Baker McKenzie.

Promoting Medical Products Gl

Handbook of Pharma and MedTech Co

Austria

Daniel Larcher

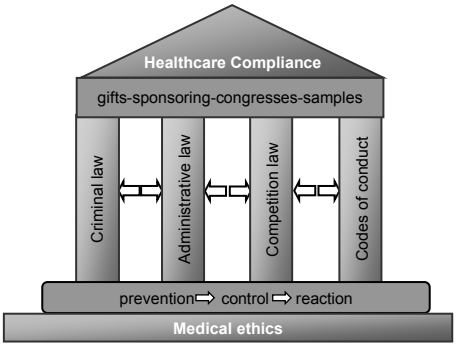
Introduction

It is well known that giving small gifts can enhance business relations. This rule is restricted where more significant interests of third parties are infringed. In the medical business, the patients' health interests must be protected from the industry's economic influence on healthcare professionals, such as physicians and pharmacists. For this reason, promotional activities in the field of healthcare are strictly limited by law, as for example, by restrictions regarding the giving of gifts or free samples.

Austrian law on the promotion of medicinal remedies has gone through significant changes in the last several years. This is due to the implementation of European Union (EU) directives, the installation of a monitoring authority in the healthcare sector, and the tightening of the applicable provisions of administrative and criminal law. A more detailed definition of the provisions dealing with promotional activities in the health sector through the competent authorities and/or case law can be expected in the future.

Restrictions Under Medical Advertising Law

The Regulatory Framework



Medical Products

EU Directive 92/28/EEC on advertising of medicinal products for human use, EU Directive 2001/83/EEC on the community code relating to medicinal products for human use, and EU Directive 2004/27/EC have been implemented in the Act on Medical Products (*Arzneimittelgesetz*, or AMG).

Pursuant to the AMG, advertising is defined as "all measures with respect to information, market investigation and market development, and all inducement measures aimed at enhancing the prescription, supply, sale or consumption of a medical product." This definition of advertising includes, in addition to advertising to health professionals and to the general public (see the human use directive, as amended), the following:

- Inducements to prescribe or supply medical products by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- Sponsorship of promotional events attended by persons qualified to prescribe or supply medical products
- Payment of travel and accommodation expenses and attendance fees of persons qualified to prescribe or supply medical products in connection with scientific congresses they attend
- Supply of samples
- Visits by medical sales representatives to persons qualified to prescribe medical products

The following are not covered by this definition:

- Correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medical product

- Trade catalogues and price lists, provided they do not include product claims
- Statements relating to human or non-human health or diseases, provided there is no reference, direct or indirect, to medical products

This provision does not apply to "general image advertising," provided there is no reference to medical products.

Competition Law

In addition to the aforementioned statutory provisions on the advertising of medical products, there are several relevant provisions under competition law. The Austrian Unfair Competition Act (*Bundesgesetz gegen den unlauterenWettbewerb*, or UWG) provides for the possibility of taking action under civil law against competitors who engage in unfair commercial practices for advertising purposes. Advertising measures usually serve the purpose of increasing one's own sales and can therefore be used as a means of interfering with competitors in their respective areas of business. According to the criteria set forth in the UWG, in this context, it needs to be investigated whether the means by which the interfering competitor hopes to achieve an increase of sales are permissible or incommensurate with the law, fairness to competitors or to the general public (Section 1 of the UWG). Additionally, the UWG prohibits misleading commercial practices (see also AMG and MPG) and/or aggressive commercial practices *vis-à-vis* consumers. Furthermore, comparative advertising is deemed permissible unless it is misleading or aggressive. However, it has to be noted that the permissibility of comparative advertising in the area of drugs is considerably restricted by the provisions in the code of conduct of the Association of Austrian Pharmaceutical Companies ("Pharmig") (see section 5).

Any violation of the provisions on advertising, as set forth in the AMG or the MPG, is usually also deemed unfair, and thus illegal, from a competition law perspective.

Any claim arising under the UWG can be directed toward a cease-and-desist order, removal, damages or the publication of a court decision sustaining the claim. Pursuant to the AMG, certain associations and corporations under public law are also entitled to apply for cease-and-desist orders against the violation of statutory provisions on the advertising of remedies.

Permitted and Prohibited Practices

Enterprises operating in the healthcare sector apply a multitude of indirect advertising measures to improve their business relations with physicians and medical facilities, which may consist of the provision of gifts or hospitality or the supply of free samples. Regarding these advertising practices, the law expressly provides that any action, however slight the implication that improper influence is exercised over any person qualified to prescribe or supply drugs, specifically on his or her decision-making to administer a certain therapy approach or in making a certain recommendation, has to be avoided (principle of independence or *Unabhängigkeitsprinzip*).

Gifts and Other Benefits (Section 55a of the AMG)

Pursuant to the AMG, granting, offering or promising any incentives, financial benefits or material benefits to any person who is qualified to prescribe or supply drugs within the scope of advertising measures for drugs, is prohibited. Demanding, accepting the promise of, or accepting any incentives, financial benefits or material benefits is also forbidden.

The prohibition on acceptance refers to gifts and other pecuniary benefits in the broadest sense of the definition. This will apply if the benefit received is in the form of money (as is the case with suppliers paying for vacation trips), the provision of vehicles, services, the waiving of interest on loans, among others. On the other hand, the prohibition also applies to other benefits, such as granting preferential treatment to third parties, providing placement services for additional occupation and accepting invitations.

As the prohibition explicitly excludes the granting of benefits that are of low (minor) value and furthermore relevant to the practice of medicine, pharmaceutical or medical technology (i.e., do not serve the private purposes of the person receiving the benefit), the granting of benefits is, however, not entirely prohibited in the sensitive area of advertising. The competent Federal Minister (i.e., Federal Minister for Health and Women) is entitled to stipulate, by way of ordinance, what is supposed to qualify as low value. However, the competent Federal Minister has not yet issued an ordinance to that effect. According to the Federal Minister, the authority to issue such ordinance will not be exercised anytime soon, since determining a fixed threshold for benefits of low value does not appear to be legally useful. The question of what is admissible would instead have to be investigated on a case-by-case basis. This would also intensify the preventive effect. The Minister furthermore wants to avoid giving physicians the impression that they have a legal claim to gifts that meet the low-value criteria. It must also be noted that there is no Austrian case law on the issue of the low-value threshold; thus, enterprises operating in the healthcare sector are facing a considerable degree of legal uncertainty.

One has to act on the assumption that whoever is granted benefits has to act with great caution and restraint because, according to the strict wording of the provision, benefits must not only be of low value, but also relevant to the practice of medicine. Where benefits are being granted on a regular basis, the overall economic circumstances will have to be investigated in order to prevent law evasions. In the course of such an investigation, the individual benefits may be added together. Consequently, as a precaution, it is advisable to take typical advertising gifts as the basis for determining the low-value threshold. This usually includes objects of daily use, those with low commercial or market value, as well as items that are relevant to the practice of medicine, such as writing materials, paper pads and calendars.

In legal literature, there are authors who, partially referring to admissibility thresholds applicable in other jurisdictions, assume higher thresholds. In this context, one should think about taking the low- value threshold under criminal law as a basis, which amounts to

approximately EUR70. It must, however, be noted that the value threshold for consequences under criminal law needs to be higher than the one for infringements of provisions regarding the advertising of remedies. This means that the value of the benefit granted must be considerably lower than EUR70. It is advisable not to grant the benefit to the medical professional but instead, if at all, to the medical facility (principle of immediacy or *Unmittelbarkeitsprinzip*).

However, in doing so, one needs to act with great care as the relevant guidelines and codes of conduct might provide for stricter criteria (see section 5), and any violation of such rules of conduct could result in severe fines and/or other sanctions.

The statutory provisions on remedies do not stipulate whether gifts may be evaluated according to their "social adequacy." If, for example, a physician receives a gift on the occasion of his promotion, it is uncertain whether this constitutes a breach of the provisions regarding advertising of remedies. It can be assumed that gifts that are given out of courtesy and customs are permissible, insofar as they are customary for the relevant group of persons related to the occasion and are of a low value. In this context, the low-value threshold can by all means be a little higher, as for example, within the scope of what is socially conventional for the respective occasion and it does not meet the criterion of medical supply. A typical example is the giving of a bottle of wine or a bouquet of flowers.

Hospitality Expenses and Assumption of Responsibility for Other Costs in Connection with Marketing and Scientific Events (Section 55a para 2 of the AMG)

Marketing Events

Pursuant to the AMG, hospitality expenses (e.g., business entertainment expenses) incurred in connection with sales promotion events must always be strictly limited to the main purpose of the event. Expenditures on hospitality may not be extended to persons other than those qualified to prescribe or supply drugs.

As far as marketing events are concerned, an organizer may not assume responsibility for costs incurred by the physician, such as business entertainment expenses that exceed the low-value threshold. In connection with marketing events, the low-value threshold bears the same uncertainties, as is the case with the giving of gifts. As a precaution, it is therefore advisable to assume as low a threshold as possible. Assuming responsibility for entertainment expenses, as for example, cultural or sporting events, should, under all circumstances, be abstained from. On the other hand, offering an entertainment program, the costs of which need to be borne by the participants themselves, seems permissible. Meals will also have to be limited to what is absolutely necessary. While offering a simple buffet will, in all likelihood, be permissible, it is probably unacceptable to offer a large meal at a restaurant. Paying a physician for his/her participation in an event where the physician does not play an active role, for example, as a lecturer or presenter, is prohibited.

For purposes of evidence keeping, any costs borne by the organizer must be documented in detail so that they can be traced (principle of documentation or *Dokumentationsprinzip*). It is advisable to address the invitation to the medical facility rather than to the medical professionals working there (principle of directness). If a medical professional receives a personal invitation, his or her participation in the event requires the prior authorization of his or her employer (principle of authorization or *Genehmigungsprinzip*).

Scientific Events

The restrictive approach applied in legislation regarding marketing events is slightly less strict when it comes to scientific events. The AMG provides that the low-value threshold is not applicable in the case of scientific events that are exclusively profession-related. The law explicitly permits the assumption of any direct or indirect responsibility for travel, subsistence and attendance costs.

In this context, it must be noted that, due to the criteria of reasonable limits, assuming responsibility for the costs of a luxury hotel or a first-

class ticket is impermissible. These costs need to be borne by the members of the medical profession themselves. What needs to be emphasized is that, with respect to scientific events, any expenditure on hospitality must be strictly limited to the scientific and main purpose of the event as well. Furthermore, travel and subsistence costs and attendance fees, as well as expenditures on hospitality incurred in connection with scientific events may not be extended to persons other than medical professionals who are qualified to prescribe and supply drugs.

Likewise, for any scientific event, the costs for which the organizer assumes responsibility for need to be documented in detail so that they can be traced. It is furthermore advisable that the relevant invitation is addressed to the medical facility itself. If a medical professional receives a personal invitation, his or her participation in the event requires the prior consent of his or her principal.

The differentiation between a marketing and a scientific event is of particular interest in this context. The law does not provide a clear answer. One can assume that the event as a whole needs to be taken into consideration, paying attention to different factors such as how often, in the course of the event, reference is made to the organizer's products. Considering the strict wording of the provision, which speaks of "events for purely professional and scientific purposes," it can be assumed that any event including even minor marketing elements has to be classified as a "sales promotion event."

By issuing ordinances, the Federal Minister for Health and Women can enact more specific provisions with respect to the AMG's public event regulations. The Federal Minister has not yet exercised such authority due to the same reason given above in the context of the low-value threshold applicable in the event of gifts.

Rebates in Kind (Section 55b of the AMG)

Granting, offering and promising rebates in kind to persons qualified to prescribe or supply drugs is prohibited, insofar as the drugs concerned are included in the Reimbursement Code

(*Erstattungskodex*) published by the Association of Austrian Social Security Authorities (*Hauptverband der Österreichischen Sozialversicherungsträger*). The Reimbursement Code is a register that includes all pharmaceutical specialties that are reimbursed by national insurance and for which a marketing authorization has been issued in Austria. Pursuant to the AMG, any person who is qualified to prescribe or supply drugs must not solicit or accept any promise of or accept rebates in kind.

This provision seeks to prevent the negative impact that the granting of rebates might have on the trust in the physician's prescription or supply of drugs, which need to be exclusively based on professional considerations (principle of independence). Another intended effect is to prevent rebates in kind being granted on the account of the statutory health insurances, which will have to ultimately bear the costs of drugs.

Conversely, when it comes to drugs that are not registered in the Reimbursement Code, rebates in kind are permissible. However, the granting of rebates in kind must not be in violation of fair trade practices.

Pursuant to the UWG, rebates in kind are permitted in a certain quantity, or in a quantity to be calculated on the basis of only fragments of one and the same product. Therefore, rebates in kind are only permissible for the same type of drugs, which means that it would be permissible to provide a group X drug as a rebate in kind for the purchased group Y medicine. Rebates in cash are not covered by the regulation and are therefore admissible under competition law.

Provision of Samples

Pursuant to the AMG, marketing authorization holders may only provide samples of pharmaceutical specialties for which a marketing authorization has been granted to physicians, dentists and veterinarians:

- in response to their written request;

- free of charge;
- bearing the legible and non-removable information "free medical sample – not for sale"; and
- in a package not larger than the smallest presentation on the market.

This allows for the supply of samples in package sizes smaller than the smallest presentation on the market. The supply of samples containing psychotropic or narcotic substances is strictly prohibited.

Pursuant to the AMG, the quantity of drugs that may be supplied per recipient is dependent on the period of time that has lapsed after the date they were first provided.

- In the first year, samples may be supplied in a range that is sufficient for evaluating the success of the treatment of a maximum of 10 patients. However, no more than 30 samples per recipient are permissible.
- After one year, a maximum of two samples per request are allowed. However, no more than five samples of one pharmaceutical specialty per year and recipient may be supplied.

Pursuant to the AMG, records must be kept for the recipients of medical samples that are not for sale, as well as for the type, scope and date of provision thereof (principle of documentation). Such records have to be presented to the appropriate health authority by request.

Additional criteria for the supply of drug samples on the occasion of events (congresses and conferences) are specified in codes of conduct. In this context, reference is made to the chapter dealing with the code of conduct as prepared by Pharmig ("Pharmig code").

Legal Consequences Breach

Any violation of a provision on advertising, as set forth in the AMG or MPG, is punishable within the scope of criminal proceedings before administrative bodies. Any person acting in violation of AMG provisions on granting benefits, events and rebates in kind, or of MPG provisions on granting benefits commits an administrative offense, provided that the action taken does not qualify as a criminal offense, and is subject to a fine in the amount of up to EUR25,000, or up to EUR50,000, in the case of recurrence. Any infringement of an AMG supply of drug samples is subject to a fine in an amount up to EUR7,500, or up to EUR14,000, in the case of recurrence.

Pursuant to the AMG, the Federal Office for Security in Health Care (*Bundesamt für Sicherheit im Gesundheitswesen*) may revoke the marketing authorization for a pharmaceutical specialty if the marketing authorization holder is penalized three times or more for the same infringement. The violation of provisions regarding the advertising of remedies may also result in the enterprise losing its authorization to carry on its trade or business within the meaning of the Austrian Trade Code (*Gewerbeordnung*) if the holder of such a trade license can no longer be trusted with the execution of the trade or business. Any violation by medical professionals of the provisions with respect to the advertising of remedies may also have disciplinary consequences, such as under the Austrian Physicians' Act (*Ärztegesetz*) or the Austrian Public Service Act (*Beamtendienstrechtsgesetz*), which may ultimately lead to them being prohibited from continuing their profession.

In addition, competitors are also entitled to seek remedies for the violation of competition law provisions under civil law in accordance with the UWG. Such claims can particularly be aimed at a cease-and-desist order (Section 14 of the UWG) and/or damages (Section 16 of the UWG). Since damages incurred as a consequence of a competitor's violation of provisions with respect to remedies are hard to prove, the claim for a cease-and-desist order is of higher practical relevance. Another option is to file a motion for a temporary

injunction against the competitor with the courts (Section 24 of the UWG). In order to do so, the claimant must only certify that fair trade practices were violated and the court can then grant a temporary injunction without hearing the competitor. Regarding the costs of the proceedings, it is not relevant whether the competitor had been asked to abstain from any future infringement of fair trade practices by means of a warning letter prior to the complaint. If, however, the competitor acknowledges the violation of fair trade practices upon service of the action, the plaintiff's claim has to be limited to the costs of the proceedings.

Additionally, it must be stated that any breach of the regulations regarding remedies may also result in penalties under the codes of conduct of the professional associations (see section 5).

Monitoring the Advertising of Remedies

In Austria, the monitoring of provisions regarding the advertising of remedies was, until 2006, limited to the monitoring of individual cases. This was done by investigations of a certain behavior performed within the scope of criminal proceedings before administrative bodies, by the relevant groups of persons themselves, or by other persons entitled to bring an action within the meaning of the AMG (Pharmig, Austrian Medical Chamber, etc.)

At the beginning of 2006, the legislator established a new regulatory authority, the Federal Office for Security in Health Care, and equipped it with the power to take inspection measures.

Advertising measures do not need to be authorized by the competent health authorities. Pursuant to the AMG, the Federal Office for Security in Health Care can, however, demand to be provided with all the records it deems necessary to investigate compliance with the provisions on advertising, as set forth in the AMG. This includes all records relating to sales promotion events and profession-related scientific events. The Federal Office for Security in Health Care and the experts commissioned by it are authorized to gain access to all

premises, as well as inspect and make copies of all documents deemed necessary to monitor the provisions on advertising.

In the event that the Federal Office for Security in Health Care becomes aware of any violation of the provisions on advertising, it may take all measures necessary to establish compliance with the associated statutory provisions. These measures include ordering that advertising material may no longer be distributed or must be recalled. However, the Federal Office for Security in Health Care does not have the authority to force the advertising company to issue a corrective statement.

The establishment of the Federal Office for Security in Health Care has drastically increased the pressure on members of the medical community to comply with the provisions regarding the advertising of remedies, as provided for in the AMG and the MPG. It remains to be seen whether, as a consequence of the establishment of the new regulatory authority, the number of proceedings following violations of provisions regarding the advertising of remedies will increase as well. Companies operating in the medical sector would therefore be well advised to pay particular attention to the documentation and transparency of their advertising practices.

Professional Codes of Conduct

In Austria, medical associations have adopted various codes of conduct that stipulate rules for cooperation between the industry and members of the medical profession, as well as ethical guidelines with respect to competition. The objective of these professional codes of conduct is to ensure quality, security and fairness in the healthcare sector.

The central codes of conduct, namely, the Pharmig Code, and the Physician's Code for the Cooperation with the Medical Industry must be singled out at this point. Other codes of conduct, such as the Austrian Self-Medication Industry code (the "IGEPHA's code"), the "Physician and Public" code or the UIADM's code only indirectly

deal with the subject of cooperation between the industry and the members of the medical profession.

The Pharmig Code

General

Since 1964, Austrian pharmaceutical companies have, as a rule, voluntarily subscribed to the restrictions imposed by Pharmig. These restrictions concern marketing activities after the approval of a medical product and they regulate the conditions for providing scientific information to the community of specialists.

Since that time, around 95 percent of Austrian pharmaceutical companies have become members of Pharmig. This association has accepted responsibility for ensuring the observation of the regulations in the Pharmig Code, which was adopted in 1970 and has subsequently been amended several times. It is considered one of the strictest pharmaceutical codes of conduct in the EU. Failure to observe the code's regulations may have far-reaching consequences for the company concerned, such as fines of up to EUR100,000 and/or even expulsion from Pharmig. The code thereby proves to be successful in the field of prevention and an inquiry to Pharmig may prevent violations in the future. Furthermore, the code also establishes guidelines on permissibility regarding marketing activities of companies that are not members of Pharmig.

General Principles

One of the Pharmig Code's primary rules is that a violation of the advertising restrictions in the AMG is automatically considered a violation of the code.

The Pharmig Code forbids pharmaceutical companies to mention brands of their competitors in their documentation or advertising materials, unless permission has been granted to do so. This regulation further restricts the rules of comparative advertising as stipulated in Section 2 of the UWG for the pharmaceutical field.

Provisions

The Pharmig Code provides for rules on the following subjects:

- Information on medical products
- Advertising medical products
- Information and advertisement via the internet
- Events for healthcare professionals
- Cooperation with healthcare professionals and institutions

Transparency

- Cooperation with patients' organizations
- Benefits
- Raffles
- Pharmaceutical company employees
- Clinical trials

Ordinances

Pharmig has adopted several ordinances that supplement the provisions of the Pharmig Code, such as ordinances on value limits for boards and hospitality, transparency requirements with regard to the granting of benefits, and rules on events.

Complaint Proceedings and Penalties

In the event of a violation of the Pharmig Code's rules, a written complaint can be filed with the Secretary General of Pharmig by members of the management of the complainant. Complaints directed against non-members of Pharmig are forwarded by Pharmig to the Trade Association of the Austrian Chemical Industry (*Fachverband der Chemischen Industrie Österreichs* or FCIO). Complaints must

contain exact information on which facts the complaint concerns and which point of the code has been violated by that fact. The company concerned must state its position within five working days. A committee of experts appointed by Pharmig is authorized to deal with the complaint.

If a violation of the code of conduct is established by the committee of experts, the committee may impose the following sanctions:

- Disclosing the violation, including the name of the company concerned, in a Pharmig publication
- Informing the parent company of the firm concerned
- Informing the general secretariats of the European Federation of Pharmaceutical Industries (EFPIA)
- In the case of a serious violation, imposing a fine of at least EUR5,000 and at most EUR100,000 (EUR200,000 in the case of repetition), which shall be donated to charities
- Expelling the firm concerned (an expulsion from Pharmig does not release the expelled or withdrawing member company from its financial obligations; neither does it release the company from the duty to pay a fine imposed)

The sanctions mentioned above may also be combined. A serious violation is one that is repeated within 24 months or a violation of the code committed for the same reason. It must be noted that a violation of regulations concerning gifts or medical events is considered a serious violation, even when committed for the first time.

Within four weeks after the resolution of the committee of experts has been served, the company concerned may file an action for the annulment of the resolution with the arbitral tribunal of Pharmig. The tribunal's arbitral award is final and enforceable, and may overturn the decision of the committee of experts.

Physician's Code for Cooperation with the Medical Industry

In 2005, the Austrian Medical Chamber (*Österreichische Ärztekammer* or ÖÄK) adopted a code of conduct that stipulates far-reaching rules for doctors and dentists vis-à-vis the pharmaceutical and medical devices industry. The Code's primary target is to ensure that cooperation between physicians and the industry does not result in an "unhealthy" commercial influence or a conflict of interests that, as a consequence, could negatively affect the treatment of patients or the reputation of the medical profession (principle of independence). The Physician's Code is not to be taken as a mere guideline, but as a body of disciplinary rules. For this reason, a violation of the Physician's Code may result in disciplinary charges against the physician. The ÖÄK has installed a committee of experts (*Ehrenrat*) in order to observe the physicians' compliance with the regulations of the code. The committee of experts is instructed to pursue a "zero tolerance policy" toward violations of the rules of the Physician's Code.

The Physician's Code, similar to the rules in the Pharmig Code, deals with the following issues:

- Acceptance of gifts and other benefits
- Scientific medical events
- Acceptance of samples
- Clinical trials and research
- Formalities

Violating the rules of the Physician's Code is considered a disciplinary offense, pursuant to the Austrian Physicians' Act (*Ärztegesetz 1998*). Disciplinary punishments involve a written reprimand, fines amounting to EUR36,340, or a temporary suspension or deletion from the register of physicians (Austrian Physicians' Act).

Criminal Law Provisions

Compared with other EU member states, Austria has so far experienced only a small number of major medical scandals involving the difficult economic relationship between the industry and physicians. However, even minor scandals pose a high risk for companies as, in addition to criminal penalties, the reputation of the company in the area now exposed to increased public scrutiny may suffer severely.

In Austria, most criminal law provisions aimed to prevent corruption are in the Austrian Criminal Code (StGB). The conduct of both the party granting a benefit (including bribery, granting of benefits or granting a benefit for "sweetening"/"grooming") and the party accepting such a benefit may be punishable. This regulative framework is complemented by the criminal law provisions contained in the Austrian Unfair Competition Act and in the Act on the Criminal Liability of Companies (*Verbandsverantwortlichkeitsgesetz* or VbVG).

Austrian anti-bribery law (*Anti-Korruptionsrecht*) has gone through significant changes in recent years. A further amendment of Austrian bribery laws will enter into force on 1 January 2013. This edition sets out the said amendment.

The succeeding sections discuss exclusively the regulations concerning the offense of offering of bribes, or the so-called active bribery.

Anti-Corruption Provisions for the Public Sector

These strict anti-corruption provisions only apply where the bribed party can be classified a public officeholder.

The following physicians can be classified as officeholders:

- Physicians (*Ärzte*) who are employed in a public hospital

- Physicians who practice in a privately organized hospital that is held (minimum stake of 50 percent) or is run by local authorities (*Gebietskörperschaft*) or by authorities abroad or is audited by an audit court
- Physicians who practice as medical health officers (*Amtsärzte*)
- Physicians who practice in hospitals operated by social insurance institutions (*Sozialversicherungsträger*)
- Physicians who practice at medical universities

The following physicians are not qualified as officeholders:

- Private (residential) physicians
- Physicians employed in private hospitals or in hospitals of order (*Ordensspital*)

It is important to point out that these qualifications are only practical guidelines. Due to the complexity of the term "officeholder" under Austrian law, the classification of a physician or a healthcare professional (HCP) as officeholder should always be assessed on a case-by-case basis.

Bribery

Whoever offers, promises or grants an officeholder (*Amtsträger*) or an arbitrator a benefit for himself or a third person for illegally performing or omitting an official act (*Amtsgeschäft*) shall be punished by imprisonment of up to three years. Whoever commits the crime of bribery by using a benefit exceeding EUR3,000 shall be punished by imprisonment from at least six months up to five years, while bribery with a benefit exceeding EUR50,000 shall be imprisoned, from at least one year up to 10 years.

Granting of Benefits

Whoever offers, promises or grants an officeholder or an arbitrator an inappropriate benefit (*ungebührlicher Vorteil*) for himself or a third person for the legal performance or omission of an official act shall be punished by imprisonment of up to two years. Whoever commits the crime by using an amount exceeding EUR3,000 shall be punished by imprisonment for up to three years while that which exceeds EUR50,000 shall face imprisonment from at least six months up to five years.

According to the StGB, the following benefits are not inappropriate benefits:

- The acceptance of benefits that are permitted by law or granted in the context of events, provided that participation in the event is justified by an official interest
- Benefits for charitable purposes as defined under tax law, provided that the officeholder or arbitrator does not exert any decisive influence over the use of the granted benefits
- In the absence of legal permission per the first point, benefits that are customary at the place where they are granted and that are of a minor value, provided that the acceptance and/or the granting of the benefits is not committed on a regular/commercial basis

Granting a Benefit for "Sweetening"/"Grooming"

Whoever intentionally offers, promises or grants an officeholder or an arbitrator an inappropriate benefit for himself or a third person in order to influence the officeholder in the course of his action as an officeholder shall be punished with imprisonment for up to two years. Whoever commits the crime by using a benefit exceeding EUR3,000 shall be punished by imprisonment for up to three years, while a similar offense with a benefit exceeding EUR50,000 will result in imprisonment of at least six months up to five years.

Forbidden Intervention

Whoever claims, accepts or promises a benefit for himself or a third person for exerting inappropriate influence on the decision-making of an office-holder or an arbitrator, or whoever offers, promises or grants a benefit to a person so that the person exerts an inappropriate influence on the decision-making of an officeholder or an arbitrator, shall be punished by imprisonment of up to two years. Whoever commits this crime in relation to a benefit exceeding EUR3,000 shall be punished with imprisonment of up to three years, while a benefit exceeding EUR50,000 for a similar crime will be punished with imprisonment ranging from six months up to five years.

Anti-Corruption Provisions for the Private Sector

Acceptance of Gifts and Offering Bribes to Employees or Authorized Representatives

An employee or an authorized representative of a company who claims, accepts or promises a benefit for himself or a third person for the illegal performance or the omission of an act in a business transaction, or whoever offers, promises or illegally grants an employee or an authorized representative a benefit for himself or a third person for the performance or omission of an act in a business transaction, shall be punished by imprisonment of up to two years. Whoever commits this crime by using an amount exceeding EUR3,000 shall be punished by imprisonment for up to three years, while that which exceeds EUR50,000 will result in imprisonment from at least six months up to five years.

Offering Bribes to Employees or Authorized Representatives

The UWG contains its own anti-bribery provisions. Competitors may claim protection under these provisions in the course of a private criminal action (which will only be instituted upon the request of the injured competitor).

Pursuant to the UWG, whoever, in the scope of business dealings and for advertising purposes, offers, promises or grants gifts or other

benefits to an employee or an authorized representative of a company in order to obtain an advantage in procuring goods or services for himself or herself or a third party as a result of the unfair conduct of the employee or authorized representative will be punished.

The penalty for offering bribes to employees or authorized representatives will be imprisonment for up to three months. Alternatively, the courts may impose a fine of up to 180 daily rates (company fine), which must not be applied if the offense triggers the same or a more severe penalty under other legal provisions.

Corporate Criminal Law Provisions

On 1 January 2006, the VbVG entered into effect in Austria. In addition to administrative penalties, the VbVG provides for criminal penalties against companies in the event that decision-makers or employees of the company committed a criminal offense for the benefit of the company or if such an act violated any obligations incumbent upon the company (Section 3 of the VbVG). According to the Act on the Criminal Liability of Companies (Section 4 of the VbVG), the courts may impose fines in the amount of up to 180 daily rates on companies; the number of daily rates will be determined individually, in each case depending on the crime or offense committed. The amount of the daily rates must be determined in accordance with the profit situation of the respective company, taking into account its general economic efficiency. The amount to be determined must correspond to the 360th share of the annual profit plus/minus one-third. A daily rate must at least amount to EUR50 but may not exceed EUR10,000. Therefore, the maximum fine that can be imposed under the VbVG amounts to EUR1,800,000.

Contracts with Healthcare Professionals and Medical Facilities

Cooperation in the healthcare sector works both ways. While medical professionals need the products and donations provided by the industry, the industry benefits from the expert knowledge and skills of the medical professionals. For this reason, contracts for the provision

of services or funding (e.g., donation and sponsoring contracts) are common and, in general, legal. Where the give-and-take relationship of the contracting parties appears non-transparent, it could easily be assumed that a contract is fictitious and merely serves to conceal unethical agreements, placing the patients at a disadvantage or jeopardizing fair competition. Considering the legal concerns connected with such contracts, it has proved beneficial for companies to develop binding internal conduct rules ("compliance guidelines") as well as standardized contracts for the collaboration with healthcare professionals.

In addition, some key principles, which may serve as a valuable guideline in drafting such contracts, should be observed. As a basic principle, contracts should never influence the independence of a physician by indirectly or directly obliging him or her to prescribe or buy products of a specific company (principle of independence). Therefore, the granting of donations or benefits should not be related to sales transactions with the recipient of such donations or benefits. Another requirement for the permissibility of donations is that the service, and the consideration offered for such service, are in due proportion and that both the contract and the exchange of services are documented in writing that can be traced (principle of equivalence and documentation). The performance to be rendered under the contract must be a scientific or professional activity performed for the company (principle of activity). Contracts should, if possible, be concluded with the medical facility rather than with individual persons (principle of immediacy). If this is not the case, any services rendered should be disclosed to and approved in writing by the employer (principle of authorization).

It is understood that these principles are not necessarily all applicable in every case but form a flexible system. If one principle is not complied with at all, or only to a minor degree in a certain type of contract, this must be compensated by the stronger presence of other principles in order to make the contract appear permissible. The following sections will discuss the aforementioned principles on the basis of certain types of contracts most commonly used in practice.

Research Contracts

Contract research is one of the most common forms of cooperation between the industry and physicians. In this context, it should be ensured that if at all possible, the research contract is concluded with the respective medical facility, but not with the experts conducting the research at the level of the facility.

The consideration the enterprise pays for the research must be adequate (i.e., at arm's length). Care should be taken not to agree on any lump-sum considerations if this can be avoided. The remuneration paid for the examination and research activities shall be based on the time and effort spent. Any publication of research results must indicate the name of the sponsor. Additionally, any services rendered must be documented. The contract should furthermore include a specific "legal compliance clause" by which the medical facility may confirm that the contract neither violates internal regulations nor statutory provisions (i.e., civil service law, professional codes of conduct, etc.) or, as the case may be, that such regulations will be complied with in the performance of the contract.

Services that only apparently serve a medical-scientific purpose or in which the other party can have no justified interest (such as fictitious services, sham contracts) raise concerns from an anti-corruption perspective. One may suspect that they merely serve to conceal unethical benefits granted to members of the medical profession by the industry. Practices that may raise concerns are, for example, renewed studies of (the relevant company's own) remedies for which a marketing authorization has already been granted (unless there is a specific reason to repeat the examination), pseudo-scientific studies or the monitoring of new drug combinations. When drafting such contracts, special care should be taken to ensure that the documentation is traceable and that the purpose of and/or reason for the research is indicated (principle of documentation and activity).

Consultancy Agreements

In practice, consultancy agreements are most likely to be concluded with the expert himself rather than with a medical facility. If the expert is working for a medical facility, it is advisable to obtain the authorization of the institution concerned. The company must pay adequate remuneration for the consultancy services rendered and what is adequate in each individual case may depend on the qualifications and reputation of the expert in question. The consultancy services should be documented and the expert should issue fee statements that would allow third parties to understand the facts and circumstances of the business relationship. The remuneration paid for the consultancy services should be based on the time and effort spent.

Contracts on Presentations and Lectures

These are also contracts that are often entered into with the speaker. In this case, the written authorization of the lecturer's employer must be obtained. The speaker must be reasonably remunerated for the lecture given (i.e., at conditions customary in the particular market). The remuneration paid for giving a lecture shall be based on the time and effort spent, as well as the speaker's reputation and/or position, if deemed appropriate..

Unilateral Funding Contracts

The industry's granting of funds to medical facilities or universities is common practice in Austria and is considered necessary. A detailed definition of the term "external funds" (*Drittmittel*) is in Section 28 of the Vienna Medical Facility Act (*Krankenanstaltsgesetz 1987*). According to this definition, external funds are financial allocations to hospitals, particular units, departments or other organizational units that do not directly serve as remuneration for a specific service rendered, or are being provided in addition to the occasion of a specific service. This collective term covers, in particular, donation contracts, sponsoring contracts, contracts on the supply of devices or outsourcing contracts.

In general, as far as funding contracts are concerned, one needs to draw attention to the fact that the reason behind a granting of benefits must not be to promote the prescription of drugs, and thus constitute an infringement of the physician's independence. Particularly, in university and hospital sectors, funding contracts are often directly entered into with university or hospital personnel. These contracts are only admissible if the principal has given his or her prior consent (Austrian University Act 2002). In no case should the funds be transferred to the account of the person procuring the funds (i.e., in most cases, university personnel or physicians), but rather to the respective facility's official

account. It is recommendable to include a provision, which stipulates that the applicable statutory provisions will be complied with, into the contract. This assures that the funds will in fact be used for the intended purpose and that the granting of funds has no bearing on the prescription of medicinal products.

In particular, when it comes to mere donations, the principle of equivalence is completely left aside, as they do not involve an exchange of performances. Consequently, there is a risk that the donation might be treated as a grant of benefits, which gives cause for concern in terms of corruption. Donation contracts should therefore be as detailed as possible regarding the intended purpose, the donated amount and the intended recipient. In the event that the contract also contains elements of sponsoring, (i.e., if the company uses the support provided for image purposes, such as in contracts relating to exhibitions), the scope and type of performances need to be specified in detail within the contract.

The granting of funds for social events (social donations), such as providing financial support for intra-company festivities of medical facilities, is not permitted.

Recommendations

In the course of cooperation with medical professionals, various civil (UWG), administrative (AMG, MPG) and criminal provisions (StGB, UWG, VbVG) must be taken note of. The granting of benefits to healthcare professionals, especially to those who have the status of civil servants, is only permissible to a very limited degree.

If there is suspicion of a violation of doctoral independence, even the granting of minor gifts may have administrative consequences and may be sanctioned by the codes of conduct.

Where no such suspicion is entertained, a contractual cooperation may be freely agreed upon. In order to avoid unpleasant consequences and possible damage to a company's public image, it is advisable to adhere to the following rules when entering into an agreement and performing it:

- The principle of independence – Benefits must not appear to be intended to hollow out the independence of professionals qualified to prescribe or supply medical remedies. Following this, benefits must not be granted in dependence on orders or sales transactions.
- The principle of writing – For reasons of evidence, agreements must generally be in writing.
- The principle of equivalence – Performance and consideration should be reasonably balanced. Unilateral agreements should be avoided as much as possible.
- The principle of activity – Any contractual performance for a company must be a scientific or medicine-related activity. Sham contracts are not permissible.
- The principle of documentation – Performance and consideration must be traceably recorded and be in writing. The payment must be based on the related work and the time

needed for the performance. Lump-sum payments should be avoided. The results of research must be published and must indicate the name of the sponsor involved.

- The principle of immediacy – The acceptance of a benefit must exclusively and directly serve healthcare purposes and, accordingly, the interests of the medical facility, university or the patient. Conversely, the acceptance of a benefit must not serve the private purposes of a recipient. As a consequence, agreements should, as much as possible, be directly entered into with the medical facility/university, and not with its employees. Invitations to a medical event should, preferably, be addressed to the medical facility/university itself. Benefits are to be transferred to the official accounts of the medical facility/university, and not to the private accounts of an employee.

- The principle of authorization – Agreements that have been concluded with an employee of a medical facility or university should be approved by the employer (head of administration) in writing before they are executed. The same rule applies to invitations to medical events.

- The principle of compliance – It is advisable to draft a clause into the agreement, stipulating that the medical facility or university shall, in the course of the execution of the agreement, comply with the regulations applicable (such as the provisions dealing with the procurement of funds) as well as its internal guidelines. Furthermore, it is advisable to draft the principle of independence into the agreement.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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