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Pharmaceutical Advertising

Switzerland: Law & Practice

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Law and Practice

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1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The advertising of medicines in Switzerland is mainly governed by the Federal Act on Medicinal Products and Medical Devices (TPA) and the Ordinance on Advertising of Medical Products (AWV). Amended provisions of the AWV came into force on 1 January 2019, with the exception of the amendments due to the new Ordinance on the Integrity and Transparency in the Field of Therapeutic Products (VITH), which came into force on 1 January 2020.

Furthermore, there are also general legal provisions that must be adhered to in connection with advertising, such as the Federal Act against Unfair Competition (UWG). In addition, provisions in connection with advertising can also be found in the Ordinance of Healthcare Insurance (KVV) and the Federal Act on the Medical Profession (MedBG).

The Swiss Agency for Therapeutic Products (Swissmedic) has published several guidelines with regard to advertising on medicines.

Both the "Code of Conduct of the Pharmaceutical Industry in Switzerland" (Pharma Code) and the "Code of Conduct of the Pharmaceutical Industry in Switzerland on Cooperation with Healthcare Professional Circles and Patient Organisations" (Pharma Cooperation Code) are self-regulatory codes and contain provisions in connection with advertising of medicines. Revised versions of the Pharma Code and the Pharma Cooperation Code entered into force on 1 January 2021. Furthermore, the Guidelines on "Collaboration between the Medical Profession and Industry" (2013 version) by the Swiss Academy of Medical Sciences (SAMW) comprise provisions regarding clinical research, basic and postgraduate medical training and continuing medical education, consultancy activities and acceptance of payments in cash or in kind.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Both the Pharma Code and the Pharma Cooperation Code were adopted by the Associations of the Pharmaceutical Industry in Switzerland. The signatories of the Pharma Code and of the Pharma Cooperation Code are listed online (eg, on www.scienceindustries.ch). These codes bind the vast majority of pharmaceutical companies in Switzerland and contain detailed provisions with regard to the authority of the Code Secretariat in case of breaches of the codes as well as the procedures to follow (Rule 7 Pharma Code; Rule 5 Pharma Cooperation Code).

The Guidelines on "Collaboration between the Medical Profession and Industry" by the SAMW are relevant for healthcare professionals. They are applicable to all members of the *Foederatio Medicorum Helveticorum* (FMH), which is the professional association of more than 42,000 Swiss doctors and the umbrella organisation of over 70 medical organisations (Article 18 of the Code of Professional Conduct of the FMH).

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

Advertising of medicines is defined as all information, marketing and incentivising measures aimed at promoting the prescription, supply, sale, consumption or use of medicines (Article 2 lit a AWV). However, general information on health and diseases without any direct or indirect references to individual medicines as well as catalogues or price lists that do not contain any medical data are not considered to constitute advertising. Furthermore, the packing material and the drug information are not deemed to be advertising, either (Article 1, paragraph 2 AWV).

Monetary benefits to healthcare professionals and healthcare organisations may be considered advertising. However, except for sample packaging, this form of advertising is regulated by the VITH, not by the AWV.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

General information on health and diseases is not considered to be advertising as long as there are no direct or indirect references to individual medicines. Therefore, general information will become advertising if an active substance is named in connection with a measure aiming at promoting the sale of a particular medicine containing the said active substance.

Since the packing material and the drug information are not subject to the AWV, they may – in principle – be made available to the public in connection with general information on health and diseases. However, if packing material and drug information are made available in connection with information on a particular disease and possible treatments, they may be considered to be a direct or indirect reference to an individual medicine and therefore to constitute advertising. If general information on health and diseases fulfils the criteria of completeness, objectivity and balance, a link to the homepage of "swissmedicinfo" would, however, be conceivable.

In light of the mentioned rules, disease awareness campaigns and other patient facing information do not qualify as advertising if there are no direct or indirect references to individual medicines.

Advertising to Target Groups

With regard to advertising to the public, general information on health and diseases may not contain any references to prescription medicines (Article 32, paragraph 2 lit a TPA; Article 14 AWV).

Advertising aimed exclusively at people prescribing or dispensing these pharmaceuticals (healthcare professionals) is, in principle, permitted for all types of medicines (Article 31, paragraph 1 lit a TPA).

2.3 Restrictions on Press Releases Regarding Medicines

Press releases regarding individual medicines are allowed in principle. However, if a press release falls within the definition of advertising, ie, if the information provided aims at promoting the prescription, supply, sale, consumption or use of a medicine, the restrictions with regard to advertising must be adhered to. In particular, press releases accessible to the public may not contain any references to prescription medicines. As such, press releases referring directly or indirectly to prescription medicines must be accessible to media for professionals exclusively and be protected by password protection (as is the case for advertising to healthcare professionals; Article 5a AWV).

If articles and contributions from other media about a company or its medicines are offered on the website of that company (press reviews), the content of these articles and contributions are attributed to that company in terms of advertising law. Therefore, the provisions of the AWV are fully applicable to such press reviews (Swissmedic Journal 8/2006, page 796 et seq).

Furthermore, advertising must be recognisable as such; advertising and editorial contributions must be clearly separated (Article 5, paragraph 4 AWV).

2.4 Comparative Advertising for Medicines

Statements relating to comparisons with other medicines are generally permitted if they are scientifically correct and based on equivalent clinical trials or data collections. Clinical trials must have been conducted in accordance with the rules of good clinical practice and be published or accepted for publication. Data collections (such as meta analysis or practical experience reports) must have been published in a scientifically recognised specialist medium. If studies are used for comparison purposes that are based on experiments in vitro or on animals, this must be disclosed openly (Article 7 AWV).

Furthermore, it is prohibited to disparage others, their goods or prices by making incorrect, misleading or unnecessarily offensive statements or to take measures that are likely to cause confusion with their goods. Also, it is prohibited to compare oneself, one's goods or prices in an incorrect, misleading, unnecessarily disparaging or similar manner with others, their goods or prices. Such advertising would constitute unfair competition (Article 3, paragraph 1 lit a, d and e UWG).

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

All information given in advertising must be in accordance with the drug information most recently approved by Swissmedic. In particular, only indications and application possibilities approved by Swissmedic may be advertised (Article 32, paragraph 1 lit c TPA; Article 5, paragraph 1; and Article 16, paragraph 1 AWV).

3.2 Provision of Information During a Scientific Conference

Information on unauthorised medicines during a scientific conference directed at healthcare professionals can be provided. However, no promotion for such medicines is allowed. The same applies to new indications, possible applications, dosages, pharmaceutical forms and packaging of a medicine. With this information, it must always be clearly stated that this medicine, or the new indication, possible application, dosage, pharmaceutical form or packing for the medicine has not yet received marketing authorisation from Swissmedic (Article 32, paragraph 1 lit c TPA; Article 5, paragraph 1 AWV; and Rules 26.2 and 26.3 Pharma Code).

3.3 Provision of Information to Healthcare Professionals

It is allowed to send information on unauthorised medicines to healthcare professionals. However, no promotion for such medicines is allowed. The same applies to new indications, possible applications, dosages, pharmaceutical forms and packings of a medicine. With such information, it must always be clearly stated that this medicine, or the new indication, possible application, dosage, pharmaceutical form or packing for the medicine has not yet received marketing authorisation from Swissmedic (Article 32, paragraph 1 lit c TPA; Article 5, paragraph 1 AWV; and Rules 26.2 and 26.3 Pharma Code).

3.4 Provision of Information to Healthcare Institutions

Healthcare institutions in Switzerland generally do not need to prepare budgets for medicines because the majority of medicines are listed in the "list of specialities" (SL) and therefore reimbursed by compulsory healthcare insurances. The prices of these listed medicines are determined by the authorities, generally after their approval and before their release on the Swiss market. Consequently, there is no reason to send information on unauthorised medicines or unauthorised indications to healthcare institutions solely for budget reasons. It is thus likely that such information would be considered to be prohibited advertising to the public (Article 16, paragraph 1 AWV).

3.5 Publication of Compassionate Use Programmes

Patients who are to be treated with a product that has been successfully tested in clinical trials in Switzerland to this point and that has not yet received marketing authorisation can be treated outside a clinical trial. For this purpose, the sponsor of the clinical trial must apply for a temporary licence for the use of pharmaceuticals in accordance with Article 9b, paragraph 1 TPA. The authorisation is granted by Swissmedic and allows the sponsor to make this pharmaceutical available for use in Switzerland.

All information given in advertising must be in accordance with the drug information most recently approved by Swissmedic. In particular, only indications and application possibilities approved by Swissmedic may be advertised (Article 32, paragraph 1 lit c TPA; Article 5, paragraph 1; and Article 16, paragraph 1 AWV).

Publishing the availability of compassionate use programmes to the public is unlawful promotion.

When informing healthcare professionals about the availability of compassionate use programmes or other forms of early access, such information should solely be communicated with the healthcare professional directly or, in case of an institution, through the medical department and not through the sales or marketing department, otherwise, the information about the unauthorised medicines could be considered an advertisement, which is prohibited.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Advertising directed at the general public for prescription only medicines is prohibited, whereas advertising for over-the-counter medicines is permitted. Advertising directed at the general public is deemed unlawful for medicines that contain narcotic or psychotropic substances and for medicines that may not, on account of their composition and their intended use, be used without the intervention of a doctor for the necessary diagnosis, prescription or treatment. This also applies to medicines that are frequently the object of abuse or that lead to an addiction or dependence. Furthermore, all advertising is deemed unlawful if it is misleading or contrary to public order and morality, if it may incite an excessive, abusive or inappropriate use of medicines or if it is for medicines that may not be placed on the market in Switzerland (Article 31, paragraph 1 lit b and Article 32 TPA; Article 14 AWV).

According to the KVV, medicines that are advertised to the public will not be included in the SL. Medicines included in the SL will be deleted if the marketing authorisation-holder directly or indirectly advertises the medicine to the public (Article 65, paragraph 2 and Article 68 paragraph 1 lit d KVV). A medicine that is not listed in the SL is not covered by compulsory healthcare insurance.

All advertisements directed at the public are further subject to the provisions regarding unfair competition. Any behaviour or business conduct that is deceptive or otherwise contrary to the principle of good faith and that affects the relationship between competitors or between suppliers and customers is deemed unlawful (Article 2 UWG). In particular, any company that disparages other companies, its goods or prices by making incorrect, misleading or unnecessarily offensive statements or that takes measures that are likely to cause confusion with their goods acts unfairly. It is further prohibited to compare a company or a company's goods or prices in an incorrect, misleading or unnecessarily disparaging or similar manner with others, their goods or prices (Article 3, paragraph 1 lit a, d and e UWG).

4.2 Information Contained in Pharmaceutical Advertising to the General Public

General Requirements

All information in advertising, especially indications and possible applications, must be in accordance with the drug information most recently approved by Swissmedic. The properties of the medicine as described in words, images and sound must be presented factually correctly and without exaggeration. The advertising must be recognisable as such and clearly distin-

guishable from editorial contributions. A medicine, an indication, a dosage, a galenic form or a package may be advertised as "new" for 18 months after its first authorisation in Switzerland and it must be clearly indicated what this attribute refers to.

Medicines in supply categories C and D must be clearly presented as such and any advertising for these medicines must include at least the name of the product, the authorisation-holder and at least one indication or possible use. It must further include the explicit and legible reference, in the case of a medicine with package leaflet, "This is an authorised medicine. Read the package leaflet" or, in the case of a medicine without package leaflet, "This is an authorised medicine. Read the information on the package." (Article 16 AWV).

Advertising in Electronic Media

There are certain special provisions for advertising of medicines of categories C and D in electronic media. For television commercials and cinema advertising, a note with the following message must be displayed at the end: "This is an authorised medicine. Read the package leaflet" or, in the case of a medicine without package leaflet, "This is an authorised medicine. Ask a specialist for advice and read the information on the package". This notice must be displayed legibly on a neutral background in a font block size of at least one third the size of the overall picture.

In the case of cinema advertising it should be in at least the font size customary for subtitles – at the same time this notice must be clearly spoken. In the case of radio spots, a note with the following wording must be inserted at the end: "[product name] is an authorised medicine. Ask a specialist for advice and read the package leaflet" or, for medicines without a package leaflet: "[product name] is an approved medicine. Ask a specialist for advice and read the information on the package". This notice must be spoken in a manner that is easily comprehensible.

Advertising on electronic display boards must display the following message at the end: "This is an authorised medicine. Ask a specialist for advice and read the package leaflet" or, for medicines without a package leaflet: "This is an authorised medicine. Ask a specialist for advice and read the information on the package". This notice must be displayed legibly on a neutral background in a text block at least one third the size of the advertisement and for at least five seconds (Article 17 AWV).

Advertising with the Authorisation Status

While medicines in supply categories C and D must use the reference to their authorisation status in any advertisements, medicines in supply category E may not use their authorisation status in advertising (Article 17a AWV).

Brand Advertising

In advertising that is only intended to recall a certain brand, only the product name or additionally the name of the marketing authorisation-holder may be mentioned. Brand advertising is not permitted in cinemas, on the radio and on television (Article 18 AWV).

Radio and Television Advertising

Advertising on radio and television for medicines for human use containing alcohol and intended for oral use is only permitted if the maximum single dose of these products according to the recommended dosage contains less than 0.5 g pure alcohol (Article 20 AWV). Advertising directed at the general public may not include indications or applications for which a medical diagnosis or treatment is required. It may not be obtrusive, blatant or appear to be an editorial contribution.

Prohibited Advertising

Orders for medicines may not be accepted on the occasion of home visits, exhibitions, lectures or the likes. Furthermore, the direct distribution of medicines for the purpose of sales promotions as well as vouchers and competitions are prohibited. Finally, advertisements may also not include any invitation to contact the marketing authorisation-holder. Some of the mentioned prohibitions do not, however, apply to medicines in category E (Article 21 AWV).

Prohibited Elements of Advertising

Advertisements may not make a medical examination or surgical intervention appear superfluous, promise a guaranteed effect or claim that the product has no undesirable effects. In addition, advertising may not raise the expectation that the effect of a medicine corresponds to another treatment or to the effect of another medicine or that it is superior to them. It may further not give rise to the expectation that the condition of a healthy person will be improved with or that such a condition will deteriorate without the use of the medicine.

Advertisements may never be aimed mainly or exclusively at children or adolescents or mention scientific publications, clinical studies, expert opinions, reports or recommendations by scientists, healthcare professionals, well-known personalities or medical–pharmaceutical lay persons. Furthermore, they may not show persons in the professional clothing of medical personnel, druggists or medical assistants or during medical activities specific to the profession.

The use of misleading, fictitious or not recognised titles or distinctions is prohibited as well as any phrases that may induce fear. The advertisement may not equate the medicine to food, feed, care products or other commodities or suggest that the safety or efficacy of the medicine is due to the fact that it is a

"natural product" or the like. In no way may the advertisement lead to a false self-diagnosis through the presentation of a medical history nor may it use in an abusive, alarming or misleading manner visual representations of changes that the human body or parts thereof have undergone as a result of disease, injury or the effect of a medicine. Finally, the number of persons treated may not be disclosed (Article 22 AWV).

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

The Pharma Cooperation Code applies to, amongst others, the co-operation between pharmaceutical companies and patient organisations. It states that such co-operation and the pecuniary benefits granted in return must not constitute an inducement to recommend, prescribe, acquire, supply, sell or administer specific medicines. Pharmaceutical companies may not offer, promise or grant any inappropriate benefits to patient organisations including, in particular, any gifts (either in cash or non-cash considerations; Rule 15 Pharma Cooperation Code).

Financial Support

The Pharma Cooperation Code contains various further provisions and principles in that regard in Rule 3. An important principle is the independence of patient organisations. Pharmaceutical companies may not demand of patient organisations to be the sole pharmaceutical company to provide financial or other support for them, both for overall support and support for individual projects. Furthermore, pharmaceutical companies may neither require patient organisations to promote certain specific prescription-only medicines nor may they agree to requests in that regard made by patient organisations. In addition, the aims, scope and agreement on support and partnerships must be evidenced in writing and be transparent.

Pharmaceutical companies must disclose the annual pecuniary benefits that they have granted to individual patient organisations and keep such information accessible to the public for at least three years after the date of disclosure.

Consultancy

The Pharma Cooperation Code further states that consultancy and services by patient organisations are permitted only if such consultancy tasks or services are provided to support healthcare or research. The need for the consultancy tasks or services must be justified and clearly designated and documented in the written agreement. The scope of the consultancy tasks or services must be no greater than is reasonably necessary to satisfy the specified requirement. Furthermore, the contractually retained pharmaceutical company must record the consultancy tasks and services provided and make expedient use thereof.

The compensation for the consultancy tasks or services must be reasonable and may not exceed the normal market value of such consultancy tasks or services. In this connection, no sham contracts may be concluded to justify payments for patient organisations. The pharmaceutical companies must include provisions in their contracts with patient organisations stipulating that the patient organisation must disclose the fact that it has provided paid consultancy tasks or services for the pharmaceutical company whenever it writes or speaks in public on a topic that is the subject of the contract or on other matters that relate to the particular pharmaceutical company.

Events and Hospitality

In connection with events and hospitality, the Pharma Cooperation Code specifies that events are to be held on premises that are appropriate and conducive to the main purpose of the event. Their choice should be guided primarily by the space and infrastructure availability with a view to the appropriate performance of the main purpose. Premises that are famous for their entertainment facilities or regarded as extravagant are to be avoided.

Hospitality in connection with events must be confined to the journey, subsistence, accommodation and participation fees. In principle, hospitality may only be granted to persons who are entitled to it as participants. Hospitality must not include the support (sponsorship) or organisation of entertainment (eg, sport or leisure activities). In principle, pharmaceutical companies may not organise or sponsor events that are held outside Switzerland.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

As a general rule, all advertising is deemed unlawful if it is misleading or contrary to public order and morality, if it may incite an excessive, abusive or inappropriate use of medicines or if it is for medicines that may not be placed on the market in Switzerland (Article 32, paragraph 1 TPA). All information given in advertising to professionals must be in accordance with the drug information most recently approved by Swissmedic. In particular, only indications and possible applications approved by Swissmedic may be advertised. If the drug information has not yet been published, the marketing authorisation-holder must include the complete content of the drug information last approved by Swissmedic in the advertisement. Advertising to professionals must be precise, well-balanced, factually accurate and provable. The statements must not be misleading and supporting documents must be made available to healthcare

professionals upon request. Advertising must be recognisable as such and must be clearly distinguishable from editorial contributions. The advertising statements must be based on and reflect the current state of scientific knowledge.

They may only refer to clinical trials that were conducted in accordance with the rules of good clinical practice and that have been published or accepted for publication as well as to data collections, such as meta analysis or reports on practical experience, that have been published in a scientifically recognised specialist medium. These publications must be quoted verbatim, completely and with their exact source. It must be indicated that the healthcare professionals can request a complete copy of the examination report and the corresponding references from the company.

"New" Medicines

A medicine, an indication, a dosage, a galenic form or a package may be advertised as "new" for 18 months after the first authorisation in Switzerland. The information must clearly indicate what this attribute refers to. Advertising of complementary medicines must be based on scientifically recognised specialist media or recognised monographs of complementary medicine. Advertising statements in this regard must contain a reference to the respective therapy direction (Article 5 AWV).

Mandatory Information

Advertisements to healthcare professionals must contain certain information. It is mandatory to include the name of the product, the active ingredients with the short designations (DCI/INN or designation of the most recent edition of the Pharmacopoeia; in the absence thereof, other generally recognised short designations approved by Swissmedic), the name and address of the marketing authorisation-holder and at least one indication or possible use as well as the dosage and the method of application.

Furthermore, a summary of restrictions on use, adverse reactions and interactions must be added. The supply category is to be indicated along with a statement that detailed information is to be found in the published drug information, citing the list in Article 67, paragraph 3 or Article 95b TPA as a reference (Article 6 AWV).

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising may refer to clinical trials or data collections that are not included in the Summary of Product Characteristics. However, advertising statements must be based on and reflect the current state of scientific knowledge. They may only refer to clinical trials conducted in accordance with the rules of good clinical practice and published or accepted for publication as well as to data collections such as meta analysis or reports on practical experience published in a scientifically recognised specialist medium.

These publications must be quoted verbatim, completely and with the exact source. It must be indicated that the healthcare professionals can request a complete copy of the examination report and the corresponding references from the company (Article 5, paragraph 5 AWV).

5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Advertising may refer to combination products or companion diagnostics that are not included in the Summary of Product Characteristics.

However, with regard to advertising to the public, general information on health and diseases may not contain any references to prescription medicines (Article 32, paragraph 2 lit a TPA; Article 14 AWV).

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

If articles and contributions from other media about a company or its medicines are offered on the website of that company (press reviews), the content of these articles and contributions are attributed to that company in terms of advertising law. Therefore, the provisions of the AWV are fully applicable to such press reviews (Swissmedic Journal 8/2006, page 796 et seq). The same holds true for reprints of journal articles provided to healthcare professionals. Consequently, the restrictions that apply to advertising to healthcare professionals must be adhered to in connection with such reprints of journal articles. In particular, advertising must be recognisable as such. Therefore, advertising and editorial contributions must be clearly separated (Article 5, paragraph 4 AWV).

5.5 Medical Science Liaisons

In Switzerland, there are no special obligations regarding Medical Science Liaisons (MSLs). However, it can be said that it is permitted to discuss scientific information on unauthorised medicines or indications with healthcare professionals if the purpose of the discussion is to obtain scientific input. Nevertheless, it should always be ensured that these discussions are conducted with the healthcare professional directly or, in case of an institution, with the medical department and not with the marketing and sales department.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Advertising directed at the general public pursuant to Article 15 lit a (advertisements in newspapers, magazines and books, brochures, posters, newsletters, etc) and lit c AWV (advertising using electronic media such as image, sound and data carriers as well as application software) for analgesics, sleeping aids, sedatives, laxatives and anorexics must be submitted to Swissmedic for approval prior to publication if the drug information mentions a potential for abuse or dependence. Swissmedic may require a marketing authorisation-holder who seriously or repeatedly infringes the provisions governing the advertising of medicines to submit to Swissmedic, for a reasonable period of time, all drafts of the planned advertising in the form specified by Swissmedic for review and approval prior to its appearance (Article 23 AWV).

6.2 Compliance with Rules on Medicinal Advertising

Designated Responsible Person

The marketing authorisation-holder must designate a person who is responsible for the advertising of the medicines that they have placed on the market. This person must have scientific, medical or other appropriate professional training or experience. This person must ensure that the advertising of medicines complies with the according provisions and that Swissmedic's instructions are complied with immediately and in full.

This person must provide Swissmedic with all the required documents and information upon request and ensure that its pharmaceutical representatives are properly trained and comply with the obligations stated in the AWV. Finally, this person must keep a copy of each distributed advertisement for six months after its last intended use as well as a register of all recipients, the method of distribution and the date of first distribution (Article 25 AWV).

Scientific Service

The Pharma Code further states that pharmaceutical companies must set up a scientific service that is responsible for the information about their medicines and their promotion to healthcare professionals. The scientific service includes a doctor or, if suitable, a pharmacist or scientist who is responsible for ensuring the conformity of all promotional and information materials with the Pharma Code before they are deployed (Rule 62 Pharma Code).

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Advertising of medicines on the internet without any access restriction is considered to be advertising to the public (see Article 15 lit c AWV). Therefore, the rules applicable to advertising to the public apply.

If articles and contributions from other media about a company or its medicines are offered on the website of that company (press reviews), the content of these articles and contributions are attributed to that company in terms of advertising law. Therefore, the provisions of the AWV are fully applicable to such press reviews (Swissmedic Journal 8/2006, page 796 et seq).

7.2 Advertising of Medicines on Social Media

In Switzerland, advertising on social media must comply with the general rules applicable to advertising on the internet. Therefore, the same restrictions apply as to advertising on the internet.

7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Advertising to healthcare professionals may not be made publicly accessible on the internet. It must be provided with an appropriate technical and password-protected access restriction and may only be made available to doctors, dentists, veterinarians, chiropractors, apothecaries, druggists and other persons authorised to dispense or apply medicines according to Article 24 and 25 TPA and Article 52, paragraph 2 of the Ordinance on Medicinal Products (VAM; Article 5a AWV).

7.4 Provision of Disease Awareness Information to Patients Online

General information on health or on diseases is not considered to be advertising, provided that it does not relate directly or indirectly to specific medicines (Article 1, paragraph 2 lit c AWV).

Companies willing to inform patients about a disease should ensure that they launch an entire campaign informing about the disease and its precautions, etc. Promoting a specific medicine would, however, infringe Article 32, paragraph 2 lit a TPA in most cases.

7.5 Online Scientific Meetings

Online scientific meetings are not explicitly regulated in Switzerland. It can therefore be assumed that the general rules pursuant to Article 55, paragraph 2 lit b TPA and Articles 5 and 6 VITH apply. Consequently, pharmaceutical companies my offer

healthcare organisations contributions for continuing medical education, provided that the contributions:

- are not offered, promised or granted to a single healthcare professional, but to the organisation employing the healthcare professional;
- are based on a written agreement stating the intended use;
- are used exclusively for the intended purpose;
- are not subject to conditions or requirements concerning the prescription, dispensing, use or purchase of certain prescription medicines;
- are transferred to a designated account of the organisation to which the healthcare professionals do not have individual access; and
- are shown in the accounts of the organisation.

Furthermore, it must be ensured that the organisation providing continuing medical education can decide on the type of education and the participating healthcare professionals independently.

The same applies for sponsoring the virtual attendance by healthcare professionals at these events. Such contributions are permitted if they are agreed on in writing and the participating healthcare professionals or the organisations employing them make an appropriate contribution to the costs of the event (Article 55, paragraph 2 lit b TPA; Article 6, paragraph 1 VITH).

Guidelines for Online Meetings

Although Switzerland does not have any special regulations for online scientific meetings, science industries enacted some guidelines and recommendations regarding the handling of digital channels.

Since online meetings are not comparable to physical congresses, it may be possible to waive a cost sharing fee even for events lasting more than half a working day (in deviation from Article 6, paragraph 3 lit b VITH).

In some cases, Swissmedic classified interactive, electronic and audiovisual trainings and access to self-study (e-learning and webinars) as benefits of monetary value which are permitted if they do not exceed the amount of CHF300 per healthcare professional per year or if the healthcare professionals pay the exceeding amount themselves.

Many companies seem to have established a cost contribution practice for conferences. In such cases, the cost-sharing calculation is based on the costs that a company has to pay to provide one or more online meetings. The total costs are then divided by the number of people attending and a fifth (for continuing education) or a third (for postgraduate education) is charged to the respective professional (Article 6, paragraph 2 VITH).

Under no circumstances may the sponsoring aim to induce to recommend, prescribe, buy, supply, sell or administer specific medicines (Rule 15.1 Pharma Code and Pharma Cooperation Code).

International Participation

Online solutions simplify international participation in abovementioned events. In case of international participation, some rules of the Pharma Code must be observed. Information materials that are given out at events with international participation may refer to medicines that are authorised in other countries but not in Switzerland, or are authorised in Switzerland under different conditions.

Such materials require a reference to the countries where the medicine is authorised and to the fact that the medicine concerned is not authorised in Switzerland, or that it is authorised under different conditions in Switzerland. Furthermore, it is necessary to refer to the possible differences in authorisation requirements and the government-approved professional information in the country or countries where the medicine concerned is authorised (Rule 27 Pharma Code).

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The bribery offences in criminal law can be found in Article 322 ter et seq of the Swiss Criminal Code (StGB). Article 322 octies StGB (bribery of private individuals) and Article 322 novies StGB (accepting bribes) regulate private corruption and include the criminal liability of both the bribing and the bribed person. The bribed person must be "an employee, partner, agent or any other auxiliary of a third party in the private sector" (Article 322 octies StGB and Article 322 novies StGB).

A doctor with a public function (eg, in a public hospital) may also fall under the active and passive bribery provisions for Swiss public officials (Article 322 ter and Article 322 quater StGB). With regard to Swiss public officials, the acceptance and granting of advantages (so-called climate care/feeding) is also punishable (Article 322 quinquies and Article 322 sexies StGB).

8.2 Legislative or Self-Regulatory Provisions

For persons who prescribe, dispense, use or purchase for this purpose prescription medicines, and organisations employing

such persons, it is prohibited to claim, be promised or accept any undue advantages for themselves or for the benefit of a third party. Similarly, it is forbidden to offer, promise or grant an undue advantage to any such person or organisation for their benefit or for the benefit of a third party (Article 55, paragraph 1 TPA; Article 3 et seq VITH). All discounts granted to persons or organisations prescribing, supplying, using or purchasing for that purpose therapeutic products must be shown in the accounts of the selling and the purchasing persons and organisations and, upon request, be disclosed to the Federal Office of Public Health (FOPH) (Article 56, paragraph 1 TPA; Article 10 VITH).

However, benefits of modest value that are related to medical or pharmaceutical practice are permitted (Article 55, paragraph 2 lit a TPA). Benefits of modest value must not exceed CHF300 per healthcare professional per year (Article 3, paragraph 1 VITH).

Persons who exercise a university medical profession in the private sector and under their own professional responsibility are obliged to exclusively protect the interests of patients and to act independently of financial advantages when collaborating with members of other healthcare professions (Article 40 lit e MedBG).

Obligation to Pass On Financial Advantages

Healthcare professionals must, in principle, pass on direct or indirect financial advantages granted to them by pharmaceutical companies to patients or healthcare insurances with regard to medicines covered by compulsory healthcare insurance (Article 56, paragraph 3 lit b KVG). Under certain conditions, such advantages may be passed on only partially (Article 56, paragraph 3 bis KVG; Article 76a et seq KVV).

Self-regulatory Provisions

The Pharma Cooperation Code states that benefits must not constitute an inducement to recommend, prescribe, acquire, supply, sell or administer specific medicines. Pharmaceutical companies may not offer, promise or grant any inappropriate benefits to healthcare professionals, healthcare organisations or patient organisations including, in particular, any gifts (either in cash or non-cash considerations). However, pharmaceutical companies may offer objects, information and training materials of moderate value to healthcare professionals if they are intended solely for the medical or pharmaceutical activity or are used for post-graduate or continuing education in medicine or pharmacy and if they are, in both cases, also beneficial to patients.

The same holds true for writing implements and note pads of modest value that are made available to participants at events by pharmaceutical companies; these writing implements and note pads may, however, not bear any references to the pharmaceutical company or to particular medicines (Rule 15 Pharma Cooperation Code).

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Benefits of modest value that are related to medical or pharmaceutical practice are permitted (Article 55, paragraph 2 lit a TPA). Such benefits must not exceed CHF300 per healthcare professional per year (Article 3, paragraph 1 VITH).

In connection with a professional discussion, it is permissible to pay for catering costs not exceeding CHF100 (Article 7, paragraph 2 VITH, Rule 15.4 Pharma Code and Pharma Cooperation Code).

9.2 Limitations on Providing Samples to Healthcare Professionals

Only a small number of sample packages may be distributed per medicine, per year and per healthcare professional. They may be distributed only on the initiative of the healthcare professional and upon their written request. Sample packages must be clearly and permanently marked as a "free sample". They must contain the necessary information and texts on the container and packaging material as well as an approved package leaflet.

In the case of medicines that may be marketed without a package leaflet, the sample package must contain the required information on the container and the packaging material. The sample package must be accompanied by the drug information last approved by Swissmedic or contain a reference to its publication in the list in accordance with Article 67, paragraph 3 or Article 95b TPA. Sample packages must always correspond to the smallest approved package size and may not be sold.

The supply of sample packages containing psychotropic substances or narcotics is subject to the provisions of the Narcotics Control Ordinance. The marketing authorisation-holder must ensure that records are kept of the distribution of sample packages (Article 10 AWV).

According to Swissmedic, the following quantities qualify as "small quantity": a maximum of five packages per healthcare professional, per year and per medicine, in the first two years after market introduction and a maximum of two packages per healthcare professional, per year and per medicine from the third year onwards.

9.3 Sponsorship of Scientific Meetings

Contributions for participation in events for postgraduate or continuing education of experts are permitted, provided they are agreed in writing and the participating healthcare professionals or the organisations employing them make an appropriate contribution to the costs of the event (cost contribution). It is prohibited to reimburse the cost contribution in whole or in part, to cover indirect participation costs such as loss of work or income, to cover the costs of supporting programmes that are not of clearly secondary importance and to cover the costs of travel, accommodation, meals or supporting programmes of persons accompanying the participating healthcare professional. The cost contribution may be waived for healthcare professionals who provide an equivalent service during the event and for events that are held in Switzerland and that last for half a day (Article 55, paragraph 2 lit b; Article 6 VITH).

The Pharma Code states that events that are organised or sponsored by pharmaceutical companies in Switzerland and that are aimed purely at participants from Switzerland should – in principle – take place in Switzerland. Refreshments or meals (including beverages) may be offered only to the participants of the event and must be modest and reasonable according to the customary local standards (in Switzerland, a maximum of CHF100 per healthcare professional per meal). The events should take place at appropriate venues conducive to the main purpose of the event and not be extravagant (Rules 15.4, 31 and 32 Pharma Code; Rule 34 Pharma Cooperation Code; Guideline II 6 of the SAMW).

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies must not offer or pay for any entertainment or other leisure or hospitality activities (Article 6, paragraph 4 lit c VITH; Rule 32.5 Pharma Code; Rule 34.5 Pharma Cooperation Code; Guideline II 6 of the SAMW).

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

For persons who prescribe, dispense, use or purchase for this purpose prescription medicines, and organisations employing such persons, it is prohibited to claim, be promised or accept any undue advantages for themselves or for the benefit of a third party (Article 55, paragraph 1 TPA; Article 3 et seq VITH). However, benefits of modest value that are related to medical or pharmaceutical practice are permitted (Article 55, paragraph 2 lit a TPA). Such benefits must not exceed CHF300 per healthcare professional per year (Article 3, paragraph 1 VITH).

Financial contributions for research, education and infrastructure are not regarded as undue advantages, provided that certain criteria are met (Article 55, paragraph 2 lit b TPA). Contributions are permissible if the following criteria are met (Article 4 lit a-f VITH):

- the contributions are not offered, promised or granted to an individual professional, but to the organisation that employs the professional;
- the contributions are based on a written agreement stating the intended use;
- the contributions are used solely for their intended purpose;
- the contributions are not subject to conditions or requirements relating to prescription medicines;
- the contributions are transferred to a designated account of the organisation, to which professionals do not have individual access; and
- the contributions are shown in the accounts of the organisation.

Pharmaceutical companies must, however, fully disclose all pecuniary benefits that they grant (Rule 15.6 Pharma Code; Rules 15.6 and 24 et seq Pharma Cooperation Code).

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

For Persons who prescribe, dispense, use or purchase for this purpose prescription medicines, and organisations employing such persons, it is prohibited to claim, be promised or accept any undue advantages for themselves or for the benefit of a third party. Similarly, it is forbidden to offer, promise or grant an undue advantage to any such person or organisation for their benefit or for the benefit of a third party (Article 55, paragraph 1 TPA; Article 3 et seq VITH). All discounts granted to persons or organisations prescribing, supplying, using or purchasing for that purpose therapeutic products must be shown in the accounts of the selling and the purchasing persons and organisations and, upon request, be disclosed to the FOPH (Article 56, paragraph 1 TPA; Article 10 VITH).

Healthcare professionals must, in principle, pass on direct or indirect financial advantages to patients or healthcare insurances with regard to medicines covered by compulsory healthcare insurance (Article 56, paragraph 3 lit b KVG). Under certain conditions, such advantages may be passed on only partially (Article 56, paragraph 3 bis KVG; Article 76a et seq KVV).

9.7 Payment for Services Provided by Healthcare Professionals

Pharmaceutical companies may entrust healthcare professionals with consultancy tasks or services, such as papers and the conduct of meetings; medical or scientific studies; clinical trials; training and participation in consultancy bodies; and provide

reasonable compensation for expenditure incurred by them in this connection according to the usual standards.

Such compensation must be based on a written agreement setting forth the nature and extent of the service and the compensation and be in reasonable proportion to the consideration. Services may not be compensated if:

- the healthcare professional performs them for his/her own benefit;
- they must be performed due to legal obligations; or
- they are otherwise remunerated.

Compensation is permitted for:

- services in connection with the purchase of prescription medicines, such as the assumption of logistics expenses, storage costs or storage risk;
- teaching, expert opinions and consulting activities or the performance of scientific studies and clinical trials;
- practical experience reports published in a scientifically recognised professional medium;
- participation in advisory committees, workshops or in market research, provided there is no advertising purpose (Article 55 paragraph 2 lit c TPA; Article 7 VITH).

According to the Pharma Code and the Pharma Cooperation Code, pharmaceutical companies must fully disclose all pecuniary benefits. They must stipulate in the agreement that the recipients of the pecuniary benefits agree to disclosure (Rule 41 Pharma Code; Rules 21 and 24 et seq Pharma Cooperation Code; see Guidelines III 1-7 of the SAMW).

9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

There are no prior authorisations or notifications (eg, regulatory authority approval) required in relation to any of the activities described in this section. However, whether the consent of an employer is required also depends on the contract between the healthcare professional and the employer.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

All discounts granted to persons or organisations prescribing, supplying, using or purchasing for that purpose therapeutic products must be shown in the accounts of the selling and the purchasing persons and organisations and, upon request, be disclosed to the FOPH (Article 56, paragraph 1 TPA; Article 10 VITH).

Furthermore, healthcare professionals must, in principle, pass on direct or indirect financial advantages to patients or healthcare insurances with regard to medicines covered by compulsory healthcare insurance (Article 56, paragraph 3 lit b KVG). Under certain conditions, such advantages may be passed on only partially (Article 56, paragraph 3 bis KVG; Article 76a et seq KVV).

According to the Pharma Cooperation Code pharmaceutical companies are required to fully disclose pecuniary benefits to healthcare professionals and healthcare organisations annually and to keep such information accessible to the public for at least three years after disclosure. The disclosure must, in principle, be made on an individual basis and clearly identify the recipients and the amounts paid. The remuneration for the agreed service or consultancy tasks and the compensation for costs incurred by the service providers must be disclosed separately. The disclosure is to be made on the company's website (Rule 24 et seq Pharma Cooperation Code).

Thus far, no exceptions to the disclosure obligation have been granted due to the COVID-19 pandemic.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The transparency requirements apply to foreign companies only if they sell medicines in Switzerland. They apply to companies that do not yet have products on the market as well.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

Swissmedic is the regulatory authority responsible for enforcing the rules on advertising as stated in the TPA and the AWV (Article 66, paragraph 1, Article 82 and Article 90, paragraph 1 TPA). The FOPH is responsible for monitoring the prohibition of promising and accepting undue benefits, and the cantons are responsible for monitoring the retail trade (Article 66, paragraph 1, Article 82, paragraph 1 and Article 90, paragraph 1 TPA). In addition, the customs authorities are entitled to detain medicines at the border, in open customs warehouses or duty-free warehouses if there is a suspicion that the recipient or sender in Switzerland is suspected of violating the provisions on the import, placing on the market or export of medicines with

the contents of the consignment (Article 66 paragraph 4 and Article 90 paragraph 1 TPA).

As a general rule, the Federal Administrative Court adjudicates appeals against decisions of Swissmedic, the FOPH and the Federal Customs Administration and the Federal Court adjudicates appeals against decisions by the Federal Administrative Court (Article 84 TPA).

The Code Secretariat is the self-regulatory body that is responsible for the implementation of the Pharma Code and the Pharma Cooperation Code (Rule 7 Pharma Code; Rule 5 Pharma Cooperation Code).

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Swissmedic, the FOPH and the Federal Customs Administration can initiate proceedings against companies for advertising infringements. They have the authority to take administrative measures and to initiate criminal prosecution (Article 66 and Article 90, paragraph 1 TPA). Companies may, however, also initiate proceedings against competitors for advertising infringements before the Code Secretariat, which is responsible for the implementation of the Pharma Code and the Pharma Cooperation Code.

If advertising of competitors constitutes unfair competition according to the UWG, companies can initiate proceedings before civil courts.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

A custodial sentence not exceeding three years or a monetary penalty can be imposed on any person who wilfully violates the prohibition of undue advantages according to Article 55 TPA (Article 86, paragraph 1 lit h TPA).

A fine not exceeding CHF50,000 can be imposed on any person who wilfully infringes the obligation of transparency according to Article 56 TPA or who wilfully contravenes the regulations on the advertising of medicines (Article 87, paragraph 1 lit h and b TPA).

In addition, Swissmedic, the FOPH and the Federal Customs Administration may take all administrative measures necessary to enforce the TPA. In particular, they may raise objections and set an appropriate time period for restoring the state of law, suspend or revoke licences and marketing authorisations and close down establishments. Furthermore, the authorities may also seize, hold in official storage or destroy medicines that endanger health or that do not conform to the regulations of the TPA as well as prohibit the distribution, dispensing, import, export and foreign trade from Switzerland of medicines, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage. Finally, they may seize, hold in official storage, destroy or prohibit the use of illegal advertising media and publish the prohibition at the expense of the responsible parties as well as temporarily or permanently prohibit the advertising of a specific medicine in the event of serious or repeated infringements of the provisions of the TPA, and publish the prohibition at the expense of the responsible parties (Article 66, paragraph 1 and 2 TPA).

In addition, Swissmedic may require a marketing authorisation-holder who seriously or repeatedly infringes the provisions governing the advertising of medicines to submit to Swissmedic, for a reasonable period of time, all drafts of the planned advertising in the form specified by Swissmedic for review and approval prior to its appearance (Article 23 AWV). Furthermore, the bribery offences in criminal law (Article 322 ter et seq StGB) apply as well (see **8.1 General Anti-bribery Rules**).

11.4 Relationship between Regulatory Authorities and Courts

Both the Pharma Code and the Pharma Cooperation Code state that pharmaceutical companies that undertake to comply with these Codes acknowledge their rules of enforcement if proceedings are taken for breach of a Code. As long as relevant proceedings are pending, they will in principle not refer the matter at the same time to a State authority or to a court on grounds of breach of the Swiss legal order. However, the safeguarding of rights, which may be endangered or defeated by compliance with these principles of conduct, is reserved.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

For a long time, Swissmedic has been the main enforcement authority for violations of the TPA. Since 1 January 2020, the FOPH has been granted the power to enforce the new provisions on the integrity and transparency in the field of therapeutic products, making it likely that the enforcement of the law will be strengthened.

However, due to the COVID-19 pandemic, the FOPH has not yet had the opportunity to start enforcing the new provisions on the integrity and transparency in the field of therapeutic products. This has allowed many companies to review their contracts and to amend them in the course of 2020.

As there are many uncertainties in connection with these new provisions, it will be interesting to see what the FOPH considers permissible and what priorities it will have when enforcing the new provisions.

Walder Wyss Ltd has 240 legal experts and office locations in Zurich, Geneva, Basel, Berne, Lausanne and Lugano. The firm has a team dedicated to life sciences and pharmaceutical regulatory law, including healthcare insurance law. The key areas of practice in relation to the pharmaceutical advertising sector are pharmaceutical regulatory law, healthcare insurance law and the law regarding research on humans and clinical trials, stem cells and blood components, genetic testing, transplantation, special nutrition, medical devices and reproductive medicine. The firm has established www.lifesciencelaw.ch, a website dedicated to all legal issues surrounding life sciences where case law is discussed and where interested people can find publications from the team.

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