The Legal 500 & The In-House Lawyer

Comparative Legal Guide

Switzerland: Pharmaceutical Advertising

This country-specific Q&A provides an overview of the legal framework and key issues surrounding pharmaceutical advertising law in Switzerland.

This Q&A is part of the global guide to Pharmaceutical Advertising.

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1. **What laws are used to regulate advertising on medicines in your jurisdiction?**

The Federal Act on Medicinal Products and Medical Devices ("TPA") and its Ordinance on the Advertisement of Medicinal Products ("OAM") were the main regulations on advertising on medicines in Switzerland until 31 December 2019. The Federal Act on Health Insurance ("HIA") also contains specific rules concerning benefits to healthcare professionals.

Provisions in the TPA regarding offering of benefits have recently been amended, in particular, in order to improve transparency, to redefine the scope of the prohibition of benefits and to include medical devices within the scope of some rules. The amendments will enter into force on 1 January 2020 together with a new Ordinance on Integrity and Transparency in the field of Therapeutic Products ("OITTP"). The OITTP will provide some details regarding offering of benefits. At the same time, the HIA and its Ordinance ("OHI") will also be slightly amended.

In addition to those specific laws, the Federal Act on Unfair Competition ("UCA") may also apply to some advertising behaviours. Moreover, some specific articles of the Swiss Criminal Code ("SCC") may also be taken into consideration in case of bribery.

Finally, healthcare professionals have some duties in regards to receiving benefits under the Federal Act on Medical Professions ("MPA") and under local public laws.

2. **Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?**

The following self-regulatory instruments may apply in Switzerland:

- The Code of Conduct of the Pharmaceutical Industry in Switzerland of 4 December 2003, revised on 6 September 2013 ("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 applicable to advertising and benefits.

- The Collaboration between the Medical Profession and Industry Guidelines (2013 version) and the Code of Ethics of the Swiss Medical Association ("FMH"), which both contain provisions concerning the acceptance of benefits by healthcare professionals, are also applicable to the acceptance of benefits.

The Pharma Code applies to all its signatories, which means a large number of pharmaceutical companies in Switzerland (see list published on https://en.scienceindustries.ch/involvement/pharma-code/pharma-code-signatories). The Code of Ethics of the FMH is applicable to doctors who are members of the association, that is to say a large number of doctors in Switzerland. The Collaboration between the Medical Profession and Industry Guidelines has been incorporated to the Code of Ethics of the Swiss Medical Association, which means that it applies to the same persons.

Self-regulatory codes are private rules that are binding for their signatories only. Therefore, in case of contradiction between self-regulatory codes and the law, the latter shall prevail.

However, in case of gaps in the law, principles provided by private rules may be used to help interpreting the law.

3. **Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?**

The law provides a definition of advertising for medicine. Advertising for medicines means any type of information, prospection and incentive, which aims at encouraging the prescription, the supply, the sale, the consumption or the use of medicines (Art. 2 let. a OAM). However, this definition does not include the packing material or medicine information, catalogues or price lists, insofar as they do not contain any medical data. General health or disease information is also excluded from this definition to the extent that it does not refer directly or indirectly to specific medicines (Art. 1 al. 2 OAM).

As explained above, it covers any type of information, which aim at encouraging the prescription, the supply, the consumption or the use of medicines. However, general information about illnesses (catalogues, disease awareness campaigns or correspondence) are not covered as long as they do not refer to a specific medicine directly or indirectly. It is considered that information about the origin and the nature of illnesses, general health advice or an advertisement-neutral list of all therapy options in the area of the illness discussed, are not covered by the definition of advertising. Swiss authorities evaluate the situation on a case-by-case basis, while taking the context into consideration.

Advertising for prescription medicines is limited to healthcare professionals. Healthcare professionals are persons authorised to prescribe, supply or use medicinal products professionally and under their own responsibility (Art. 2 let. c OAM).

The type of advertising allowed depends on the audience:

- Advertising to healthcare professionals is allowed as follows (Art. 4 OAM):
  - advertisements published in professional journals and other printed material for professionals;
  - advertising on objects;
  - advertising spread by electronic media (such as image, sound and data media) or by computer applications;
  - advertising presented at scientific congresses or at promotional events;

organising and financing promotional events, hospitality offered at scientific conferences or promotional events (from 1 January 2020 no more considered as advertising but as benefit subject to Art. 6 OITTP);

- advertising mailings and promotional material, visits by medical representatives and samples deliveries.

- Advertising to the general public is allowed as follows (Art. 15 OAM):
  - advertisements published, in particular, in newspapers, magazines and books, leaflets, posters, circulars; advertising on objects;
  - advertising spread by electronic media (such as image, sound and data media) or by computer applications;
  - advertising presentations made at home or at conferences held in front of nonspecialists;
  - advertising made at doctors' or veterinary surgery, and at places of delivery (showcases, sales containers) and samples deliveries.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Press releases advertising for medicines depend on the type of medicine:

- Advertising for prescription medicines is only allowed in professional journals or printed documents for professionals because they may be addressed only to professionals (Art. 4 OAM). The advertising text shall be clearly separated from the editorial text (Art. 5 par. 4 OAM).

- Advertising for over-the-counter medicines is allowed in any type of newspapers, magazines or books (art. 15 OAM). The advertising text shall be clearly separated from the editorial text (Art. 16 par. 3 OAM).

It may be difficult to decide whether a press release constitutes advertising or mere information. For instance, there are issues about press release for future investors. According to the guidelines on advertising on the Internet, information for investors must be strictly limited to the scientific, technical, organisational or financial aspects of the activity of the company that are of interest to potential investors (such as the company, presentation of the company's research activities, etc.). However, it shall not have the aim of promoting a medicine. For developing medicines or future prospects and priorities of the company in the field of research and development, very limited information may be addressed to investors and nothing about the therapeutic effectiveness of the medicine shall be mentioned. For other types of press releases, Swissmedic (i.e. the Swiss agency for therapeutic products) considers that access to press releases that refer, directly or indirectly, to a prescription medicine should be restricted to the media (Swissmedic Journal 08/2006 p. 805).

5. **Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?**

There is no specific internal approval process provided by Swiss law. However, the OAM provides a duty to designate a responsible person for advertising within the company. This person will have the duty to ensure compliance with the law and with Swissmedic's instructions to provide it with all the necessary information and documents, to give proper training to medical delegates and to store all kind of advertising (as well as their recipients, the way of publishing and the date of the first publication) during six months (Art. 25 OAM).

The Pharma Code provides a duty to have a department for information and advertising, including a doctor, a pharmacist or a scientist in charge of verifying the compliance of all the advertising material and to give confirmation to the person responsible for authorising advertisements (Art. 531 and 533 Pharma Code). Companies shall send a list of the information and advertising materials and of the recipients (i.e. healthcare professionals) to the Code Secretariat (Art. 541 Pharma Code).

6. **Do companies have to have material approved by regulatory bodies prior to release?**

In principle, advertising for medicine is not subject to prior control from Swissmedic but there are exceptions.

Since 1 January 2019, there are only two exceptions requiring prior approval from Swissmedic (Art. 23 OAM):

- Advertising for analgesics, sleeping pills, sedatives, laxatives and anorectics – addressed to the public in newspapers, magazines, books, leaflets, posters or circulars, as well as by electronic media – shall be approved before the release when the medicine information indicates a risk of misuse or dependence advertising.

- In case the holder of a marketing authorisation repeatedly or seriously infringed provisions on advertising, Swissmedic may require the holder to submit all future advertising projects for prior approval, for an appropriate period.

Other types of advertising to the public do no longer require any approval since 1 January 2019.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

In the OAM, the right to do comparative advertising depends on the targeted audience:

- Comparative advertising aimed at healthcare professionals: comparative advertising is only allowed as long as the comparisons are scientifically correct and are supported by clinical trials or on equivalent collection of data (meta-analysis or reports of practical experience published in a recognised scientific media aimed at professionals) (Art. 7 OAM). If comparison is based on *in vitro* or animal studies (or on other animal species for veterinary medicines), this must be specified.

- Comparative advertising aimed at the general public: it is prohibited to imply that the effect of a medicine is equal to or greater than that of another treatment or medicine (Art. 22 let. c OAM).

Moreover, in both cases, general rules concerning the prohibition of unfair competition are also applicable to pharmaceutical companies. Therefore, comparative advertising is allowed but must be accurate, not misleading, unnecessarily hurtful or cause confusion with other goods (Art. 3 par. 1 let. e UCA). To denigrate others, their goods, works, services, prices or business by inaccurate, misleading or unnecessarily hurtful allegations is also prohibited (Art. 3 par. 1 let. a UCA).

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

Information on unauthorised medicines/indications: advertising for medicines or indications, for which no marketing authorisation was granted, either at the national level or at the cantonal level (i.e. Swiss states), is prohibited (Art. 32 al. 1 let. c TPA; Art. 5 and 16 OAM). As mentioned above, general information is allowed but shall not directly or indirectly refer to specific medicines (Art. 1 par. 2 let. c OAM). Nevertheless, information about future medicines to investors may be allowed but strictly limited (name of the composition, name of the active substance, therapeutic area and application scope), and nothing about the therapeutic effectiveness of the medicine shall be mentioned.

Information on unauthorised medicines or indication during a scientific conference directed at healthcare professionals or sent to them: Swissmedic has considered to date that information to

healthcare professionals about future medicines or indications through scientific journals or conferences is only possible provided that no direct or indirect reference to specific medicines is made (Swissmedic Journal 06/2006 p. 622). For the sake of clarity, the Pharma Code specifies that information directed at healthcare professionals on unauthorised medicines, new indications, possible application, dosages, pharmaceutical forms and packaging of a medicine is allowed as long as it does not constitute advertising (Art. 241 Pharma Code). Moreover, such information shall always clearly specify that the medicines, indications, possible applications, dosages, pharmaceutical forms and packaging are not authorised yet (Art. 242 Phama Code).

9. **Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.**

<u>General rules:</u>

In principle, advertising for over-the-counter medicines and for medicines with marketing authorisation at a cantonal level is permitted. It shall be specified that a medicine for which advertising to the general public is made (directly or indirectly), are not allowed on the Specialities List (i.e. official document listing the medicines covered by the Swiss compulsory health insurance) (Art. 65 par. 2 and 68 OHI).

There are many exceptions to the right to advertise to the general public.

Prohibitions regarding the type of products (Art. 32 par. 2 TPA):

- prescription medicines; medicines containing narcotic or psychotropic substances;
- medicines that may not be used without the intervention of a doctor for the necessary diagnosis, prescription or treatment considering their composition and their intended use;
- medicines that are frequently the object of abuse or which lead to an addiction or dependence;
- radio and television advertising for medicines containing more than 0.5 grams pure alcohol per single dose (for oral use) (Art. 20 OAM).

Prohibitions regarding the content of advertising (Art. 21 OAM):

- advertising for indications or use requiring medical diagnosis or treatment;

- intrusive and showy advertising (allowed for supply category E medicines);
- advertising giving the impression of being an editorial text;
- orders for medicines during door-to-door sales visits, exhibitions, conferences, advertising trips and other such events, as well as direct mailing (allowed for supply category E medicines);
- direct delivery of medicines for promotional purposes and of vouchers for medicines, competitions and any other type of encouragement to contact the marketing authorisation holder (allowed for supply category E medicines).

Moreover, 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 medicinal products or if it is for medicines, which do not have any marketing authorisation (national authorisation or cantonal authorisation) (Art. 32 par. 1 TPA). Moreover, as mentioned above, the general rules concerning comparative advertising are also applicable (the comparison must be accurate, not misleading, not unnecessarily hurtful and not lead to confusion with other goods) (Art. 3 par. 1 let. e UCA). To denigrate others, their goods, works, services, prices or business by inaccurate, misleading or unnecessarily hurtful allegations is also prohibited (Art. 3 par. 1 let. a UCA).

Information required:

For any advertising to the general public, the following requirements apply (Art. 16 OAM):

- information in advertising must be in accordance with the latest information on the medicine approved by Swissmedic;
- advertising must be limited to the indications and possibilities of use approved by Swissmedic;
- the properties of the medicine must be presented truthfully and without exaggeration;
- advertising must be identifiable as such (separated from editorial texts);
- medicines, indications, dosages, pharmaceutical forms and packaging may only be mentioned as "new" for eighteen months following their first authorisation in Switzerland.

For specific categories of medicines (supply categories C and D), depending on the type of advertising, some further warnings and notices shall clearly be made, as well as a mention of their status of authorised medicines (Art. 16 par. 5 to 17a OAM). This last mention is prohibited for supply category E medicines (Art. 17a par. 2 OAM).

Advertising for medicines with cantonal authorisation shall clearly specify that the medicine does not hold a national marketing authorisation delivered by Swissmedic and that it may only be distributed in the canton for which an authorisation was granted (Art. 17b OAM).

However, in case of advertising only aiming at reminding a brand, the mandatory mentions are limited to the name of the product with or without the name of the marketing authorisation holder (Art. 18 OAM).

Information prohibited:

The following information is prohibited in advertising to the general public (Art. 22 OAM):

- elements suggesting that:
  - a medical consultation or a surgery is superfluous;
  - the effect of the medicine is guaranteed or that there is no undesirable effect;
  - the effect is equal to or greater than that of another treatment or medicine;
  - the state of a healthy person may be improved by using the medicine or may be affected by not using a medicine;
  - the safety or efficacy of the medicine is due to the fact that it is a "natural product".

- elements that would:
  - be addressed mainly or exclusively to children or teenagers;
  - mention or refer to scientific publications, clinical studies, expert opinions, testimonies or recommendations from scientists, health professionals, famous people or non-specialists persons;
  - represent persons dressed or working as healthcare professionals;
  - refer to deceptive, non-existent or unrecognised titles or distinctions;
  - assimilate the medicine to food, cosmetic or other consumer products;
  - lead the person to a wrong self-diagnosis;
  - use abuse, alarmist or misleading visual representations of changes in the body, as well expressions that may induce fear or mentions of the number of persons treated.

10. **Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.**

There is no specific rule regarding this issue in the law. However, if such interaction is considered as advertising, it will not be permitted unless it is included in the restrictive permitted types of advertising to the general public (Art. 15 OAM). For instance, in case of a website offering patients to download general information tools on various symptoms in order to facilitate the diagnosis by the doctor, the tools cannot contain any reference to prescription medicines and must comply with the advertising rules for over-the-counter medicines (Swissmedic Journal 08/2006 p. 806).

The Pharma Cooperation Code provides some rules regarding the cooperation between pharmaceutical companies and patient organisations at its Article 3. For instance:

- pharmaceutical companies may neither require patient organisations to promote certain specific prescription medicines nor may they consider corresponding requests made by patient organisations;
- the aims, scope and agreement on any support and partnerships must be evidenced in writing and transparent;
- where pharmaceutical companies grant financial or other support on a significant scale to a patient organisation, they must agree such support in writing with the patient organisation before it begins and include relevant details;
- pharmaceutical companies must not try to influence the content of documents of patient organisations to which they are granting financial or other support in their own commercial interest;
- if the pharmaceutical company wishes to use logos or legally protected documents of patient organisations for publications, it must obtain the written permission of the organisation concerned;
- in case of benefits in favour of patients' organisations, the pharmaceutical companies shall disclose the pecuniary benefits granted, on an individual basis and annually for a full calendar year (accessible to the public for at least three years);
- contracts between pharmaceutical companies and patient organisations, in virtue of which the latter provide consultancy tasks or services of any kind for the pharmaceutical company, are permitted only if such consultancy tasks or services are provided to support healthcare or research and at certain conditions;
- pharmaceutical companies may ask representatives of patient organisations to act as experts for consultancy or services, for instance to attend meetings of consultancy bodies or to provide speaker services;

- events and hospitality are to be held on premises, which are appropriate and conducive to the main purpose of the event.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

Information requirements:

In the same way as advertising to the general public, advertising to healthcare professionals shall be deemed unlawful if it is misleading or contrary to public order and morality, if it may incite an excessive, abusive or inappropriate use of medicinal products or if it is for medicines having no marketing authorisation (Art. 32 par. 1 TPA). Moreover, as mentioned above, the general rules concerning comparative advertising are also applicable (Art. 3 par. 1 let. a and e UCA).

Advertising to healthcare professionals shall be made in accordance with the information approved by Swissmedic while granting the marketing authorisation. Advertising shall be precise, well-balanced, truthful, verifiable, not misleading, identifiable as such (clearly separated from the editorial text) and supported by documents upon request from healthcare professionals (Art. 5 OAM). Advertising texts must be drafted in accordance with the state of scientific knowledge and reflect it. They may only refer to clinical trials carried out in accordance with the rules of good clinical practice and whose results are published or ready to be published, as well as to data collection, such as meta-analyses or practical experience reports, published in a recognised scientific media addressed to healthcare professionals. These publications must be quoted in an accurate and complete manner, as well as with the exact source. The texts shall also mention that professionals may ask the company concerned for a complete copy of the clinical studies and the corresponding references (Art. 5 par. 5 OAM).

Medicines, indications, dosages, pharmaceutical forms and packaging may only be qualified as "new" for eighteen months following their first authorisation in Switzerland (Art. 5 par. 6 OAM).

Advertising for complementary medicine shall be based on recognised scientific media for healthcare professionals or on recognised monographs in the field of complementary medicine. Advertising texts must specify the therapeutic orientation concerned (Art. 5 par. 7 OAM).

Compulsory information elements:

All advertising shall include, at least, the name of the product, the active substance, the name and address of the marketing authorisation holder, one or more indications or possibilities of use, the dosage and administration instructions, a summary of limitations in use, the undesirable effects and interactions, the supply category, a reference to the publication of information on the medicine for more details and the waiting period for food-producing animal medicines (Art. 6 OAM). Some of the aforementioned elements are not mandatory in case of advertising solely aiming at reminding the supply category of the medicine (Art. 8 OAM). In case of brand advertising, it is only mandatory to mention the name of the product with or without the name of the marketing authorisation holder (Art. 9 OAM).

Prohibited information elements:

Advertising shall not (Art. 13 OAM):

- use the qualifier "safe", unless the information provided clearly indicates what this qualifier refers to;
- claim that the medicine has no side effects, is safe or harmless;
- give the impression of being an editorial text;
- claim that a medicine for human use is not addictive.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

Persons prescribing, delivering, using or purchasing prescription medicines and organisations employing such persons may not solicit, be promised or accepted, for themselves or for a third party, an unlawful benefit (*new* Art. 55 TPA).

Therefore, gifts are not allowed. However, gifts of a modest value (not more than CHF 300 per year per professional) and related to the practice of medicine or pharmacy (directly connected to the professional activity or when patients directly benefit from them) are allowed (new Art. 3 OITTP). Year-end gifts are not considered as connected to the professional activities. For contest gifts, it is additionally required that the gift shall not be connected with the purchase of prescription medicines (new Art. 3 par. 3 OITTP).

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

Yes, but only upon written request of healthcare professionals based on their own initiative (Art. 10 OAM).

The following requirements apply to offering medicine samples (Art. 10 par. 2 to 5 OAM; new Art. 9 OITTP):

- only a small number of samples per medicine and per year may be provided per professional (according to Swissmedic: five for two years since product launch; two since the third year).
- the sample shall be designated as a "free sample";
- the sample shall include the texts and data that shall appear on the medicine package, as well as an approved notice;
- the sample shall be provided with the most recent information on the medicine approved by Swissmedic or with a reference to its publication on the electronic list;
- the package of the samples shall correspond to the smallest authorised package supplied
- (or be even smaller);
- the sample for psychotropic and narcotic drugs is subject to specific rules of the Narcotic Control Ordinance; the sale of samples is prohibited; the marketing authorisation holder shall keep records of the samples submitted.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Only sponsoring for participation in postgraduate or continuing education events for professionals is permitted provided that it has been agreed in writing and that the professionals participating (or the organisations employing the professionals) bear an appropriate share of the costs (own contribution) (*new* Art. 6 par. 1 OITTP).

The own contribution shall be, for each participant in a continuing training event and a postgraduate training event, respectively at least one third and one fifth of the registration fees, the travel fees, the accommodation and food fees, and of the optional activities fees clearly of a secondary importance (*new* Art. 6 par. 2 OITTP).

However, it is possible to waive the requirement for an own contribution if the professional provides an equivalent service during the event or if the participation does not involve an overnight stay on site and does not last more than half a day of work, plus a possible meal following the professional part (*new* Art. 6 par. 3 OITTP).

It is prohibited to reimburse all or part of the own contribution and to pay indirect participation costs (e.g. loss of income), as well as the costs of optional activities, which are not clearly of a secondary importance (*new* Art. 6 par. 4 OITTP). Sponsoring fees for persons accompanying professionals participating in the event is prohibited (*new* Art. 6 par. 4 OITTP).

The Pharma Code adds some details to the rules concerning sponsorship of such type of events (Art. 31 et seqq). For instance, events, which are organised or receive financial support from pharmaceutical companies with subsidiaries in Switzerland (sponsored) and which are aimed purely at participants from Switzerland, should fundamentally take place in Switzerland, unless the relevant information for the topic are only available abroad. Moreover, a Swiss subsidiary of an international company may invite Swiss participants abroad for an event organised by the headquarters or the company's regional centre, provided that the participants pay for the main part of the fees.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

As explained, each participant in a continuing training event and each participant in a postgraduate training event shall pay, at least, respectively one third and one fifth of the optional activities fees, which are clearly of a secondary importance (user-friendly programs) (*new* Art. 6 par. 2 OITTP). If the activity is not considered as of secondary importance – considering its cost, duration or content (especially when it is particularly extensive or overlaps the professional part) – its costs shall be entirely borne by the participant. Moreover, none of user-friendly programs (secondary or not) for the person accompanying the participant shall be borne by the pharmaceutical company (*new* Art.
6 par. 4 OITTP).

On the self-regulatory level, the Pharma Code clearly prohibits pharmaceutical companies to offer or pay for any entertainment or other leisure or hospitality activities (Art. 322 *in fine*).

16. **Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?**

It is possible to pay compensation in return for equivalent services, in particular those granted for orders and deliveries of therapeutic products. This means they shall be connected to the purchase of prescription medicines, teaching, expert/advisory activities, clinical studies, experience report in scientific journals and participation to consultative committees or market studies (Art. 7 par. 4 OITTP).

The compensation shall be agreed by written agreement, be proportionate and not for a service that the professional (or the organisation) does for himself (or itself), be part of a legal duty or already paid by other means (*new* Art. 7 OITTP).

17. **Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?**

Donations for research, postgraduate education or continuous education are permitted as long as they are offered to the organisation (not directly to the professionals) by written agreement. The agreement shall not provide any requirements related to the prescription, the delivery, the use or the purchase of prescription medicines. The donation shall be used exclusively for the purpose agreed and shall be paid on a specific bank account, which may not be accessible for healthcare professionals. The donations shall be reported in the organisation accounting (*new* Art. 4 and 5 OITTP).

Considering the requirements for this exception to the prohibition of benefits, only monetary gifts may be allowed. Donation in kind may be considered as a gift only allowed if it is of modest value and connected with the professional activity.

18. **Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?**

As from 1 January 2020, except from medicines belonging to the supply category E and medical devices belonging to the supply category I, anyone who grants or accepts discounts or rebates when purchasing therapeutic products shall indicate them in supporting documents and accounts, as well as in the books of accounting. Upon request, the company must report them to the Federal Office of Public Health (*new* Art. 56 TPA and *new* Art. 10 OITTP). Donations for research, postgraduate education or continuous education shall also be reported in the organisation accounting (new Art. 4 and 5 OITTP). Moreover, all agreements with healthcare professionals or organisations concerning benefits shall be kept for ten years and a list of all the healthcare professionals and the organisations having benefited from benefits shall be established (*new* Art. 11 OITTP).

The Pharma Cooperation Code provides several rules about disclosure of benefits (Art. 23 et seqq) and the details requested (on an individual basis, name of recipients and amounts paid) (Art. 27). According to this Code, the pharmaceutical company shall disclose, in each case, any kind of pecuniary benefits granted to healthcare professionals and healthcare organisations annually for a full calendar year. Some kind of benefits are excluded though (samples, some benefits of modes value). This information must remain accessible to the public for at least three years after its disclosure on its website (Art. 251, 253 and 261).

Moreover, each benefit shall be mentioned in the healthcare professional's invoice and the direct or indirect benefits he/she receives shall be passed on to the final debtor of the medicine (patient/insurance) (Art. 56 HIA and new 76a OHI).

There is no derogation for companies that do not yet have products on the market or for foreign companies for the disclosure of discounts and rebates when selling therapeutic products and donations for research in Switzerland. Concerning other kind of benefits, the Pharma Code only applies to the signatories.

19. **When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?**

Authorisation for advertising:

As mentioned above, in principle, advertising for medicine is not subject to prior control from Swissmedic but there are exceptions. Since 1 January 2019, there are only two exceptions requiring prior approval of advertising from/to Switzerland (Art. 23 OAM):

- Advertising for analgesics, sleeping pills, sedatives, laxatives and anorectics (press release or electronic media) shall be approved in case of a risk of misuse or dependence;
- Swissmedic may require from the holder of a marketing authorisation to submit for prior approval all future advertising projects, for an appropriate period, in case the holder repeatedly or seriously infringed provisions on advertising.

Advertising on the Internet:

Advertising on the Internet, including social media, is encompassed by the general definition of advertising for medicines either to healthcare professionals or to the general public under "advertising spread by electronic media" (such as image, sound and data medium) (Art. 4 and 15 OAM). Therefore, the same requirements and restrictions are applicable to advertising on the Internet as other types of advertising.

Swissmedic established guidelines for the application of the advertising restrictions to this specific way of advertising (Swissmedic Journal 08/2006 p. 802 et seqq), which includes also rules on domain names and hyperlinks. Articles from other media about a company or its medicines that are on the company's website are considered as information or advertising from this company (Swissmedic Journal 8/2006, p. 802 et seqq).

Access restrictions to advertising on the Internet for healthcare professionals:

Advertising for prescription medicines spread by any electronic media shall be protected by password access (Art. 5a OAM). If a website is not protected by a password access for healthcare professionals, it is considered as advertising to the general public.

20. **Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?**

Swiss criminal Code ("SCC") prohibits active and passive bribery in the private sector (Article 322octies and 322novies SCC). In the case of healthcare professionals working in a public hospital (with public function), the prohibition of active and passive bribery of public officials is applicable (Art. 322ter and 322quater SCC), as well as the prohibition of the acceptance and the granting of an advantage (without any relationship of exchange with the undue advantage) (Art. 322quinquies and 322sexies SCC).

As a general rule, the mere "granting of an advantage" is not punishable between private parties in the SCC. However, in the pharmaceutical sector, the TPA provides criminal sanctions in some cases. From 1 January 2020, the acceptance or the granting of unlawful benefits in favour of persons who prescribe, supply, use or purchase prescription medicines or in favour of organisations that employed such persons (new Art. 55), commits a criminal offence (new Art. 86 TPA). Negligence (failure to consider or disregard of the consequences of his conduct due to a culpable lack of care) is also a criminal offence (Art. 86 par 4 TPA).

21. **What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?**

Offering of benefits or inducements to healthcare professionals rules were part of the amendments agreed to the TPA and the adoption of the new OITTP. According to the new Art. 55 TPA, persons prescribing, delivering, using or purchasing prescription medicines and organizations employing such persons, may not solicit, be promised or accepted an unlawful benefit. It is also prohibited to offer, promise or to grant these persons or organisations an unlawful benefit.

Are not considered unlawful benefits and are therefore allowed, the following benefits (new Art. 55 par. 2 TPA):

- Benefits of a modest value (not more than CHF 300 per year per professional) and related to the practice of medicine or pharmacy (directly connected to the professional activity or when patients directly benefit from it) (new Art. 3 OITTP) (see Answer 12 above).
- Donations for research, postgraduate education or continuous education, as long as they are offered to the organisation and under certain conditions (new Art. 4 and 5 OITTP). There are

specific rules for donations for the participation to events related to postgraduate or continuous education (new Art. 6 OITTP) (see Answers 14, 15 and 17 above).

- Compensation granted in return for equivalent services, in particular those granted for orders and deliveries of therapeutic products under certain conditions (new Art. 7 OITTP) (see Answer 16 above).
- Discounts (difference between the standard price or the factory price for listed medicines and the paid price) or rebates granted on the purchase of therapeutic products as long as they do not influence the choice of treatment (new Art. 8 par 1 OITTP). Delivery of a greater quantity than the one ordered and invoiced is prohibited (new Art. 8 par. 2 OITTP) (see Answer 18 above).

All agreements with healthcare professionals or organisations concerning the abovementioned benefits shall be kept for ten years. A list of all the healthcare professionals and the organisation having benefited from advantages shall be established (new Art. 11 OITTP).

Moreover, any benefit shall be mentioned in the invoice and the direct or indirect benefits he/she receives shall be passed on to the final debtor of the medicine (patient/insurance) (Art. 56 HIA and new 76a OHI). However, from 1 January 2020, insurers and service providers will be allowed to provide, in an agreement, that a minor part of the benefits are not to be passed on but to be used in a verifiable way to improve the quality of treatment (new Art. 56 par. 3bis HIA).

The Pharma Code also provide rules on offering benefits or inducement that are similar to the abovementioned rules (and more detailed), which may be slightly amended following the adoption of the new rules of the TPA and the OITTP.

22. **Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.**

The enforcement body concerning administrative measures are Swissmedic, concerning advertising rules, and the Federal Office of Public Health concerning integrity (i.e. grant/acceptance of benefits) and transparency rules (new Art. 82 par. 1 TPA). Appeals to the Federal Administrative Tribunal followed by an appeal to the Federal Tribunal are possible in general.

In principle, the enforcement bodies concerning criminal measures are Swissmedic, the Federal Office of Public Health or the local public prosecutor's office (depending on the offence committed) and the criminal tribunal of the canton where the offence was committed. Appeals

to the canton Criminal Appeal Court, following by an appeal to the Federal Tribunal are possible in general. However, for active and passive bribery of public officials, the subject-matter jurisdiction may lie with the Federal Office of the Attorney General if the offence was committed abroad to a substantial extent or if it has been committed in two or more cantons with no single canton being the clear focus of the criminal activity (Article 24 Swiss Criminal Procedure Code). An appeal to the Federal Criminal Tribunal, followed by an appeal to the Federal Tribunal is possible in principle.

On the self-regulatory level, the Code Secretariat is the enforcement body concerning the Pharma Code and the Pharma Cooperation Code rules (Art. 6 Pharma Code; Art. 5 Pharma Cooperation Code).

23. **On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?**

First, the companies may file a complaint to Swissmedic (advertising) or to the Federal Office of Public Health (integrity and transparency) for any infringement of the rules set out in TPA, OAM and OITTP.

Second, the companies may file a claim to the civil courts in case of unfair competition according to the UCA.

Third, companies may also initiate a proceeding against a competitor before the Code Secretariat in case of breach of the Pharma Code or of the Pharma Cooperation Code.

24. **What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?**

Swiss authorities may order either administrative measures (in particular, to order to cease the infringement, to prohibit advertising for a certain period or definitively, to seize or destroy advertising materials, to prohibit distribution, and to submit any further advertising projects to prior approval) (Art. 66 par. 1 and 2 TPA and Art. 23 OAM) or criminal penalties. The criminal penalties depend on the type of violations as well as on the seriousness of the case. The new TPA provides penalties reaching up to custodial sentence not exceeding three years or a monetary penalty for unlawful benefits (up to ten year plus a monetary penalty in case of acting for commercial gain and achieving a high turnover or a significant gain) (new Art. 86 TPA) and up to a

fine not exceeding CHF 50,000 for infringement to advertising and transparency rules (new Art. 87 TPA).

For bribery of public officials, the perpetrator may be sentenced to a custodial sentence not exceeding five years or to a monetary penalty. For bribery of private persons, the penalty is limited to a custodial sentence not exceeding three years or to a monetary penalty.

The Code Secretariat may order the company to discontinue the breach. If the company does not, the Code Secretariat may only forward the case to the competent Swiss authorities.

25. **What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?**

Both procedures are independent, may be conducted simultaneously and order independent measures. If pharmaceutical companies refer conduct to a government authority or to a court, the Code Secretariat shall suspend any proceedings which have already been opened for as long as none of the participating pharmaceutical companies ask for the proceedings to be terminated (Art. 671 Pharma Code; Art. 571 Pharma Cooperation Code).

Nevertheless, pharmaceutical companies which undertake to comply with the Pharma Code and the Pharma Cooperation Code acknowledge the rules of enforcement of those Codes and refrain from referring the matter at the same time to a State authority or to courts, as long as relevant proceedings are pending, unless this is deemed necessary for the safeguarding of rights which may be endangered or defeated by compliance with the above-mentioned principles (Art. 15 Pharma Code/Pharma Cooperation Code).

26. **Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.**

The most recent trends in Switzerland concern the amendments of the rules on integrity and transparency, which will finally enter into force in 2020. Indeed, there were many discussions about the interpretation of unlawful benefits, which led to the establishment of a more detailed ordinance (new OITTP). The need for more transparency (disclosure duty which extend now also

to the purchase of some medical devices) and of more severe criminal penalties were addressed in this amendment of the law too.

Concerning advertising, recent case law was mainly about unlawful phrasing used for advertising or about the difficulty to distinguish general information from advertising. Moreover, Swiss authorities decided to take measures against advertising for authorised complementary medicines without indication that appeared to be often unlawful. Such kind of medicines may only be distributed under their common name and without any indication on recommended scope and dosage. Therefore, notices, posters, brochures or Internet links provided information on recommended scope and dosage are prohibited (Swissmedic Journal 09/2018 p. 812 et seqq).