Chambers

GLOBAL PRACTICE GUIDE

Definitive global law guides offering comparative analysis from top ranked lawyers

Pharmaceutical Advertising

Switzerland
Walder Wyss Ltd

chambers.com

2019

Law and Practice

Contributed by Walder Wyss Ltd

Contents

Walder Wyss Ltd has 200 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.

Authors

Andreas Wildi is a partner at Walder Wyss Ltd. His key practice areas are Swiss and international reimbursement and pricing law of pharmaceuticals and other therapeutic products, as well as regulatory issues of pharmaceuticals, medical devices, special nutrition, cosmetics, genetic testing, stem cells and blood products. Andreas has published widely on legal issues arising from pharmaceuticals and healthcare.

Celine Weber is an associate at Walder Wyss Ltd. Her key practice areas are medical law, regulatory law in life sciences (pharmaceuticals and medical devices, specialist nutrition, cosmetics, genetic testing, stem cells and blood products etc), healthcare insurance law and competition law.

1. Regulatory Framework

1.1 Laws and Self-regulatory Codes

Advertising on medicines in Switzerland is mainly governed by the Federal Act on Medicinal Products and Medical Devices (HMG) and the Ordinance on Advertising of Medicinal Products (AWV), which has just been revised (the amended provisions came into force on 1 January 2018, with the exception of the provisions concerning transparency). 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 on 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 Organizations" (Pharma Cooperation Code) are self-regulatory codes and contain provisions in connection with advertising of medicines.

Furthermore, the Guidelines on "Collaboration between the Medical Profession and Industry" (version of 2013) 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

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 scienceindustries' website). 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 6 Pharma Code; rule 5 Pharma Cooperation Code).

The Guidelines on "Collaboration between the Medical Profession and Industry" by the SAMW are directed at healthcare professionals. They are applicable to all members of the Foederatio Medicorum Helveticorum (FMH), which is the professional association of more than 40,000 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. However, general information on health and diseases with-

out any direct or indirect references to individual medicines is not considered to constitute advertising. Furthermore, the packing material and the drug information are not deemed to be advertising, either (Article 1 paragraph 2 lit. a and c; Article 2 lit. a AWV).

2.2 Difference Between Information and Advertising

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 turn into 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 do not qualify as advertising if there are no direct or indirect references to individual medicines.

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

2.3 Restrictions on Press Releases

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. Therefore, press releases referring directly or indirectly to prescription medicines must be accessible to media professionals exclusively and be protected by way of password access restriction (as is the case for advertising to healthcare professionals; art. 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, p. 796 et seqq.).

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

2.4 Comparative Advertising

Statements relating to comparisons with other medicines are generally permitted if they are scientifically correct and based on equivalent clinical trials or data collections. Such 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-analyses 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 para. 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 para. 1 lit. c HMG; Article 5 para. 1 and Article 16 para. 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 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 Swiss-

medic (Article 32 paragraph. 1 lit. c HMG; Article 5 paragraph 1 AWV; rules 241 and 242 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 HMG; Article. 5 paragraph 1 AWV; rules 241 and 242 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).

4. Advertising to the General Public

4.1 Main Restrictions on Advertising 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 HMG; 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 who 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 Advertising to the General Public

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 distinguishable 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).

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).

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). Advertising for medicines with a cantonal authorisation is subject to special provisions (Article 17b AWV).

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).

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. 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).

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 laypersons. 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 14 Pharma Cooperation Code).

The Pharma Cooperation Code contains various further provisions and principles in that regard in rule 3. An important principle is that of 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.

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.

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.

4.4 Restrictions on Endorsements by Healthcare Professionals

Advertising to the public must not contain any recommendations or testimonials by healthcare professionals or references to expert opinions (Article 22 lit. g AWV).

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 HMG).

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-analyses 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.

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).

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 para. 3 or Article 95b HMG as a reference (Article 6 AWV).

Where the advertising of medicines does not make any statement as to its use, but merely provides information on the indications in the sense of a reference to the therapeutic category of the medicine (recall advertising), the information referred to in Article 6 lit. d (at least one indication or possible use as well as the dosage and the method of application) and lit. e AWV (summary of restrictions on use, adverse reactions and interactions) may be disregarded. If the advertisement is only intended to recall a brand (brand advertising), only the product name or additionally the name of the marketing authorisation-holder as well as the active substances may be mentioned (Article 8 et seq. AWV).

Advertising to healthcare professionals must neither use the term "safe" unless the information provided clearly indicates what this attribute refers to, nor must it indicate that a medicine has no undesirable effects and that it is safe or harmless. Furthermore, it must not appear to be an editorial contribution or indicate that the medicine in question does not create habituation (Article 13 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-analyses 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 para. 5 AWV).

5.3 Restrictions on Reprints of Journal Articles

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, p. 796 et seqq.).

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).

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

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. Furthermore, 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).

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 53 Pharma Code).

7. 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 (cf.

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, p. 796 et seqq.).

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

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 HMG and Article 52 para. 2 of the Ordinance on Medicinal Products (VAM; Article 5a AWV).

8. Inducement/Anti-bribery

8.1 General Anti-bribery Rules

The bribery offences in criminal law can be found in Article 322ter et seqq. of the Swiss Criminal Code (StGB). Article 322octies StGB (bribery of private individuals) and art. 322novies 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 322octies StGB and Article 322novies 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 322ter and Article 322quater StGB). With regard to Swiss public officials, the acceptance and granting of advantages (so-called climate care/feeding) is also punishable (Article 322quinquies and Article 322sexies StGB).

8.2 Legislative or Self-regulatory Provisions

It is prohibited to grant, offer or promise material benefits to persons who prescribe or dispense medicines or to the organisations that employ them and for such persons or organisations to solicit or accept such material benefits. However, material benefits of modest value that are related to medical or pharmaceutical practice as well as commercially and economically justified discounts that directly reflect on the price are permitted (Article 33 HMG). Material benefits of modest value must not exceed CHF300 per healthcare professional or healthcare organisation and per year.

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).

Healthcare professionals must, in any case, 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).

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 14 Pharma Cooperation Code).

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Material benefits of modest value that are related to medical or pharmaceutical practice are permitted (Article 33 paragraph 3 lit. a HMG). Such material benefits must not exceed CHF300 per healthcare professional or healthcare organisation and per year.

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 para. 3 or Article 95b HMG. 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 on.

9.3 Sponsorship of Scientific Meetings

Representation expenses in connection with scientific congresses or promotional events must remain within reasonable limits and be of subordinate importance in relation to the main purpose of the event. They may not benefit persons who are not healthcare professionals authorised to prescribe, dispense or use medicines for professional means at their own responsibility (Article 11 AWV).

The Pharma Code states that events that are organised or receive financial support (sponsored) from pharmaceutical companies with subsidiaries 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: maximum of CHF150 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. Pharmaceutical companies must generally require that participants make an appropriate financial contribution, which may be reduced for healthcare professionals who are still in post-graduate medical training and may be waived for events that are held in Switzerland and that last for less than one day (rules 143.5, 313, 322 et seqq. and 331 et seqq. Pharma 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 (rule 322 Pharma Code; Guideline II. 6 of the SAMW).

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

It is prohibited to grant, offer or promise material benefits to persons who prescribe or dispense medicines or to the organisations that employ them and for such persons or organisations to solicit or accept such material benefits. However, material benefits of modest value that are related to medical or pharmaceutical practice as well as commercially and economically justified discounts that directly reflect on the price are permitted (Article 33 HMG). Such material benefits of modest value must not exceed CHF300 per healthcare professional or healthcare organisation and per year.

However, pharmaceutical companies may provide financial or other support to healthcare organisations for research or other services in the healthcare sector, provided that such support is limited to research or other services in healthcare, that it is set down in writing and that the relevant documents are available at the pharmaceutical company. Pharmaceutical companies must, however, fully disclose all pecuniary benefits that they grant (rules 222 and 23 et seqq. Pharma Cooperation Code).

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

Commercially and economically justified discounts that directly reflect on the price of the medicine are permitted (Article 33 paragraph 3 lit. b HMG).

Economically justified rebates are rebates where the buyer provides an economic counter-value. Examples include purchase orders placed by the buyer via the internet, which save the supplier administrative and logistical costs, the handling of transport by the buyer or the purchase of large quantities, which relieves the supplier of storage costs. In contrast to an economically justified rebate, a commercially justified rebate is granted independently of a consideration from the customer. A rebate is commercially justified if it is granted over a certain period in a specific business relationship, so that both parties assume that it also applies in the future. In such a case, the discount no longer has any influence on the purchase decision. Discounts that are commercially justified can also be benefits that are granted upon the introduction of a new product or to acquire new customers or that serve to maintain the existing clientele with regard to new competing products.

Swiss courts have held that a rebate of 33% for one month to introduce a new medicine was exceptionally high, whereas a rebate of 1-25% was economically and commercially justifiable (Decision of the Federal Criminal Court BV.2005.28 of 28 November 2005 consid. 2.2; Decision of the Federal Administrative Court C-669/2008 of 17 December 2010 consid. 5.5.4).

Healthcare professionals must, in any case, 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).

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 consultancy tasks or services are permitted only if they are agreed upon in writing beforehand, if there is a justified need for them, if the healthcare professional is qualified for them, if not more healthcare professionals are entrusted with them than are needed, if the pharmaceutical companies document them and if the agreements provide that the healthcare professionals will disclose their relationship if they write or speak in public about matters that are the subject of the agreement or otherwise related to the commissioning pharmaceutical company. Sham contracts are prohibited. In addition, pharmaceutical companies must fully disclose all pecuniary benefits and call the attention of the healthcare professional to that obligation in the contracts with them. They must stipulate in the agreement that the recipients of the pecuniary benefits agree to disclosure (rules 21 and 23 et seqq. Pharma Cooperation Code; Guidelines III. 1-7 of the SAMW).

9.8 Prior Authorisations or Notifications

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. Transparency

10.1 Requirement to Disclose Details of Transfers of Value

Swiss law does not contain any disclosure obligations. However, healthcare professionals must 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).

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 23 et seqq. Pharma Cooperation Code).

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

The transparency requirements according to the Pharma Cooperation Code apply to the signatories of the Pharma Cooperation Code. It applies to companies that do not yet have products on the market as well. Foreign companies cannot become signatories of the Pharma Cooperation Code (with the exception of companies from the Principality of Liechtenstein). Consequently, they do not need to adhere to these requirements.

11. Enforcement

11.1 Enforcement Bodies

Swissmedic is the regulatory authority responsible for enforcing the rules on advertising as stated in the HMG and the AWV (Article 66 paragraph 1, Article 82 and Article 90 paragraph 1 HMG). As a general rule, the Federal Administrative Court adjudicates appeals against decisions by Swissmedic and the Federal Court adjudicates appeals against decisions by the Federal Administrative Court.

The Code Secretariat is the self-regulatory body that is responsible for the implementation of the Pharma Code and the Pharma Cooperation Code (rule 6 Pharma Code; rule 5 Pharma Cooperation Code).

11.2 Initiating Proceedings for Advertising Infringements

Companies can initiate proceedings against competitors for advertising infringements before Swissmedic, which has the authority to take administrative measures and to initiate criminal prosecution (Article 66 and Article 90 paragraph 1 HMG). 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 Advertising Rules and Rules on Inducements to Prescribe

Any person who wilfully contravenes the regulations on the advertising of medicines is liable to a term of detention or to a fine not exceeding CHF50,000. If the person concerned acts in a professional capacity, the penalty is a term of imprisonment not exceeding six months and a fine not exceeding CHF100,000. If the person concerned acts through negligence, the penalty is a fine not exceeding CHF10,000. Attempts and aiding and abetting are also offences. The right to prosecute contraventions and execute the penalties for contraventions are subject to a time limit of five years. In particularly minor cases, prosecution and sentencing may be waived (Article 87 paragraph 1 lit. b and paragraph 2-6 HMG).

In addition, Swissmedic may take all administrative measures necessary to enforce the HMG. In particular, it 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, Swissmedic may also seize, hold in official storage or destroy medicines that endanger health or that do not conform to the regulations of the HMG 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, it 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 HMG, and publish the prohibition at the expense of the responsible parties (Article 66 para 1 and 2 HMG).

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 322ter et seqq. StGB) apply as well (see **8.1 General Anti-bribery Rules** above).

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 a rather recent decision concerning price agreements and competition law, the Federal Administrative Court had the opportunity to contemplate the effect that the general prohibition of public advertising of prescription medicines has on the transparency of the market with regard to especially comparative prices amongst medicines of the same kind. The process of searching for price information exercised by consumers prior to purchasing requires market and price transparency. The Court stated that the prohibition of public advertising enshrined in Article 32 paragraph 2 lit. a HMG considerably restricts the effective intra-brand price competition in the interest of health protection without completely excluding it. The conclusion of the Court in this respect was that the sales market of a prescription drug cannot be compared with that of a regular consumption good. This decision has been appealed before the Swiss Federal Court (Decision of the Federal Administrative Court B-843/2015 of 19 December 2017 consid. 6).

In another decision the Federal Administrative Court examined the difference between permitted information of a general nature and inadmissible information of an advertising nature. It held that information cannot be qualified in an abstract way, but that its qualification depends on the overall circumstances of the individual case. The magazine advertisements and exhibition stands in the case at hand obviously aimed at promoting the medicine and thus constituted advertising, according to the Court. It further examined the informative quality of those advertisements that are permitted only when directed exclusively at professionals. Incomplete, shortened, factually inaccurate and unspecific slogans violate the provisions of Article 5 paragraphs 1 and 3 AWV. Any information not included in the authorised drug information may not be used in advertising (Decision of the Federal Administrative Court C-5490/2015 of 28 March 2017 consid. 6, 7.1.2, 7.3.5.3, 7.3.6 and 7.4.5.2).

Swissmedic has recently published a statement with regard to approved complementary medicines without indication. Swissmedic has found that advertising to the public of authorised complementary medicines without indication very often does not comply with the relevant advertising regulations. In September 2018, Swissmedic has informed those pharmaceutical companies that market complementary medicines without indication that Swissmedic would in the future specifically check compliance with the relevant advertising provisions even for medicines authorised without indication and, if necessary, initiate according measures. Swissmedic has granted the pharmaceutical companies a period of six months to comply with the advertising pro-

visions. After expiry of this period, Swissmedic will check compliance with the legal requirements on a random basis and, in the event of advertising infringements, will initiate administrative measures to restore the state of law. In the case of intentional violations, criminal proceedings may be initiated pursuant to Article 87 paragraph 1 lit. b HMG.

Walder Wyss Ltd
Walder Wyss Ltd.
Seefeldstrasse 123
P.O. Box
8034 Zurich
Switzerland

walderwyss

Tel: +41 58 658 58 58
Fax: +41 58 658 59 59
Email: andreas.wildi@walderwyss.com
Web: www.walderwyss.com/en/home