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Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

SWITZERLAND

Switzerland

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Introduction

Like advertising in other industries, medical promotions strive to maximize the turnover resulting from the sale of pharmaceuticals and medical devices that they manufacture or distribute. The marketing has to respect the limits imposed by law. Anti-corruption law prohibits the grant of an undue advantage to an official, and the grant of such an advantage is basically also subject to criminal sanctions if granted to a private person, unless such person's employer or principal approves the advantage.

When selling pharmaceuticals and medical devices, further restrictions apply to ensure, in particular, that persons who supply or prescribe pharmaceuticals or medical devices are not influenced by financial incentives when supplying or prescribing pharmaceuticals or medical devices. This is secured by a general prohibition on accepting any pecuniary advantage, but also by the obligation to pass on any rebates to the patients and their health insurance.

The Regulatory Framework

On 1 January 2002, when the Federal Act on Pharmaceuticals and Medicinal Products (*Bundesgesetz über Arzneimittel und Medizinprodukte*; the "Act") of 15 December 2000 entered into force, Swiss pharmaceutical law was unified. Up to this date, almost the entire pharmaceutical regime, with the exception of medicinal products that were then already regulated by federal law, was regulated by cantonal law or intercantonal regulations.

Advertising rules are primarily set out in the Ordinance on the Advertising of Pharmaceuticals (*Verordnung über die Arzneimittelwerbung*; the "Ordinance") of 17 October 2001. In addition, the Act contains provisions on the promise and acceptance of pecuniary advantages. The Ordinance, as well as Article 33 of the Act,

exclusively applies to pharmaceuticals but not to medicinal products. The Act now at least authorizes the Swiss federal government to issue an ordinance regulating the advertisement of medicinal products. So far, the federal government has not used that power.

The Act prohibits the grant, offer or promise of pecuniary advantages to persons who prescribe or supply pharmaceuticals, and also to organizations that employ such persons, provided that such advantages are given as a consideration for the prescription or the supply of a pharmaceutical. The prohibition is directed to both sides, and addresses not only the healthcare industry but also the professional, who may neither ask for nor accept such pecuniary advantages. The Act applies to all situations in which the occupational behavior of a person who prescribes or supplies pharmaceuticals might be influenced by economic incentives. Due to the fact that a wholesaler neither prescribes nor supplies pharmaceuticals, the wholesaler has no influence on the decision on how the patient shall be treated. Therefore, the relationship between manufacturer and wholesaler is not covered by the Act.

However, all persons who are authorized to supply pharmaceuticals on their own, for example, midwives, but not assistants, fall under the prohibition of the Act. Pharmaceuticals that can be sold at any sales outlet without any obligation to advise the patient (pharmaceuticals of category E) are likewise not covered by the Act.

According to the Act, pecuniary advantages of modest value that are relevant for the medicinal or pharmaceutical practice, as well as rebates that are commonly granted in trade and rebates that are economically justified provided they have an effect on the price, are permissible. The meaning of the latter exception has been deleted. At least, it is commonly acknowledged that two alternative forms of advantages are allowed. Swissmedic, the Swiss pharmaceutical regulator that has the task of enforcing the Act, has, in its publication on the permissibility of rebates in the context of Article 33 paragraph 3 lit. b of the Act (*Zulässigkeit von Rabatten im Rahmen von Artikel 33 Absatz 3 Buchstabe b des Heilmittelgesetzes*), explicitly

acknowledged that the two forms are alternative rather than cumulative.

Therefore, the following two alternative advantages are permissible: On the one side, rebates that are economically justified or permissible; and on the other side, rebates and advantages that are commonly granted in trade. Advantages that allow a party to penetrate a certain market, to adapt to the conditions of a particular market, or to secure the competitiveness of its products are considered economically justified. Besides rebates in the context of the market launch of a new product, rebates that are granted for a limited period of time when a competitor enters the market are considered economically-justified rebates. Further, economically-justified rebates are discounts granted for payment within a short payment term or quantity rebates that are justified by actual cost savings on the side of the seller, as well as rebates that are granted for the use of a particular order mode such as electronic orders.

According to Swissmedic, rebates exceeding such advantages constitute rebates commonly granted in trade if they are granted during a certain time period in the context of the relationship between pharmaceutical companies and healthcare professionals (HCPs), in such a way that the HCPs (can be well assumed to) benefit from such rebates in the future. Due to the fact that the rebate commonly granted in trade is predictable, it loses its influence on the purchase decision of the healthcare professional because the net price (gross price minus rebate commonly granted in trade) is considered to be the base price and constitutes the only reference price. It is, however, required that the gross price will, irrespective of the customer, never be applied.

Payments by which the manufacturer pays a consideration to the customer for assuming certain tasks do not constitute a pecuniary advantage from the outset. According to Swissmedic, it is at least required that the change in the ordinary distribution of tasks is in the sole interest of the party that grants the rebate. This is, for example, the case if a pharmacist himself collects the pharmaceuticals at the wholesaler's premises rather than have the wholesaler deliver them to

the pharmacy. If, however, the consideration (also) has value for the manufacturer or the wholesaler, the corresponding consideration will regularly qualify as a rebate that is economically justified in the sense of the Act.

The Act requires that the rebate commonly granted in trade or that is economically justified has a direct impact on the price. According to Swissmedic, this has to be the case irrespective of whether the health insurance pays for the costs of the pharmaceutical. Therefore, rebates granted only at the end of a certain period are not permissible because it is generally excluded that the rebate can be passed on to the patients and the health insurances, respectively. An exception applies at least in connection with inpatient treatment because the rebates are always indirectly passed on via the hospital lump sum agreed between health insurances and hospitals.

In the author's opinion, no obligation exists to pass on such rebates to the extent rebates are economically justified because they are motivated by the cost savings of the supplier. It obviously was not the intent of the legislator to abandon any interest on the part of the service recipient in acting in an economically sensible and cost-efficient way. This is obvious where the recipient of the rebate himself, to a certain extent, provides a certain consideration, for example, by prematurely paying an invoice to obtain a discount or by shifting the storage costs from the seller to the buyer due to the fact that the buyer procures less frequently, but in bigger quantities.

Article 33 of the Act does not ask that such rebates be passed on, because this provision exclusively wants to avoid rebates having an effect on the prescription or supply of pharmaceuticals, which is likely excluded under such circumstances. It is also questionable whether, indeed, a pecuniary advantage exists at all, because a consideration exists.

According to parliamentary debate, an amount of up to CHF300 to one recipient per year and company can be considered an advantage of limited value, which is permissible as long as the advantage is of

relevance to the medicinal or pharmaceutical practice. The price that the recipient would have to pay to obtain the advantage, and which might be much higher than the one the party who grants the advantage has to pay, is decisive as to whether the threshold is met. However, the threshold of CHF300 is not applicable to invitations to congresses.

The wording of the Act only prohibits the grant of pecuniary advantages if they are given as consideration for the prescription or the supply of a pharmaceutical. The Swiss Federal Supreme Court in a decision of 7 July 2014, stated that this is already the case if the pecuniary advantage is apt to influence the prescription or supply behavior of the healthcare professional by giving him an incentive to prescribe or supply additional pharmaceuticals. Swissmedic also requires a certain connection between the grant of an advantage and the prescription or supply of pharmaceuticals for the application of Article 33 of the Act. However, according to Swissmedic, it is sufficient that this connection is only very weak or even concealed, and if it can only be inferred from the circumstances. According to Swissmedic, that would, for example, be the case if healthcare professionals were invited by a pharmaceutical company to a congress or were accompanied to such congress by more employees of the pharmaceutical company than required for merely organizational reasons. Swissmedic argues that such context already qualifies as advertising of healthcare professionals and that advertising in connection with the grant of an advantage qualifies as a prohibited influence. In the author's opinion, this view is very questionable.

Socially acceptable gifts generally do not have any influence on a healthcare professional's prescription or supply behavior. Therefore, a box of chocolates or a bottle of inexpensive wine given by an employee of a pharmaceutical company to a friend who is a healthcare professional at the occasion of that healthcare professional's 50th birthday should be in line with the law because the causal link between the grant of the advantage and the supply and prescription of the pharmaceutical is arguably not given. However, as soon as the gift (or the frequency by which gifts are given) can no longer be considered socially acceptable, there will be an influence on the

prescription or supply of a pharmaceutical and the gift would not be permissible.

On 18 March 2016, the federal parliament adopted an amendment of the Act; it is not yet clear, however, when it will enter into force. The amendment replaces Article 33 of the Act by a new Article 55, which is to a large extent, identical to the old Article 33. However, it is now prohibited for persons who not just prescribe or dispense but who also supply or buy prescription drugs, as well as for organizations who employ them, to ask for themselves or a third party to be promised or to accept any undue advantages. is This means that the prohibition is limited to prescription drugs and does not include medical devices and over-the-counter (OTC) drugs. However, the federal government is given the competence to extend the prohibition to further groups of therapeutic products. The law also no longer explicitly requires a causal link between the grant or promise and the prescription, dispensation, supply or purchase of the prescription drug even though such link will still need to exist. The law explicitly states that no undue advantages exists in the following cases: (i) advantages of minor value that are relevant for the medical or pharmaceutical practice; (ii) payments to support research, professional education or development, provided that certain criteria are met; (iii) the consideration given for equivalent considerations, in particular in connection with the purchase and delivery of therapeutic products; and (iv) price rebates and reimbursements granted in connection with the sale of therapeutic products, provided they do not have any impact on the treatment decision. Furthermore, rebates and pecuniary advantages granted in connection with the sale of therapeutic products have to be stated in the relevant evidence, invoices and accounts of the purchasing and of the selling persons and organizations and, upon request, have to be disclosed to the authorities. The federal government can exclude certain therapeutic products with small risk potential. A violation of this obligation can trigger a fine of up to CHF50,000, while a violation of the provisions under Article 55 of the Act can be sanctioned by up to three years of custodial sentence or fine. The enforcement of the relevant parts of the Act shall no longer be only the task of Swissmedic, but also of the Federal Office for

Public Health. This new assignment of competence will likely trigger stricter enforcement because Swissmedic did not consider the enforcement of the prohibition to grant advantages to constitute one of its core tasks while the Federal Office for Public Health will do so.

In this context, the Federal Act on Health Insurance (*Bundesgesetz über die Krankenversicherung* or KVG) of 18 March 1994, has to be mentioned. According to this provision, a professional has to pass on such rebates to the patients or their health insurers. This obligation, however, exists exclusively within the scope of application of the KVG, that is, only for pharmaceuticals (also medicinal products) whose costs have to be borne by the health insurers. The Federal Office for Social Security has issued three official recommendations with respect to this topic:

- The Recommendation of 15 March 2002, concerning the passing on of rebates obtained when buying pharmaceuticals for consumption in inpatient treatment (*Empfehlung betreffend die Weitergabe der beim Einkauf verwendungsfertiger Arzneimittel erhaltenen Vergünstigungen im stationären Spitalbereich*)

- The Recommendation of 11 July 2002, concerning the passing on of rebates received when buying pharmaceuticals ready for consumption outside hospitals (*Empfehlung betreffend die Weitergabe der beim Einkauf verwendungsfertiger Arzneimittel erhaltenen Vergünstigungen im ambulanten Spitalbereich*)

- The Recommendation of 20 September 2002, concerning the behavior and passing on of pecuniary advantages, particularly in the context of professional development activities (*Empfehlung betreffend den Umgang mit und die Weitergabe von geldwerten Vorteilen, insbesondere im Zusammenhang mit Weiter- und Fortbildungen*)

Permitted and Prohibited Practices

Gifts, Seminars, Hospitality and Entertainment

As set out above, gifts given to persons who prescribe or supply pharmaceuticals, or to organizations that employ such persons may under no circumstances exceed CHF300 per recipient, year and company. Whether the maximum amount of the gift should be even lower should be assessed on a case-by-case basis. This author is of the opinion that the gift has to be socially acceptable. This means that the reason why a gift is given is important. A gift given on the occasion of a 60th birthday will have to be considered differently from a gift given at the end of an ordinary discussion on the sale of products. In the latter case, the existence of an illegal causal link between the gift and the prescription or supply, respectively, is likely, whereas it is at least questionable whether such link is also given in the first case. The application of the Act at least requires that the gift be of importance to medical or pharmaceutical practice. Gifts that are socially acceptable, such as a bottle of wine at the occasion of a promotion of a doctor, could comply with the Act as there is no influence on the prescription and supply of pharmaceuticals.

The participation in professional development events may neither directly nor indirectly be contingent upon the prescription, supply or purchase of pharmaceuticals.

Under the title "Re prohibition on promising or accepting pecuniary advantages according to Article 33 of the Act, particularly in connection with the support of the professional education of healthcare professionals by the pharmaceutical industry" (*ZumVerbot desVersprechens und Annehmens geldwerterVorteile gemäss Art. 33 des Heilmittelgesetzes, insb. in Zusammenhang mit der Unterstützung der Weiter- und Fortbildung von Medizinalpersonen durch die Pharmaindustrie*) that it published in 2006, Swissmedic stated how it will classify the support of the professional development of healthcare professionals under the Act. According to this statement, events that last longer than half a day or consist of an expense that is for more than a light meal during breaks (in the case of events between two to

four hours) or a preceding or subsequent simple lunch or dinner (in case of half- day events) are only in line with the Act if the invited healthcare professionals pay cost contribution. The amount of the cost contribution depends on various factors like the place, duration and content of the event; the content and extent of the required representation expense; the degree of dependence of the event organization on the supporting entities, if any; and the personal qualification of the recipient of the advantage. As a general rule the participants have to bear at least one third of the entire cost. For healthcare professionals in education, this contribution can be reduced down to 20 percent of the costs and, under certain circumstances, they can even be released altogether from the payment of cost contribution. Furthermore, the side program of an event must not exceed 20 percent of the entire cost or time of the entire event. Furthermore, the side program needs to be offered immediately before, during or immediately after the event, and the side program's individual elements must not compete with parts of the scientific event that are scheduled at the same time. If elements of the side program do not meet these criteria, the cost would have to be fully paid by the participants. This also applies with respect to any expense for travel, accommodation and meals that are not required.

Clearly, the payment of flight costs for spouses or the reimbursement of costs that are not objectively justified like first class tickets or, in Swissmedic's view (which is at least discussable with respect to intercontinental flights), business class flights, are not allowed.

To ask healthcare professionals to make a cost contribution if they attend a one-day educational event within Switzerland does not really make sense. This is particularly true because the physicians, due to the fact that they cannot work while the costs of their practice continue to run, already incur quite considerable costs which, of course, must not be compensated. Furthermore, it is difficult to see why a sales representative might invite a doctor for lunch but the very same doctor has to contribute to the cost if the lunch is not granted in the context of a visit of the sales representative but at the occasion of a one-day scientific event.

The Ordinance states that the expense in connection with scientific seminars needs to be in a reasonable amount and needs to be secondary compared to the main purpose of the event. Participation expenses may not relate to persons who are not authorized to prescribe or supply pharmaceuticals.

Promotional Activities

The Ordinance requires that the expenses connected to a promotional activity be of a reasonable amount and of minor importance compared to the main purpose of the event. In particular, the expense may not relate to persons other than persons active in the healthcare business. Therefore, the invitation of a spouse of a healthcare professional to a congress is prohibited. Entertaining physicians at events is not generally prohibited, but needs to be clearly of minor importance compared to the scientific and business-related event, both in terms of cost and duration.

The relationship between the Ordinance and the Act, which in principle prohibits the grant of pecuniary advantages, is not entirely clear. Because entertainment is not relevant to a medicinal or pharmaceutical practice, it cannot – at least based on the wording of the Act – benefit from the exemption of the Act. However, as long as the entertainment is very modest, it is unlikely to have an influence on prescriptions by the healthcare professional. As the purpose of the Act is to avoid any influence on prescription activities by the granting of irrelevant incentives, this provision, in this author's opinion, does not prohibit secondary and modest entertainment. Swissmedic also allows for a social program. According to Swissmedic, a social program is limited to the representational expense, which relates to performances rendered in the context of an event but are not necessary for such event. In Swissmedic's opinion, a healthcare professional is not required to pay for the entire cost of the social program only if all elements of such social programs are offered immediately prior to, during or immediately after the event and if the related time or financial expense of the social program does not exceed 20 percent of the entire cost or duration of the scientific event, as well as if the

agenda of the social program does not compete with parts of the scientific event that are scheduled at the same time. An exception applies for social programs that are organized by the congress organization itself and are covered by the registration fee or paid by the congress organization itself.

Samples

According to the Ordinance, samples may be granted to healthcare professionals only in a small number and upon written request. In principle, not more than five packages may be given to healthcare professionals, but this number is further reduced if the packages are of significant value.

Furthermore, samples may not be bigger than the smallest original package admitted on the market. The sample, furthermore, needs to be clearly and permanently marked as such. It needs to contain the latest information normally required for pharmaceuticals. The sample has to be accompanied by the information leaflet that was approved by Swissmedic. If the information leaflet has already been published in the compendium of pharmaceuticals, the compendium of veterinary pharmaceuticals or in another publication that is recognized by Swissmedic as being equivalent, a reference to such publication is sufficient. Furthermore, the firm that is responsible for the distribution has to make sure that the grant of samples is recorded in writing.

The grant of samples to the public is possible for pharmaceuticals of categories C, D and E, that is, for OTC drugs. Samples that are given to the public, however, have to be limited to the dosage recommended for one single day, have clearly visible directions, and be permanently marked as samples that are not for sale. In addition, they have to meet the requirements set by Swissmedic regarding the supply and the information on the packaging. Samples of pharmaceuticals of categories C and D (i.e., OTC-products that require consultation by a healthcare professional) may only be handed out to the public at the appropriate outlets (e.g., drugstores for category C). Self-service is not allowed. Finally, samples must not be sold.

Consequences of Breach

Swissmedic can order a company that seriously or repeatedly violates the Ordinance to submit, during an appropriate period of time, all drafts for any planned promotion prior to publishing them for review and prior approval. These include, in this author's opinion, invitations to healthcare professionals in the form designated by Swissmedic. The company responsible for the distribution has to bear the cost of this review.

According to the Act, the intentional violation of the provisions concerning advertisement for pharmaceuticals can be sanctioned with a fine of up to CHF50,000. If the person who violated these provisions acted on a commercial basis, he can imprisoned for up to six months and incur a pecuniary fine. A negligent violation can be sanctioned with a fine of up to CHF10,000. In principle, the natural person who commits the illegal act is subject to criminal sanctions. The principal or employer who deliberately or negligently and in violation of a legal obligation does not prevent such a violation from being committed by their employee, mandatee or representative, or does not eliminate its effects, is subject to the same criminal sanctions as the person who is acting on his behalf. If the principal or the employer is a legal person, the corporate body who should have acted is subject to the criminal sanctions. If the sanction is a fine not exceeding CHF5,000 and if finding the person who is responsible would necessitate an investigation that would be disproportionate considering the sanction, the judge can instead order the legal entity to pay the fine in lieu of the sanction against such person.

Under the Swiss Criminal Code, the pharmaceutical company may be liable for a fine of up to CHF5 million if the punishable act can not be imputed to a specific individual.

Professional Codes of Conduct

Code of Business Conduct of the Pharmaceutical Industry in Switzerland

On 4 December 2003, the associations of the pharmaceutical industry in Switzerland – the Swiss Society of Chemical Industries (SSCI), ASSGP, Intergenerika, Interpharma and Vereinigung Pharmafirmen in der Schweiz (VIPS) adopted the Code of Business Conduct of the pharmaceutical industry in Switzerland (the "Pharma Code"). The contracting associations shall encourage their members, as well as manufacturing and trading companies in the pharmaceutical industry, to comply with the Pharma Code and sign the relevant declaration. Such a declaration can also be signed by companies who manufacture or distribute pharmaceuticals in Switzerland, even though they are not members of any of the named associations. Companies that agree to observe the Pharma Code, which has since been revised on 6 September 2013, have to respect the regulation concerning the procedure in case of violations of the Pharma Code and, in principle, must not bring the matter in front of Swissmedic for a violation of the healthcare law or in front of a court for unfair competition as long as such a procedure is still ongoing. The Pharma Code applies to the promotion of pharmaceutical products for humans aimed at healthcare professionals, to information provided to healthcare professionals on pharmaceuticals for humans, to events in that context, and to the professional development of healthcare professionals. The Pharma Code also regulates the sponsoring of clinical trials with pharmaceuticals for humans, including non-interventional studies.

The Pharma Code prohibits the grant or promise of undue advantages to HCPs. However, the Code explicitly reserves the following: usual remuneration for HCPs in connection with orders and deliveries of medicinal products; delivery of free of charge samples of medicinal products to HCPs; objects, information and training materials of moderate value provided for HCPs that are intended solely for a medical or pharmaceutical activity or are used for post-graduate or continuing education in medicine or pharmacy and which, in both cases, are also beneficial to patients; writing implements and pads of

modest value, made available to participants at events by pharmaceutical companies (such writing implements and pads may not bear any references to the pharmaceutical company or to particular medicinal products); and payment for meals (including beverages) on a reasonable and modest scale, subject to a maximum amount of CHF150 per healthcare professional per meal. This amount applies only to events that are held in Switzerland. For events held abroad, the limits set out in the code where the event takes place apply to all participants, regardless of where they are located.

The Pharma Code regulates the grant of samples. Samples may be supplied to healthcare professionals to familiarize them with the corresponding pharmaceutical products and to enable them to gain experience with the products in practice.

The Pharma Code states that symposia, congresses and similar events are recognized means for the dissemination of knowledge and experience. The main purpose of such events has to be the imparting of scientific or professional information. The time allotted to scientific and professional education has to clearly outweigh the time for entertainment and hospitality. The financial investment for the event should equate to what the average of the participants would pay if they had to pay themselves for this event. The invitation of healthcare professionals who are not employed by the company that organizes or financially supports the event as participants or speakers may not depend on the suggestion, prescription or supply of certain pharmaceuticals.

Companies may pay adequate fees for speakers and reimburse the expenses they incur by participating in the event, including travel expenses. On the other hand, companies must not pay for travel and accommodation costs of persons who merely accompany healthcare professionals to the event.

In principle, companies have to ask the healthcare professionals who participate in an event for an adequate contribution to the costs to secure their independence. These rules equally apply to events that are

financially supported by companies. With respect only to events taking place in Switzerland that last for less than one day, no contribution to the costs has to be asked. However, Swissmedic is of the (questionable) opinion that a cost contribution is due even if the event lasts for more than half a day. Companies may neither entirely nor partially reimburse or have reimbursed the cost contributions of the participants.

If companies financially sponsor professional development events that are offered or organized by medical associations, universities, hospitals, healthcare professionals or other institutions, the fact that such an event is financially supported and the identity of the sponsoring companies must be clearly mentioned in the announcement of the event, during the event itself and in publications concerning the event. The sponsoring amounts have to be paid to an account of the organizer that is specifically designed for the event and out of which all speakers and all expenses in connection with the organization and the event itself are paid. The topics of the program have to be designated by the organizer.

The Pharma Code requires that the financial sponsoring of clinical trials be regulated in a written agreement. The agreement has to be duly signed by the company that finances the clinical trial as a sponsor, the healthcare professional who is mainly responsible for the clinical trial, and the institution in which the clinical trial takes place. The consideration for clinical trials which that been carried out in cooperation with institutions has to be paid to an account of the institution with which the clinical trial is carried out. This account has to be audited by an independent person.

The company that sponsors the clinical trial has to make sure that the responsible investigator and his or her employees carry out the clinical trial independently from the interests of the sponsoring company and that they do not have any financial interest in the results of the trial. Obviously, a clinical trial may neither directly nor indirectly be made contingent upon the purchase of pharmaceuticals or other products for therapeutic need or upon certain purchase conditions. The results of

clinical trials have to be published, and the fact that the trial was sponsored and the undertakings that sponsored the clinical trial must be mentioned. Furthermore, the relevance of the results has to be assessed, taking into account the significance of the illness as well as the clinical and financial expense of the investigated measure.

Scienceindustry, the Swiss business association of the chemical, pharmaceutical and biotech industry, asked a healthcare professional, who was independent of any member firm, to lead the secretariat of the Pharma Code ("Code Secretariat"). The Code Secretariat is responsible for the objective supervision of the advertisement of pharmaceuticals and the information on pharmaceuticals made or initiated by companies, as well as for the termination, withdrawal or correction of advertisements and information directed to healthcare professionals by undertakings that clearly violated the Pharma Code. The Code Secretariat furthermore acts as a mediator to settle disputes between companies that are involved in a proceeding concerning a suspected violation. Furthermore, the secretariat of the Pharma Code investigates any violation of the Pharma Code.

If an undertaking does not comply with the requirements of the Code Secretariat within the set deadline, refuses to accept requirements or does not keep its promise to amend a violation, the Code Secretariat may refer the matter to Swissmedic for final decision.

Code of Conduct of the Pharmaceutical Industry in Switzerland on Cooperation with Healthcare Professional Circles and Patient Organizations ("Pharma Cooperation Code")

The Association of the Pharmaceutical Industry in Switzerland on 6 September 2013, adopted the Pharma Cooperation Code. The Pharma Cooperation Code applies to the cooperation between pharmaceutical companies and healthcare professionals, healthcare organizations and patient organizations, together with the disclosure of pecuniary benefits provided by pharmaceutical companies for such persons and organizations. The Code applies to pharmaceutical companies that have signed the respective declaration. Like the Pharma Code, the Pharma Cooperation Code is based on the principle of integrity.

Cooperation with healthcare professionals, healthcare organizations or patient organizations and pecuniary benefits granted in return must not constitute an inducement to recommend, prescribe, acquire, supply, sell or administer specific medicinal products for humans. Pharmaceutical companies may not offer, promise or grant any inappropriate benefits to healthcare professionals, healthcare organizations or patient organizations, including, in particular, any gifts. However, the usual remuneration for healthcare professionals in connection with orders and deliveries of medicinal products, the delivery of free of charge samples of medicinal products to healthcare professionals, as well as objects, information and training materials of moderate value provided for healthcare professionals that are intended solely for the medical or pharmaceutical activity or are used for post-graduate or continuing education in medicine or pharmacy and which, in both cases, are also beneficial to patients, are reserved. Equally admissible are writing implements and pads of modest value, made available to participants at events by pharmaceutical companies, provided that they do not bear any references to the pharmaceutical company or to particular medicinal products.

Payments for meals (including beverages) are only permitted on a reasonable or modest scale, subject to a maximum of CHF150 per healthcare professional per meal. This amount applies only to events held in Switzerland. For events held abroad, the limit set out in the Code where the event takes place will apply to all participants, regardless of where they are located. Consultancy or service contracts with healthcare professionals have to be agreed on in writing before the work begins. The consultancy task or service to be provided and the compensation for it have to be adequately specified. There has to be a justified need for the proposed consultancy task or service, the healthcare professional must be qualified to perform such task or service, and the number of healthcare professionals utilized must not exceed the number needed for the task's or service's completion.

Pharmaceutical companies shall disclose pecuniary benefits that they grant to healthcare professionals or healthcare organizations. They have to state in the contract with the healthcare professionals or

healthcare organizations that they are required to disclose the pecuniary benefits connected with the contractually agreed service and shall stipulate that the recipient of the pecuniary benefits agrees to such disclosure.

The Pharma Cooperation Code provides for certain exceptions to the disclosure obligation. Payments to healthcare professionals for orders or deliveries of medicinal products, the delivery of free of charge samples of medicinal products to healthcare professionals, the provision of objects intended for healthcare professionals, information and training materials of moderate value that are intended exclusively for the medical or pharmaceutical activity or used for advanced or further medical or pharmaceutical training and which in both cases are also of benefit to patients, do not have to be included. The same is true with respect to meals (including beverages) and writing implements and pads to the extent allowed under the Pharma Cooperation Code. The pharmaceutical company shall disclose pecuniary benefits annually for a full calendar year within a six month period from the end of such year. This information has to remain accessible to the public for at least three years after its disclosure. The disclosure has to be satisfied on the pharmaceutical companies' corporate website, which is accessible to the public either in Switzerland or internationally. Disclosure has to be made in English and whenever possible, also in German, French and Italian. For the indication of healthcare organizations, their name in the relevant language or languages has to be used.

In principle, disclosure has to take place on an individual basis by clearly identifying the healthcare professional and the amount paid. Pharmaceutical companies may disclose pecuniary benefits by category if the individual disclosure is only made in justified exceptional cases to the relevant recipients or to the appropriate authorities at their request. Pharmaceutical companies may also disclose pecuniary benefits that they have granted to the healthcare organizations in an aggregated form for each such healthcare organization and without identifying the individual healthcare professionals who are the indirect beneficiaries in this connection, but

only if they constitute donations, grants and other pecuniary benefits, contributions to the costs of participation of the healthcare professional within the framework of their activity for the healthcare organization at events, regardless of whether the contributions directly benefit a healthcare professional or do so via the healthcare organization or a third party. Equally, compensation for services and consultancy tasks with a healthcare organization or healthcare professional acting on its behalf that has been provided under a contractual agreement does not have to indicate the individual healthcare professional but the compensation for the agreed service or consultancy task and the compensation for the related costs of the service provider have to be disclosed separately.

If for legal reasons the amounts of the pecuniary benefits cannot be disclosed individually for each healthcare professional or healthcare organization, they have to be disclosed in an aggregate form, including the number of healthcare professionals covered, the total amount of the pecuniary benefit granted and its percentage distribution between the healthcare professional concerned.

The Pharma Cooperation Code also deals with the relationship with patient organizations and the disclosure of pecuniary benefits to them. Pharmaceutical companies have to safeguard the independence of the patient organizations and may neither require patient organizations to promote certain specific prescription-only medicinal products nor consider corresponding requests made by patient organizations. The aims, scope and agreement on support and partnership must be evidenced in writing and be transparent. Patient organization shall be supported by more than one pharmaceutical company. The Pharma Cooperation Code furthermore lists the content of an agreement with the patient organizations.

Pharmaceutical companies must not try to influence the content of documents of patient organizations to which they are granting financial or other support in their own commercial interest.

Like for pecuniary benefits granted to healthcare professionals, pecuniary benefits granted to patient organizations have to be disclosed on an individual basis and annually for a full calendar year within six months of the end of such year. The information has to be accessible to the public for at least three years after its disclosure. The modalities for the disclosure are identical to the disclosure of advantages granted to healthcare professionals.

Federation of Swiss Medical Technology Trade and Industry Associations (FASMED)

On 26 May 2010, FASMED issued the FASMED Code of Conduct, which replaced the former Code of Business Conduct of 2003. It applies to the members and their interactions with professionals admitted to practice a profession in Switzerland or elsewhere. It is supplemented by "Application Guidelines dated 23 March 2015 for the FASMED Code of Business Conduct dated 26 May 2010 - Recommendation."

The FASMED Code of Business Conduct is based on four basic principles. The separation principle prohibits any interaction to influence the decision of professionals with regard to products or to make such interaction dependent on the use of the products. According to the transparency principle, the interaction has to be transparent and consistent with local laws, regulations and professional rules. The equivalence principle requires that whenever a member engages a professional to perform a service for or on behalf of the member, the compensation paid for the services rendered must be reasonable and in line with its fair market value. The documentation principle requires that a written agreement be entered into for interactions. Such agreement has to include provisions on the purpose of the interaction, the services to be performed, the compensation and reimbursement of expenses. The intended activities have to be substantiated and evidenced by activity reports or the like. The documentation principle also requires that all documents be retained by the member.

The FASMED Code of Business Conduct prohibits members from directly or indirectly making, offering or promising payments of money or other non- cash benefits to professionals so that they will use the products, or to obtain orders or other benefits.

Agreed services and consideration shall be shown on the invoice or otherwise documented in writing. Non-cash benefits of nominal value that are of relevance to the medical or pharmaceutical practice as well as customary and commercially-justified discounts, which directly affect the price, are permissible.

The FASMED Code of Business Conduct prohibits members to directly or indirectly make, offer or promise monetary payments or pecuniary advantages to employees of medical institutions or other healthcare organizations to obtain orders or other advantages. Any performance and the consideration thereof agreed upon in the context of transactions creating a turnover have to be documented on the invoice or otherwise have to be documented in writing to the medical organization. Rebates that are common in trade and economically justified are permissible provided that they directly have an impact on the price.

Members may offer product training and advanced trainings for professionals in order to facilitate the safe and effective use of their products. However, the event has to be held in an appropriate setting. Members may offer participants reasonable meals in conjunction with the event and also overnight accommodation for training and advanced training events.

Additional hospitality may be appropriate. Hospitality should have reasonable financial limits and should be secondary to the purpose of the event from the standpoint of time and subject matter.

If permitted under the guidelines of professional associations and organizations responsible for such conferences, members may support independent, educational, scientific or guideline-drafting conferences that promote scientific expertise, medical advances and provision of

effective healthcare. Members may, in particular, absorb the costs of participation by a particular professional, although costs should be limited to the participation fee and reasonable and actual meals, travel, and lodging costs arising in connection with the participation in the conference. Prior written consent of the hospital administration, the professional's superior or any other responsible agency, with complete disclosure of the purpose and scope of the sponsoring, should be obtained. The costs of merely social or cultural activities during a scientific event must not be paid for. Modest, socially acceptable activities could be paid if the entertainment aspect does not prevail. Members may also provide direct financial support to the organizer in order to reduce the amount shouldered by the participants. The organizer must make a written request, and the support must be paid directly to the organizer or educational institution. Members may be involved in specifying the content of the event only to the extent of recommending speakers or commenting on the program upon appropriate request.

Consulting agreements with healthcare professionals may only be entered into when a legitimate need for the corresponding service has been identified in advance. The consultant has to be selected based on his or her qualifications and specialized knowledge in the field of the defined project, and not based on his or her use of the products. Prior written consent of the hospital administration, the professional's superior or any other responsible agency, with complete disclosure of the purpose and scope of the consulting agreement, have to be obtained.

Members may make donations for exclusively charitable or non-profit purposes, provided that the recipient is allowed to accept such donations under applicable law. However, donations must not be tied to the use of the products in any way. Furthermore, donations may not be made at the request of a professional unless the professional is an employee of an organization and makes the request on behalf of the organization. The professional's preferred organization should not be supported thereby at the request of such professional. Furthermore,

members should not have control over the actual use of their donations.

Members may make research grants to support independent medical research. Research grants are permissible to support customer-initiated studies that concern clinical or non-clinical research in areas in which the member has a legitimate interest. All requests for such grants must be made in writing, naming the type and goal of the research activity. No support should be granted until the written agreement is signed. Complete disclosure to the hospital administration or the professional's superior or any other responsible agency is necessary, and the recipient should promise to mention the support of the research by the member in all oral and written presentations of the results.

Liability Under Criminal (and Civil) Law

The Regulatory Framework

The grant of advantages to professors at universities, physicians and pharmacists at hospitals, or other personnel of hospitals could violate the Swiss criminal law relating to corruption. The relevant provisions are embodied in the Swiss Criminal Code (*Schweizerisches Strafgesetzbuch* or StGB). Article 323ter StGB prohibits, among others, offering, promising or granting to an official any advantage in favor of such official or any third person that is not due in connection with the official's public activity as a consideration for an activity or an omission that is against the official's duties or is in the official's discretion. From this definition, the grant of an advantage as described in StGB has to be distinguished. Whoever offers, promises or grants to an official, in view of the exercise of a public function, an advantage that is not due may be sentenced under this provision.

Therefore, not only the granting of gifts to a large number of officials, but also specific goodwill payments that do not relate to a specific activity of the official, constitute criminal offense. Nevertheless, only grants that aim at influencing the official are covered. Therefore, the advantage has to be apt to influence the exercise of the public function

of an official. StGB states that advantages that the official may accept under the provisions to which he or she is subject, as well as small and socially common advantages, are not covered by the criminal provision. These provisions only relate to officials. The notion of an official is defined in the StGB and covers institutional as well as functional officials. Therefore, the role in which the functional official fulfils does not matter. It is, however, essential that the official carries out a public task. Private persons who discharge a public task equally qualify as officials. Therefore, all healthcare professionals who are employed by a public hospital will likely qualify as officials, regardless of whether their employment is one under public or private law. Physicians who practice on their own are, on the other hand, clearly not covered by the provisions of the criminal law on corruption unless they perform a public task in addition to their private activity. Also, wholesalers and employees of pharmacies and drugstores do not fall under the term of an official in the sense of the Swiss criminal code. It is always required, however, that such persons do not perform any public task in addition to their private activities, and receive advantages in this context. Private physicians who treat their patients in private and also in public hospitals do not discharge any public function. While it is true that safeguarding the public health is a public task, one cannot, for this sole reason, categorize any physician as an official. Rather, categorization as an official requires that the person in question is acting as a representative of public rights and duties, and that the activity in question is discharged on behalf of and not merely instead of the state. Because Swiss corruption law aims to protect the objectivity and integrity of public activity, the functional connection has to be stronger the weaker the institutional incorporation into the state organization is. It is, therefore, decisive that a task can be imputed to the state, because only in this case is the integrity and the objectivity of the administration endangered. A physician who renders emergency services in a public or private hospital, therefore, does not qualify as such an official because his or her activity is not perceived as an activity of the state and because the physician neither performs an official task nor is embedded in the public administration.

According to Federal Act on Unfair Competition (*Bundesgesetz über den unlauterenWettbewerb* or UWG), the grant of an advantage to healthcare professionals who do not qualify as officials in the sense of the criminal law may constitute an act of unfair competition. This provision states that whoever offers, promises or grants to an employee, shareholder, an agent or another auxiliary person of a third party within the private sector, in connection with the recipient's occupational or business activity as a consideration for an activity or an omission that contravenes the recipient's duties or which is in the recipient's discretion, engages in unfair competition, any undue advantage to the recipient or another person, as well as the person acting on behalf of the Employer, who asks for or accepts such an undue advantage is criminally liable for an act of unfair competition. If the Employer, however, accepted the advantage or if the advantage is only of limited value and socially acceptable, there is no undue advantage and, therefore, no unfair competition exists.

Permitted and Prohibited Activities

Bribery, as well as the grant of advantages, is contingent upon the offer, promise or grant of an advantage that is not due. Any legal, economic or personal advantage of the recipient qualifies as an advantage. Besides actual cash payments, the grant of any property or the right to use a certain property (e.g., the donation of precious objects, the lending of a car free of charge, the grant of rebates or an invitation to travel) and the renouncement of pecuniary claims (e.g., a waiver of claims) constitute an advantage. A certain transaction can qualify as an advantage if the parties' respective performances are not equivalent. The grant of advantages is permissible provided that the advantages are minor and socially acceptable. The report that the Swiss federal government submitted to parliament in connection with the amendment of the criminal code gives the example of a bunch of flowers given to a nurse – such a present primarily honors honest service rendered in the past and does not intend to influence the future discharge of a public function. On the other hand, it is prohibited to invite officials who will have to decide on a public procurement in the future, even if for the time being no specific decisions are pending.

Besides the amount of the advantage, which may only under very exceptional circumstances amount to CHF300 but will, in general, need to be much lower, the specific circumstances of the case are relevant. For example, in a case of a pending public procurement procedure, almost no advantage will be acceptable, while the standards will be somewhat lower if an advantage is granted without any concrete public service being expected in the future.

It has recently become common in the context of financing public tasks by third parties or through sponsorships, that public institutions ask private persons to finance certain public functions. In this case, private persons take over a public task and declare this fact openly, or could at least declare it openly and take over those public tasks voluntarily and in a responsible manner. This case has to be distinguished from the case where officials receive advantages as a consideration for their discharge of a public function or even for activities in violation of their tasks. Also, if the principal physician of a public hospital receives a profit because he prefers the products of a specific company when buying pharmaceuticals for the hospital, there is a clear case of bribery rather than sponsoring. Transparency is an important criterion to distinguish bribery from sponsoring or financing of public tasks by third parties. There is *prima facie* evidence that (permissible) sponsoring exists where it has been made public, while prohibited sponsoring is generally kept secret. Obviously, sponsorships may not be dependent on a certain turnover level.

In summary, one should be very reluctant to grant advantages to persons who qualify as officials in the sense of StGB. In particular, one should refrain from inviting such persons to events unless they are delivering a speech. In such a case, the advantages that such speakers obtain have to be in line with market conditions and have to be adequate. An invitation may only be contemplated if it enables reasonable professional development and thus can qualify as sponsoring of a public task. In this event, however, the consent of the competent authorities (e.g., the administration of the hospital) has to be obtained in advance, and the invitation has to be disclosed.

Public Procurement and Fraud

The principles set out above apply equally in the context of public procurement. The grant of an advantage that is not justified in this context always qualifies as bribery in the sense of StGB, and not only as a mere grant of a certain advantage.

Sanctions

The bribery of Swiss officials under the StGB can be sanctioned with imprisonment of up to five years or a pecuniary fine. The grant of certain advantages under the StGB can be sanctioned with imprisonment of up to three years or a pecuniary fine. If both the illicit act and the fault are so small that a punishment would not be appropriate, the competent authority renounces the prosecution, the filing of the criminal complaint with the court or the punishment.

At least in those cases where a causal link exists between the prohibited grant of an advantage in a contract between the healthcare professional or the medical institution on the one hand and the distributor on the other, the legal grant of the advantage triggers the nullity of such an agreement.

If the grant of an advantage to a healthcare professional constitutes an act of unfair competition, the responsible person not only has to pay damages, but also has to compensate the victim for any profit derived from such unfair activity, if any. The intentional unfair competition can, upon the Employer's request, furthermore be sanctioned with imprisonment of up to three years or a pecuniary fine. The requirement for a request by the Employer will lapse in 2016 except for minor cases.

Contracts with Healthcare Professionals and Medical Institutions

To the extent that the mutual rights and obligations arising out of contracts with healthcare professionals or medical institutions are of equal economic value, no further problems arise in principle. If,

however, the performance that the healthcare professional or medical institution receives clearly outweighs the consideration that such healthcare professional or institution has to give based on that contract, there is a grant of an advantage. Reference is made to the details given above.

In addition, the disciplinary rules to which an official or an employed healthcare professional is subject might require that prior approval be obtained from the supervisory authority or the employer before the official or healthcare professional may enter into a contract and, for example, agree to deliver a speech, participate in a clinical study or render consultancy services.

Recommendations

The permissibility of any grant of advantage or benefit to a healthcare professional must be diligently checked in advance. In general, pharmaceutical companies should be rather reluctant in that respect, particularly with regard to the grant of advantages to persons who discharge public functions like physicians or pharmacists employed by public hospitals. The advantages may be reduced by asking the healthcare professionals to give consideration. If the healthcare professional's performance is compensated at market value, no grant of an advantage that could give rise to any concerns exists. To the extent that not only minor advantages are granted, the grant should be made public, because transparency is a strong indication that sponsoring or financing of public tasks by private means rather than corruption are at issue. Of course, internal hospital regulations, if any, also have to be observed and the consent of the employer or the hospital administration obtained.

In the case of sponsoring, one has to assess whether, indeed, a public task should be financed. If this is the case, the responsible superior (in particular the hospital administration) has to be contacted and consent to the sponsoring. At the same time, one will have to ensure that the payments made are indeed used for the performance of the state activities in question. Cash has to be exclusively paid to official

accounts of the state or to research accounts of departments or divisions that have been approved and are controlled by the competent governmental authorities. Payments to officials and to associations or other legal entities that are not clearly controlled by the state are strongly discouraged. Only if the institutions in question are independent from officials can such institutions be financially supported. However, in this case, neither a sponsoring nor the financing of a public task by private third parties are at issue, but rather a donation to an organization, which may not be made with a view of influencing any activity of an official.

Because the KVG asks that rebates be passed on to the patient or the health insurer and because a violation of this obligation constitutes a criminal act, it is recommended to ask for a written declaration from the recipient of the advantage, that is, the hospital or the physician, stating that the hospital or the physician guarantees to live up to its obligation to pass on the advantages. With regard to hospitals, the obligation to account for the prices actually paid and to live up to the KVG as well as the Ordinance on the Assessment of Costs and the Performance by Hospitals and Nursery Homes in Health Insurance (*Verordnung über die Kostenermittlung und die Leistungserfassung durch Spitäler, Geburtshäuser und Pflegeheime in der Krankenversicherung*) of 3 July 2002 is sufficient, at least to the extent of inpatient treatment.

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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