assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The *International Comparative Legal Guide* series is also available online at www.iclg.com.

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PREFACE

It is a pleasure to have again been asked to provide the preface to *The International Comparative Legal Guide to: Pharmaceutical Advertising*, which is now in its fourteenth edition.

This year the guide contains one general chapter written by Arnold & Porter Kaye Scholer LLP and 29 individual chapters, the new ones of which are Russia, Singapore, Taiwan and Ukraine. The general chapter comprehensively covers the area of medicine off-label use in the EU and the U.S. Despite plenty of activity in the area, including a European Commission Report, the chapter suggests that little has been decided in either jurisdiction in this vexed area to provide certainty for manufacturers, and thereby patients, going forward.

As with other current editions in the ICLG series that I use as a reference point, this edition will be my first port of call when faced with thorny questions concerning pharmaceutical advertising.

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1 General – Medicinal Products

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

- 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 40/2017, sections 6 and 50-56a.
- Section 351g paragraph 5 of the General Social Security Act ("*Allgemeines Sozialversicherungsgesetz*" – in the following referred to as "*ASVG*"), BGBl No 1955/189, as last amended by BGBl No I 26/2017.
- 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 99/2016.
- The Austrian Pharmaceutical Industries Association's (Pharmig) Code of Conduct, in its current version of July 1, 2015 (in the following referred to as "Pharmig CoC").

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);
- the 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 indirectly, 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 are no explicit requirements to provide for specific compliance arrangements in the AMG or in the Pharmig CoC.

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

- that any promotion for its products complies with sections 50 to 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 or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no explicit requirements for companies to have SOPs on advertising activities in place. However, as there are a number of

requirements to be fulfilled (see sections 3 and 6 below), it seems advisable (and is common in the industry) to establish such SOPs (see question 1.6).

However, there is a requirement to employ personnel with a specific role: as stated in question 1.4, the authorisation holder has to nominate a person to ensure that any promotion for its products complies with the rules regarding advertising ("*Informationsbeauftragter*").

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, either in general or in any specific situation. Furthermore, the law 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 €25,000 or even €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? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

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 the 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 has been 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. We are not aware of any major proceedings against pharmaceutical companies in this respect.

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 the 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.

To sum up, 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 Pharmig

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 paragraph 1 No 1 and/or No 2 UWG (and, eventually, section 2 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 healthcare 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 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 on an authorised medicine (e.g. on a new indication); 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.

Furthermore, 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 and/or off-label information be published? If so, in what circumstances?

As any promotion for unauthorised medicines as well as off-label information is prohibited, no publications of a promotional nature are allowed. However, it is possible to provide promotional material on unauthorised medicines or off-label information during scientific events if the majority of participants come from outside Austria (section 50b paragraph 2 AMG, see the answer to question 2.1 above).

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.

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 apply, the issuance of a press release on an unauthorised medicine or containing off-label information will most likely violate section 50a paragraph 1 AMG.

Although there are differences depending on the target audience (advertising and information to health care professionals and to laymen) in general, there are no specific differences regarding press releases (see section 3).

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare 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 your jurisdiction?

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

2.6 May information on unauthorised medicines or indications 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 unauthorised medicines/off-label promotion 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 healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications 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 healthcare professionals would not 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 cooperation with specialist circles and institutions laid down in section 8 Pharmig CoC apply, as no more specific guidelines exist in this respect.

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

- Any service rendered by members of the specialist circles for pharmaceutical companies (e.g. for lectures, consulting, clinical trials, non-interventional studies) must serve the purpose of training/education, research, support of the healthcare system or be provided within the framework of scientific and specialist activities.
- A written contract must be concluded, clearly indicating the service and remuneration to be provided, as well as the scope, type and purpose of the service. Remuneration may only consist of money and must be proportionate to the service provided. Hourly fees may be agreed to compensate for the time spent in providing the service. Any expenses incurred, including travel costs, may be additionally reimbursed to an appropriate degree. Among other options, the fee schedule for physicians can be used to assess the proportionality of remuneration.
- The provision of services by members of the specialist circles must not be linked to any conditions relating to the recommendation, prescription or the administering of medicinal products.

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) in the case the service refers to a non-interventional study.

Further, the companies need to consider the transparency requirements laid down in Article 9 Pharmig CoC (see section 7 below).

3 Advertisements to Healthcare Professionals

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

Section 54 AMG requires that any advertising of a medicinal product directed to persons authorised to prescribe or supply medicinal products needs to 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 paragraphs 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.

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

Further to paragraph 6 AMG prohibiting any misleading advertising for medicines, paragraph 50a section 3 Nos 1 to 4 AMG needs to be observed, which requires that pharmaceutical advertising describes the property of the pharmaceutical product objectively and without exaggeration and 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, user information or SPC; whereby promotional claims complementing the information contained in the labelling, user information or SPC may be used in promotion to specialist circles (but not to lay persons) if they are compatible with and confirming or clarifying that information.

Section 50a paragraph 3 No 3 AMG has been amended and a new section 50a paragraph 4 AMG has been added following the ECJ's decision in C-249/09 (*Novo Nordisk AS vs Ravimiamet*). Therefore, in the context of advertising to specialist circles, reference may (again) be made to studies which are not mentioned in the SPC as long as the requirements as set out above are met.

However, in the context of lay advertising (allowed for non-prescription requiring medicines), reference to studies not mentioned in the SPC might not be allowed, as lay advertising may not contain any claims that go beyond the labelling, user information or SPC (see below section 6).

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; the general restrictions apply (see questions 3.1 and 3.2 above).

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 may be 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 question 3.5 below). The presence of data of at least one head-to-head study is highly recommended, as the comparison of data from different studies in the context of comparative claims may easily be misleading.

(See the answer to question 3.1 above.)

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 or indication which had not yet been authorised in your jurisdiction?

Comparative claims in advertisements are not regulated in the AMG. However, according to section 5.7 b). Pharmig CoC, 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 misleading the addressed public.

Regarding the question of whether it would be possible to refer to a competitor's product that has 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 the competitor's product has not yet been authorised needs to be clearly and visibly mentioned in order to avoid 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 healthcare professionals?

Section 7.8 Pharmig CoC 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 the 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 (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

Neither the AMG, nor the Pharmig CoC 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 healthcare professionals with samples of medicinal 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 (but smaller!) 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, 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 healthcare professionals? If so, what restrictions apply?

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

The above-mentioned rules do not in principle 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".

However, the CoC does not allow the provision of giveaways anymore, but – in contrast – states in its section 11.2 that no advantages may be offered, promised or granted to healthcare professionals, unless they are allowed by other provisions of the CoC or by the law.

4.3 Is it possible to give gifts or donations of money to healthcare organisations 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? If monetary limits apply, please specify.

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

In principle, gifts or donations to such organisations would be 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 the case of a public hospital being the recipient – whether the respective gift or donation is indeed provided to a public official ("*Amtsträger*") or an authorised person or employee ("*Beauftragte*"/"*Bedienstete*") and could therefore violate the Austrian anti-corruption regulations, in particular, sections 153a and 307 *et seq.* Austrian Penal Code ("*Strafgesetzbuch*", BGBl 60/1974, as latest amended by BGBl I 61/2012 with regard to anti-corruption regulations). In principle, these rules apply to all kinds of advantages; only section 153a requires an advantage which is *not just minor*, whereby case law regards advantages of less than EUR 100 as minor in this context.

In addition, section 8.5 Pharmig CoC contains the following regulations regarding donations and subsidies (see the answer to question 7.3 below for disclosure obligations):

- Pharmaceutical companies are permitted to make financial or material donations or provide subsidies to institutions, organisations or establishments which predominantly comprise members of the specialist circles, only for the purpose of training/education, research or support of the healthcare system or within the framework of scientific or specialist activities.

When making financial donations or providing subsidies, pharmaceutical companies are obligated to keep records which clearly list the donations or subsidies – and in particular the scope, type and purpose of the same – and the recipient of the donation or subsidy as well as the permission of the same to disclose the donation or subsidy provided by the pharmaceutical company. Donations and subsidies must be made accessible to the public on the internet in accordance with Article 9 CoC, unless they are inexpensive.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals 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?

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 (which seems most unlikely); section 8.5 d prohibits any donations to individual HCP. Furthermore, the general rules of fair competition and antitrust law need to be observed in this context.

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 an offer would violate the provisions of the AMG and the Pharmig CoC 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 Pharmig CoC do not contain any specific rules referring to such situation. However, the offering of a refund scheme would most likely involve the statement that a treatment's success can be expected for sure or that no adverse effects arise and would therefore be 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 to persons entitled to prescribe or supply medicinal products are prohibited by section 55a paragraph 1 AMG. The sponsoring of continuing medical education for a specific physician or pharmacist is likely to be covered by that prohibition, as it would not qualify as inexpensive if the exception in section 55a paragraph 3 AMG is not applicable: 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 Pharmig CoC contains more detailed rules regarding this issue (see the answer to question 5.1 below).

4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

The Austrian Penal Code ("*Strafgesetzbuch*", BGBl 60/1974, as latest amended by BGBl I 61/2012 with regard to anti-corruption regulations) contains anti-bribery rules applying to any advantages given to a public official ("*Amtsträger*") or an authorised person or employee ("*Beauftragte*"/"*Bedienstete*") in its sections 307 *et seq*. Austrian Penal Code. Physicians in a public hospital or physicians in private practice acting on the basis of a contract with the sick funds could be the subject of these prohibitions. The most relevant provisions are sections 307 (bribery), 307a (granting of advantages), 307b (granting of advantages

for the purpose of inducement), 308 (forbidden intervention), and 309 (bribery of authorised persons or employees).

There is no formal interaction between the anti-bribery competent authorities (i.e. the public prosecution service and the penal courts) and the authorities competent for the enforcement of the pharmaceutical advertising rules. However, these might (as any other authority) refer any circumstances they are made aware of to the public prosecution service in case they suspect that a criminal offence (e.g. a violation of the anti-bribery provisions of the penal code) is given.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

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 respective persons entitled to prescribe or supply medicinal products (i.e. for speakers and attendees), but not for an accompanying person.

Section 7 Pharmig CoC contains more detailed rules regarding this issue. Section 7.2 Pharmig CoC 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 Pharmig CoC 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 Pharmig CoC 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 Pharmig CoC.

Section 7.5 Pharmig CoC 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).

Section 7.5 b) Pharmig CoC 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.

In an ordinance issued in 2014 (VO 1/2014 to Articles 7 and 8), Pharmig has held that the only costs that may be paid by a company to participants include the participation fee as well as reasonable travel, food and accommodation costs. The ordinance further defines the costs for a meal of less than €75 (including tax and tips) per person and meal as reasonable.

In an ordinance issued on September 1, 2015 (VO 1/2015 to Articles 7.1–7.4), Pharmig obliges its members to require a confirmation from the congress organiser that the event is in line with the Pharmic CoC requirements and that support paid by the undertaking will only be used to pay for participation fees, travel, food and accommodation costs.

5.2 Is it possible to pay for a healthcare professional 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. Section 7.6 Pharmig CoC 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 healthcare professionals to attend?

A pharmaceutical company will not be held responsible for the contents, and the general hospitality arrangements, of independent meetings where it just provides sponsorships to individual doctors to attend, but it is in any case responsible for individual sponsoring provided by it and the authority may (theoretically) challenge whether the event is indeed a truly scientific event relating to the profession of the sponsored individual.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

The law does not contain further guidance on this subject; in principle, the provision of services by HCPs to pharmaceutical companies is permitted if made in compliance with the legal provisions.

According to the Pharmig CoC, it is possible to pay healthcare professionals ("members of specialist circles" according to the Pharmig CoC) for the provision of expert services under the following conditions (section 8.2 Pharmig CoC):

- any service rendered by members of the specialist circles for pharmaceutical companies (e.g. for lectures, consulting,

clinical trials, non-interventional studies) must serve the purpose of training/education, research, support of the healthcare system or be provided within the framework of scientific and specialist activities;

- a written contract must be concluded, clearly indicating the service and remuneration to be provided, as well as the scope, type and purpose of the service. Remuneration may only consist of money and must be proportionate to the service provided. Hourly fees may be agreed to compensate for the time spent in providing the service. Any expenses incurred, including travel costs, may be additionally reimbursed to an appropriate degree. Among other options, the fee schedule for physicians can be used to assess the proportionality of remuneration;
- the provision of services by members of the specialist circles must not be linked to any conditions relating to the recommendation, prescription or the administering of medicinal products; and
- the member of a specialist circle shall not be granted, offered or promised any remuneration or benefit in kind to ensure that he/she agrees to receive a medical sales representative or accept information from other staff members.

Visits to members of the specialist circles and hospitals should not seem importunate with regard to frequency and the manner in which they are conducted. Employees who work as medical sales representatives must be obliged by their pharmaceutical companies to observe the standard practices in the trade.

Please note that such contracts with healthcare professionals would need to be disclosed in accordance with section 9 CoC.

5.5 Is it possible to pay healthcare professionals 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.

Pharmig adopted an ordinance on non-interventional studies in March 2010 which contains more detailed requirements regarding such studies (regarding their content and documentation). 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, as amended). 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).

Please note that such contracts with healthcare professionals would need to be disclosed in accordance with section 9 CoC.

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

It would at first have to be determined if such service serves the purpose of training/education, research, support of the healthcare system or is provided within the framework of scientific and specialist activities (section 8.2 a) Pharmig CoC). If this can be answered in the affirmative, it would be necessary to determine whether the other requirements of section 8.2 Pharmig CoC are met (see the answers to questions 5.4 and 5.5 above).

Please note that such contracts with healthcare professionals would need to be disclosed in accordance with section 9 CoC.

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 that need to be followed.

The general rule to follow is that any pharmaceutical advertising has to describe the properties 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, user information or SPC or goes beyond these (see question 3.1 above).

Section 50a paragraph 3 No 4 requires that lay advertising may not contain any claims that go beyond the labelling, user information or SPC.

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 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.

Lay advertising 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.

Lay advertising for traditional herbal medicinal products needs to contain the additional written information that the respective medicine is a herbal medicine for use in the specific indications exclusively based on the long-term use of the said medicine (section 52 paragraph 3 AMG).

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;
- are 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;
- use, 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 a medicinal product requiring prescription is available by distance selling.

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 being 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 directly or indirectly, to a specific medicinal product.

A Supreme Court decision (4 Ob 96/14t) has qualified a vaccination campaign (not state-organised) as non-promotional disease awareness therewith indicating a broader interpretation of the term disease awareness than in the past. However, the question of whether such campaign can indeed be qualified as non-promotional has to be decided on a case-by-case basis.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

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 e) Pharmig CoC 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 the 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 the funding of, patient organisations?

The AMG does not contain any specific provisions in this respect; however, such rules have been implemented in Article 10 Pharmig CoC.

Patients' organisations are defined as "voluntary, non-profit orientated associations, which predominantly comprise patients and/or their families and/or patient 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 financial contribution as well as any indirect contribution or any non-financial contribution" to patients' organisations.

The provisions of Article 10 Pharmig CoC do not apply to indirect contributions or non-financial contributions provided that they are of small value (without such small value being defined in the Pharmig CoC).

Section 10 paragraphs 1 to 8 Pharmig CoC require that:

- Any advertising with support of patients' organisations, as well as any use of logos or copyright-protected materials by pharmaceutical companies or patients' organisations, is subject to advertising restrictions per the Pharmig Code of Conduct and must be exercised exclusively on the basis of a written agreement per Article 9.3.
- Any support of patients' organisations shall serve solely the interests of the patients and/or their families.
- The exclusive support of patients' organisations and/or their programmes must not be agreed by pharmaceutical companies and/or granted by patients' organisations.
- Any support may only be provided on the basis of a written agreement.
- This agreement shall contain comprehensive information about the type, scope and purpose, as well as a description of the support involved and the consent of the patients' organisations, to disclosure by the pharmaceutical companies in accordance with Article 9.6. The value of the support must also be detailed.

- Pharmaceutical companies shall ensure that patients' organisations disclose to the public the relevant support provided by pharmaceutical companies transparently at all times and clearly from the outset.
- Services provided by patients' organisations to pharmaceutical companies must only be supplied for the purpose of training/education, research, support of the healthcare system or within the framework of scientific or specialist activities and based on a written contract; the remuneration must be appropriate and must constitute fair market value.
- Service agreements must obligate the patients' organisations to disclose their activities in full, where verbal or written public notifications of the patients' organisations refer to the subject or contents of the service agreements or, in general, to the pharmaceutical companies.
- Conclusion of an agreement regarding the provision of services must not be linked to the recommendation of certain medicinal products.
- Agreements regarding the provision of services by the pharmaceutical companies to the patients' organisations must be concluded in writing – unless they are inexpensive.
- The cooperation between pharmaceutical companies and patients' organisations must be transparent in nature.

Specific rules concerning the invitation of members of patients' organisations to scientific events are observed.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

The AMG does not contain a general prohibition to provide advantages to patients (except regarding the prohibition to provide medicines to the patient for free).

The general rules – no lay promotion for prescription-only products and no violation of the fair rules of competition – have to be observed. If the items are meant to be used with certain medicinal products, the supply of such items will most likely have to be regarded as lay promotion. Furthermore, section 55a paragraph 1 AMG, prohibiting the granting, offering or promising of gifts, pecuniary advantages or benefits in kind to persons entitled to prescribe or supply medicinal products, needs to be observed.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

Currently, no such obligation has been implemented in Austrian law. Regarding the Pharmig CoC, see the answers to questions 7.2 and 7.3 below.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

Austrian law does not require pharmaceutical companies to disclose information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations – see, however, question 7.3 with regard to the CoC and question 5.5 with regard to non-interventional studies.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

The Pharmig CoC provides for detailed rules on transparency and disclosure, which apply to all information, advertising and marketing activities for medicinal products implemented by a pharmaceutical company itself or on its behalf. It does not restrict the exchange of medical and scientific information during the development of a product before its authorisation in Austria.

1. Disclosure of transfers of value to healthcare professionals and/or institutions

According to Article 9.2 CoC, pharmaceutical companies have to document and disclose any and all "transfers of value" granted to healthcare professionals and/or institutions. Disclosure has to be made for one calendar year; the obligation is valid for the first time for the year 2015 and is due six months after the end of that calendar year.

The duty to disclose relates exclusively to transfers of value in connection with:

- research and development;
- donations and subsidies;
- events; and/or
- services rendered and consulting provided, including expenses incurred.

The CoC requires individual disclosure in principle for all types of transfers of value except for transfers for the purpose of research and development, where aggregate disclosure is sufficient.

Disclosure at individual level (Article 9.4 CoC) shall comprise specific information identifying:

- each healthcare professional and/or each institution; as well as

- the total of the transfers of value granted throughout the reporting period regarding donations and subsidies, and events (whereby separate information as to which transfers have been made for admission and attendance fees as well as for travel costs and accommodation have been made), as well as services rendered and consulting provided, including expenses incurred, whereby the information to be disclosed has to be detailed as mentioned below.

Aggregate (summarised) disclosure – without stating the names of the individual healthcare professionals and/or institutions – suffices if the relevant transfer of value relates to research and development, which includes the reimbursement of expenses for attendance at events in connection with research and development activities.

Furthermore, those transfers of value are to be disclosed in aggregate form where "legal reasons do not permit the names of individual healthcare professionals and/or institutions to be disclosed" (Article 9.5 CoC).

In such cases, transfers of value have to be allocated to the relevant types and disclosed in aggregate form. Detailed information has to be provided on the total number of recipients as well as their percentage as compared to all recipients of transfers of value of this type and the aggregate amount attributable to the relevant category.

As under data protection laws, a disclosure requirement in an industry code does not justify the publication of personal data of the individual or institution, the companies need to get the consent of its contracting partners to such disclosure.

In case the relevant data subject does not give his consent, only aggregate disclosure is allowed.

The Pharmig CoC further contains disclosure obligations regarding "donation and subsidies" to healthcare organisations (section 8.5 Pharmig CoC) and regarding support to patients' organisations (section 10.6 Pharmig CoC).

2. Donations and subsidies to healthcare organisations (section 8.5 Pharmig CoC)

- Financial or material donations and subsidies to healthcare organisations (i.e. organisations or establishments which predominantly comprise of members of the specialist circles) are only permitted for the purposes of training/education, research or support of the healthcare system or within the framework of scientific or specialist activities.
- When making financial donations or providing subsidies, pharmaceutical companies are obliged to keep records, in particular regarding the scope, type and purpose, as well as the recipient of donations and subsidies and its permission to disclose the donation or subsidy.
- Donations and subsidies must be made accessible to the public on the internet, unless they are inexpensive.
- *Article 8.5 Pharmig CoC does not contain any further requirements regarding the time of disclosure and the kind of information to be disclosed, but globally refers to Article 9 Pharmig CoC.*

3. Support to patient organisations (Article 10.6 Pharmig CoC)

- All patients' organisations that receive support from a pharmaceutical company, or that have concluded services agreements with a pharmaceutical company, need to be listed on that company's website.
- The above information needs to detail the type, scope and purpose of the support or the type, scope and purpose of the service, the total value of the financial contributions or non-financial contributions, as well as the total of the service charges per calendar year and per patient organisation. If no precise monetary value can be determined in the case of indirect contributions or non-financial contributions, then the advantage gained by the patients' organisations must be described comprehensively and in verifiable form.
- Indirect contributions or non-financial contributions, as well as inexpensive service agreements, are exempted from the publication obligation.

All published details must be updated at least once a year (no later than by 30 June for the preceding respective calendar year). The CoC rules only apply to Pharmig members.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

Only an aggregate disclosure is possible in such case (section 9.5 Pharmig CoC). For any further cooperation with the HCP, the companies need to decide whether they want to cooperate with an HCP refusing to agree to the disclosure of his data. Many companies have adapted their standard contracts and introduced an explicit consent of the HCP regarding the disclosure of his personal data.

8 The Internet

8.1 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 Pharmig CoC contains specific provisions regarding information and advertising via the internet in its Article 6. According to these provisions, companies are required, *inter alia*, to regularly check their websites for accuracy and update them 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 Pharmig CoC refers to information about the company provided on websites and states that websites may contain:

- information of interest to investors, the media and the 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 Pharmig CoC contains provisions on the information for patients and the general public:

- Information addressed to the general public and containing advertisements 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 (however, in accordance with the ECJ's decision in C-316/09 [*MSD Sharp & Dohme vs Merckle*], only the faithful reproduction of the packaging of the medicinal product, and the literal and complete reproduction of the package leaflet or SPC would qualify as non-promotional information).
- 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, patients' 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 Pharmig CoC specifically requires that information for specialist circles is clearly indicated as such. Further, 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 as to whether the authorities have been specifically active in controlling information provided over the internet so far.

8.2 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 healthcare professionals?

There are no specific legal requirements in place. However, in order to comply with the general advertising restrictions of the AMG, as well as with the specific internet provisions of the Pharmig CoC, 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.

8.3 What rules apply to the content of independent websites that may be accessed by a 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, the general rules apply. The Pharmig CoC states that links containing reliable information on medicinal products (websites of authorities, medical research institutions, patients' organisations, etc.) are permitted.

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 a 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.

8.4 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 (lay persons) needs to comply with the general advertising restrictions (see section 6 above). Most companies provide restricted access to information on medicinal products to healthcare professionals on their websites, as the information and advertisement to the general public (lay persons) is strictly limited with regard to content and appearance (see question 6.1 above). Please also refer to question 7.1 above.

According to the ECJ's decision in C-316/09 (*MSD Sharp & Dohme vs Merckle*), the dissemination of information on prescription-only medicinal products on (generally accessible, i.e. including for lay persons) 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 SPC, as approved by the competent authorities; and
- is accessible on the website only to someone who seeks to obtain it.

Therefore, any information on such websites relating to a (prescription-only) medicinal product that has been selected or rewritten by the pharmaceutical undertaking, which can be explained only by an advertising purpose, is prohibited.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

Currently, no specific legislation is in place regarding the use of social media, which means that the normal rules apply.

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 AMG has not been amended since the last edition of this guide, whereas the Pharmig CoC was amended in July 2015. 2015 was the first year for which disclosure of "transfers of value" was required, and the first disclosure will be due by June 2016. It will be interesting to see these first disclosures (which will mostly be aggregate because consent of the respective data subjects is missing) and to learn which actions the undertakings will take in order to comply with the disclosure obligations and what Pharmig will do in order to enforce the transparency obligations of the Pharmig CoC.

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

No significant developments are expected; in particular, no amendment of the AMG relating to the advertising provisions is currently pending.

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction 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 lay persons.

The Austrian Federal Competition Authority has announced a sector inquiry of the pharma industry for 2017; in this context a closer look may also be taken on compliance with the rules on pharmaceutical advertising (in particular on sections 55a and 55b AMG).

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Languages: German, English and French.

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