International
Comparative
Legal Guides

# Pharmaceutical Advertising 2020

A practical cross-border insight into pharmaceutical advertising

**17th Edition**

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# Expert Chapter



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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The statutory basis for the regulation of advertising for medicinal products is the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, hereinafter "**TPA**", https://www.admin.ch/opc/en/classified-compilation/20002716/index.html).

The Federal Ordinance on the Advertisement of Medicinal Products (hereinafter "**AWV**", https://www.admin.ch/opc/de/classified-compilation/20011778/index.html) specifies the advertising provisions of the TPA and provides detailed rules on advertising of ready-to-use medicinal products.

The Federal Act against Unfair Competition (Unfair Competition Act, hereinafter "**UCA**", https://www.admin.ch/opc/de/classified-compilation/19860391/index.html) provides for limits for all types of advertising and is also applicable to the advertising of medicinal products.

In addition, there are several guidance documents issued by Swissmedic, the Swiss Agency for Therapeutic Products, regarding specific forms of advertising of medicinal products, published on the Swissmedic website (https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/advertising-of-medicinal-products/instructions.html) and in the Swissmedic Journal (https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/swissmedic-journal.html).

Of great practical importance are the Pharma Code and the Pharma Cooperation Code issued by scienceindustries (https://en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code), which are industry codes based on private law and bind the vast majority of pharmaceutical companies operating in Switzerland. Several recommendations for the proper application of these Codes exist (https://en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code/pharma-code-and-pharma-cooperation-code-practice).

Because offers of monetary benefits to healthcare professionals (hereinafter "**HCPs**") and healthcare organisations (hereinafter "**HCOs**") may also be regarded as medicinal product advertising (*cf.* answer to question 1.2), the Ordinance on Integrity and Transparency in the Therapeutic Products' Sector (hereinafter "**VITH**", https://www.admin.ch/opc/de/classified-compilation/20190088/index.html) should also be taken into account.

### 1.2 How is "advertising" defined?

According to article 2(a) AWV advertising of medicinal products is defined as all information, marketing and incentive measures intended to promote the prescription, supply, sale, consumption or use of medicinal products. Advertising includes both advertising addressed to HCPs and advertising addressed to the general public.

Not regarded as medicinal product advertising are: (i) the packaging material and the product information; (ii) sales catalogues and price lists, provided that they do not contain medical information about medicinal products; and (iii) information of a general nature concerning health or diseases, provided that this information does not relate directly or indirectly to specific medicinal products (article 1(2) AWV).

According to the above definition, offers of monetary benefits to HCPs and HCOs may also be regarded as medicinal product advertising. This form of advertising is, with the exception of the rules on sample packaging, not regulated in the AWV, but in the VITH.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The marketing authorisation holder (hereinafter "**MAH**") is required to designate a person who is responsible for the advertising of the medicinal products it distributes in Switzerland (article 25(1) AWV). This person must have a scientific, medical or similar formation or experience (article 25(2) AWV). She or he has to ensure that the advertising materials are compliant with the legal requirements (which requires a sign-off), keep a copy of such materials for six months after their last publication, and hold a register with the names of all addressees, the details of the publications and the date of the first publication. The person responsible for advertising has to ensure that the sales representatives of the pharmaceutical company are appropriately trained and comply with the legal obligations regarding advertising of medicinal products. The responsible person has to ensure that Swissmedic's instructions are immediately and fully carried out (article 25(3) AWV).

Since 1 January 2020, article 11 VITH obliges MAHs and distributors of medicinal products (except sales category E) to: (i) designate a person who will provide the Federal Office of Public Health (hereinafter "**FOPH**") on request all the documents and information required; (ii) keep all agreements concluded with medicinal persons and organisations within the meaning of the VITH for 10 years after their last use; and (iii) keep a list of all medicinal persons and organisations that have received due benefits within the meaning of the VITH.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

As mentioned under question 1.3 above, the MAH has to designate a person who is responsible for ensuring that the advertising material is compliant with the legal requirements (article 25 AWV) and appoint a person who is responsible for ensuring that the provisions regarding integrity and transparency are observed.

In addition, the Pharma Code requests that pharmaceutical companies set up a scientific service which is responsible for information about their medicinal products and appoint a person who ensures the conformity of all promotional and informational materials with the Pharma Code and applicable laws. Pharmaceutical companies have to inform the Pharma Code Secretariat of the name of this person (rule 53 Pharma Code). Apart from this, no explicit requirement for SOPs exists, however SOPs are often put in place.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

Advertising in writing or electronic form addressed to the general public for analgesics, sleep-inducing products, sedatives, laxatives and anorexics with a potential risk of addiction or abuse mentioned in the product information must be submitted to Swissmedic for prior approval (articles 15(a) and (c) and 23(1) AWV, *cf.* Swissmedic Journal 8/2016, p. 644 *et seqq.*).

MAHs who seriously or repeatedly infringe the provisions regarding advertising of medicinal products can be obliged by Swissmedic for a certain period of time to submit all drafts of planned advertising to Swissmedic for prior assessment and approval (article 23(2) AWV).

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Swissmedic is authorised to enforce the provisions regarding advertising in the TPA and the AWV through different administrative measures (article 66 TPA). Swissmedic may seize, hold in official storage, destroy or prohibit the use of illegal advertising material, and publish the prohibition at the expense of the responsible party (article 66(2)(f) TPA). Moreover, Swissmedic may temporarily or permanently stop the advertising of a specific medicinal product in the event of serious or repeated violations of the TPA and AWV, and publish the prohibition at the expense of the responsible party (article 66(2)(g) TPA).

In addition to these administrative measures, Swissmedic can also initiate an administrative criminal procedure. The administrative criminal procedure is conducted in accordance with the provisions of the Federal Act on Administrative Criminal Law (hereinafter "**VStrR**", https://www.admin.ch/opc/de/classified-compilation/19740066/index.html).

Administrative measures ordered by Swissmedic can be appealed to the Federal Administrative Court and thereafter to the Federal Supreme Court.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

A fine up to CHF 50,000 may be imposed on any person who wilfully contravenes the regulation on the advertising of medicinal products (article 87(1)(b) TPA and article 333(3) of the Swiss Criminal Code, hereinafter "**SCC**", https://www.admin.ch/opc/en/classified-compilation/19370083/index.html). If the person concerned acts professionally, he or she shall be liable to a monetary penalty of up to 180 daily penalty units (article 87(2) TPA). If the person concerned acts through negligence, the penalty shall be a fine not exceeding CHF 20,000 (article 87(3) TPA). Attempts, aiding and abetting are also offences (article 87(4) TPA). In particularly minor cases, prosecution and sentencing may be waived (article 87(6) TPA).

In case that a fine of more than CHF 5,000 is imposed, an entry is made in the criminal register according to the Criminal Records Ordinance (hereinafter "**VOSTRA Ordinance**", https://www.admin.ch/opc/de/classified-compilation/20061863/index.html).

In principle, the proceedings are conducted against a natural person. If a fine not exceeding CHF 20,000 is envisaged and the investigation of the persons punishable would require investigative measures that would be disproportionate in view of the penalty imposed, these persons may be exempted from prosecution and in their place the pharmaceutical company may be forced to pay the fine (article 7 VStrR and article 89 TPA).

Swissmedic may criminally prosecute cases against persons and companies violating the TPA, insofar as the prosecution is conducted at federal level. If the prosecution is conducted at cantonal level, the penal cantonal authorities are responsible (article 90 TPA).

An example where action has been taken against a pharmaceutical company was the prosecution of Pfizer for the distribution of a brochure on migraines and their medical treatment, in which Swissmedic found an illegal promotion of the medicinal product Relpax (decision of the Federal Supreme Court 2A.63/2006).

The TPA does not contain rules regarding civil claims. Competitors may base civil claims in particular on the UCA. Such claims have to be filed in front of the civil courts.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

Swissmedic is authorised to enforce the statutory advertising provisions through different administrative measures. In addition to these administrative measures, Swissmedic can also initiate administrative criminal procedures (*cf.* answer to question 1.6). These competences are not limited by the self-regulatory process for advertising addressed to HCPs. In practice however, the focus of the surveillance activities of Swissmedic is on advertising addressed to the general public

and the Pharma Code Secretariat deals with most complaints regarding advertising addressed to HCPs.

The self-regulatory process provides for an engagement in principle of the signatories of the Pharma Code to go through the self-regulatory process first before bringing a complaint to Swissmedic or the courts (rule 152 Pharma Code).

The procedure under the Pharma Code should be carried out within the shortest possible time and should not take longer than one month. If the Pharma Code Secretariat comes to the conclusion that a pharmaceutical company has violated the Pharma Code, it calls upon the pharmaceutical company concerned to cease the conduct and to ensure that the conduct does not occur in the future. If the pharmaceutical company concerned does not comply with the assessment of the Pharma Code Secretariat within the set time limit the Pharma Code Secretariat may, after prior unsuccessful warning, refer the matter to Swissmedic.

Sometimes, pharmaceutical companies contact Swissmedic directly and require its intervention when they become aware of an infringement of advertising provisions by a competitor. Swissmedic may take up matters even if a self-regulatory process is pending. In the field of advertising to HCPs, it is more likely that Swissmedic takes up a case if the advertising carries risks for public health.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Misleading or incorrect statements about own products (article 3(1)(b) UCA) or about the products of others (article 3(1) UCA), and any measures that may cause confusion with products or business of competitors (article 3(1)(d) UCA), can be challenged in civil or penal unfair competition proceedings. These proceedings fall within the jurisdiction of the cantonal courts and their decisions can be appealed with the Swiss Federal Court. In civil proceedings, provisional measures may be obtained and decisions may be enforceable in other countries.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

It is permissible to supply scientific information about an unauthorised medicinal product, but advertising such unauthorised medicinal product is not allowed (article 32(1)(c) TPA). Information concerning unauthorised medicinal products provided to HCPs must always clearly indicate that the medicinal product is not yet authorised (rule 242 Pharma Code). The same rules basically apply to off-label information. Advertisement for off-label use of a medicinal product is prohibited (article 5(1) AWV), but information on off-label use of a medicinal product is allowed. Such information is most often made available at scientific meetings. With regard to discussions at scientific meetings, it does in principle not make a difference whether the meeting is sponsored by the company responsible for the product or not.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Publishing such information is permitted, provided this information cannot be qualified as advertising.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.**

It is permissible for pharmaceutical companies to issue press releases to journalists about unauthorised medicines and off-label information. Using the brand name for such press releases is allowed; however, the International Non-proprietary Name ("**INN**") of the compound has to be used as well. Pharmaceutical companies have to ensure that a press release does not constitute unlawful advertising (rule 241 Pharma Code). Such press releases can only be given to journalists. On the Internet, such press releases must therefore be password-protected.

It is also permissible for pharmaceutical companies to issue *ad hoc* information to the public as mandated by stock exchange regulations.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

The proactive distribution of information about unauthorised medicinal products and/or off-label indications to HCPs is delicate and could be seen as disguised advertising. Sending such information (e.g. study publications) on request should not pose problems in most cases.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

Switzerland as a non-EU member country is not bound by the Directive and the judgment in the *Ludwigs* case.

Article 1(2)(b) AWV states, however, since 2002 that sales catalogues and price lists are not considered advertising. Therefore, it is unlikely that the sole communication of price lists for non-approved medicinal products to pharmacists would be considered non-permitted off-label advertisement if the provisions on compassionate use are otherwise respected.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

According to article 2(a) AWV, advertising of medicinal products is defined as all information, marketing and incentive measures intended to promote the prescription, supply, sale,

consumption or use of medicinal products. If information on unauthorised medicines or indications will be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future, this must be qualified as a promotional purpose. Therefore, it is likely that such information will be qualified as unlawful advertising.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

It is permissible for pharmaceutical companies to engage HCPs for consultancy services. Compensation for such services are permissible if: (i) the compensation is based on a written agreement specifying the nature and extent of the services and compensation; and (ii) the compensation is equivalent to the services received (article 7 VITH).

According to the Pharma Cooperation Code, the engagements of HCPs must be transparently disclosed.

If market research is conducted with the principal purpose of advertising off-label products or indications, the engagement of HCPs and the market research would have to be considered as prohibited advertising.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

All information in advertising to HCPs must be in accordance with the most recent medicinal product information approved by Swissmedic; in particular, only indications and possible applications authorised by Swissmedic may be advertised (article 5(1) AWV).

Generally, the following information must appear in advertisements to HCPs: (i) the name of the medicinal product (brand); (ii) the active substances with the abbreviated designation (DCI/INN); (iii) the name and address of the MAH; (iv) at least one indication or use of the medicine, as well as the dosage and the method of application; (v) a summary of any restrictions on use, adverse reactions and interactions; (vi) the distribution category; and (vii) the mention that further information can be found in the product or patient information (article 6 AWV).

In certain forms of advertising not all information must appear (articles 8 and 9 AWV).

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

All information in advertisements addressed to HCPs must be in accordance with the most recent medicinal product information approved by Swissmedic (which corresponds to the SmPC). In particular, only indications and possible applications approved by Swissmedic may be advertised (article 5(1) AWV). If the product information has not yet been published, the MAH must include the full content of the most recently approved product information (article 5(2) AWV).

Advertisements addressed to HCPs must be accurate, well-balanced, factually correct and verifiable in their statements. The statements must not be misleading, incite abusive, excessive or inappropriate use of medicinal products, or be contrary to public morality and order (article 32(1) TPA). The supporting references must be made available to HCPs on request (article 5(3) AWV).

Advertising and editorial contributions must be clearly separated (article 5(4) AWV).

The advertising statements must be based on and reflect the current state of scientific knowledge. They may only refer to clinical trials that have been conducted in accordance with the rules of good clinical practice and have been published or accepted for publication, and to data collections such as meta-analyses or reports on practical experience that have been published in a scientifically recognised journal. These publications must be cited with the accurate source. It should be noted that HCPs can request a complete copy of the corresponding references from the company (article 5(5) AWV).

According to certain Swissmedic decisions and case law (*cf.* decision of the Federal Administrative Court C-5490/2015 E.6.4.3), statements based on finding of new studies which are not written in the approved product information may not be used for advertisement. The practice of the Pharma Code Secretariat is less strict in this respect.

A medicinal product, an indication, a dosage, a pharmaceutical form or a package may be advertised as "new" for 18 months after the initial marketing authorisation in Switzerland (article 5(6) AWV). According to the Pharma Code, medicinal products, indications, possible applications, dosages, pharmaceutical forms and packaging may only be designated as new within one year of their approval in Switzerland (rule 237).

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Endorsements by HCPs are generally permitted in promotional materials to HCPs, insofar as they are well-balanced, not misleading and the endorsing HCPs are identifiable.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

Advertising statements concerning comparisons with other medicinal products are only permitted if they are scientifically correct and based on equivalent clinical trials or published data collection (article 7(1) AWV). If the comparative statement is scientifically correct, the study must not necessarily be a "head-to-head" clinical trial.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Comparative advertisements are permitted (article 7 AWV). It is permissible to use the brand name of another company's product as part of such a comparative advertisement. Swiss law prohibits the advertisement of unauthorised medicines or indications and promotion which is misleading. It may be misleading to refer in a comparative advertisement to a competitor's product or indication which has not (yet) been authorised.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

There are no specific legal provisions governing the distribution of scientific papers and/or proceedings of congresses to HCPs. Therefore, the general advertising rules apply. In particular, a clear distinction must be made between advertising and scientific information. Advertising may not be disguised as scientific papers and/or proceedings of congresses (article 5(4) AWV). The proactive distribution of study results that are off-label could, for example, be seen as disguised advertising.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Any medicinal product advertisement addressed to HCPs has to be accurate, well-balanced, factually correct and verifiable in its statements (article 6 AWV). A teaser advertisement to alert HCPs that something new will follow without any additional information is not informative and does not comply with these requirements.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

The promotion of the combination for Product A by the holder of the MA of Product A would not result in off-label advertising, because Product A is authorised for a particular indication to be used in combination with Product B.

In contrary to the above, in the situation described, Product B would not be authorised for the indication in question. Therefore, the promotion of the combination use by the holder of the MA of Product B could be seen as prohibited off-label advertising.

Therefore, it might be argued that the holder of the MA of Product A would be allowed to advertise the combination use, whereas the holder of the MA of Product B would be prohibited from doing so. However, it is doubtful whether Swissmedic could enforce a prohibition to advertise the combination use by the holder of the MA for Product B as it has approved the combination use. There is no published decision on this specific situation.

The issue could be avoided by the holder of the MA for Product B if it obtains an amendment of the product information of Product B.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Samples of medicinal products may only be distributed in small quantities to HCPs. Swissmedic considers the following sample quantities to be the maximum permitted levels: Within two years of market launch, a maximum of five packs per HCP, per year and per medicinal product, i.e. per dosage form and per dosage. From the third year after market launch, a maximum of two packs per HCP, per year and per medicinal product, i.e. per dosage form and per dosage.

The samples may only be distributed on specific written request of the applying HCP. They must be clearly and permanently marked as "free sample".

Samples must correspond to the smallest approved package size. They must contain the necessary information and texts on the container and packaging material as well as an approved package leaflet. For medicinal products which may be placed on the market without a package leaflet, the sample package must contain the necessary information on the container and packaging material. Samples must be accompanied by the most recently approved product information or a reference to its publication. The MAH must keep records of the supply of samples. The distribution of samples containing psychotropic substances or narcotics is regulated in the Narcotics Control Ordinance (article 10 AWV).

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Persons who prescribe, dispense, use in their own responsibility, purchase for this purpose, or participate in purchase decisions for prescription-only medicinal products, and organisations employing such persons, shall not claim, be promised or accept any undue advantage for themselves or for the benefit of a third party. Similarly, it is forbidden to offer, promise or grant an undue advantage to any such person or organisation for their benefit or for the benefit of a third party (article 55(1) TPA). Article 55 para. 2 TPA lists certain exceptions from this rule. Advantages of modest value which are of relevance to medical or pharmaceutical practice are not regarded as undue advantages (article 55(2)(a) TPA).

Advantages of modest value according to article 55(2)(a) TPA are benefits with a total value of no more than CHF 300 per HCP and per year (article (3)(1) VITH). An advantage is of relevance to the medical or pharmaceutical practice if it is directly related to the practice of the HCP or directly benefits its patients (article (3)(2) VITH).

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Under certain conditions this is admissible. Although article 55 TPA generally prohibits undue financial advantages in relation to prescription-only medicinal products granted to HCPs or HCOs, grants or donations related to such products given to HCOs are permissible under certain conditions. Article 55(2)(b) TPA and articles 4 and 5 VITH list as admissible support contributions for research, teaching, education and training as well as infrastructure. Such support contributions are permissible if they are: (i) not offered, promised or granted to an individual HCP, but to the organisation employing the HCP; (ii) based on a written agreement stating the intended use; (iii) used exclusively for the intended purpose; (iv) not subject to conditions or requirements concerning the prescription, dispensing, use or purchase of certain

prescription-only medicines; (v) transferred to a designated account of the organisation to which no individual HCPs have access; and (vi) shown in the accounts of the organisation (article 4 VITH).

Medical or technical services falling under one of the four abovementioned categories can therefore be funded.

In relation to prescription-only medicinal products, article 55 TPA in our view only allows monetary contributions and no contributions in kind.

In relation to medical devices exclusively, article 55 TPA in its current version is not applicable so the donation of medical devices is admissible if it is in line with the rules applicable to the HCO.

According to the Pharma Cooperation Code, any donation in kind or in cash must be openly disclosed to the public by the donating manufacturer of medicinal products (rules 22–293 Pharma Cooperation Code).

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

According to article 55(2)(a) TPA and article 3(1) VITH, it is possible to provide medical or educational goods to HCPs, provided that the value of these goods does not exceed CHF 300 per year and per HCP and such goods are of relevance for the medical or pharmaceutical practice (*cf.* answer to question 4.2 above). The legislator assumed that such modest benefits would not change the prescription behaviour of HCPs.

The provision of educational services is in principle allowed according to the provisions on educational services (*cf.* answer to question 4.10 below).

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

The rules on discounts in the TPA changed as per 1 January 2020. Article 55 TPA in its present version only regulates discounts on prescription-only medicinal products. Pharmaceutical law does not therefore restrict volume-related discounts on non-prescription medicinal products.

Discounts granted on prescription-only medicinal products are permissible, if they have no influence on the choice of treatment (article 55(2)(d) TPA). It is not possible to say in general terms when discounts, e.g. discounts related to volume, can influence the choice of treatment.

A discount is inadmissible if it can lead to a situation where: (i) an unsuitable prescription-only medicinal product is prescribed, dispensed or used; (ii) a prescription-only medicinal product is excessively prescribed, dispensed or used; or (iii) a prescription-only medicinal product is prescribed, dispensed or used although the use of a medicinal product is not indicated.

It can also be argued that discounts which are passed on to the patients or their healthcare insurers – as required by article 56 of the Health Care Insurance Act (hereinafter "**KVG**", https://www.admin.ch/opc/de/classified-compilation/19940073/index.html) – do not have any influence on the choice of treatment, as no relevant advantage remains with the HCP/HCO.

In particular, the risk of an undue benefit is considered to be low if discounts are negotiated with an institution in which the purchasing and prescribing/dispensing function are separated. Therefore, more caution is required when granting discounts to HCPs than to organisations that have a purchasing department.

In addition, it is to be expected that case law under the new article 55 TPA will refer to the case law on the former article 33 TPA. Accordingly, the decision of the Federal Supreme Court 2C_92/2011 of 12 April 2012 and the decision of the Federal Administrative Court C-669/2008 of 17 December 2010 will probably remain valid. The criteria mentioned in these decisions are as follows: (i) the higher the price discount or reimbursement, the higher the risk of influence; (ii) the cheaper the product compared to competing products, the higher the risk of influence; (iii) the higher the profit margin, the higher the risk of interference; and (iv) the cheaper a retailer can offer his end customers a product, the higher the risk of interference.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?**

The new article 55 TPA in principle prohibits financial benefits related to prescription-only medicinal products. As an exception to this rule, discounts or pay backs offered in relation to the purchase are permissible, if they have no influence on the choice of treatment (article 55(2)(d) TPA). Other advantages like the offer to provide, or to pay for, additional medical or technical services or equipment are not permissible. Package deals are less critical if only the package is sold.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

It is not expressly prohibited to offer HCPs or HCOs a refund scheme if the product does not work. If the refund scheme is decided or approved by the FOPH, it is admissible. Apart from this situation, there are no established rules on refund schemes. A refund scheme would require a lot of organisation. Repayments on reimbursed products would have to be passed on by the HCP or HCO to the debtor of the price of the product, i.e. the patient or his health insurance. For non-reimbursed products a refund scheme related to prescription-only medicinal products may raise concerns as it could be seen as an undue monetary benefit that may influence the choice of therapy (article 55(1) TPA) and a refund scheme related to non-prescription medicinal products could be seen as inciting an excessive or inappropriate use of medicinal products.

**4.8 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?**

If the scheme is decided or approved by the FOPH, it is

permitted. Discounts or repayments on non-prescription and on prescription-only medicinal products that are transparently displayed and do not influence the treatment decision are also admissible. Schemes going beyond this may raise concerns under the rules on monetary benefits (article 55 and the provisions of the VITH).

**4.9 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?**

The Swiss health system includes various players, such as public and private hospitals, health insurance companies, the federal and cantonal health authorities, etc. Therefore, various rules can apply. There are various forms of permitted cooperation. In the field of mandatory social health insurance, the areas of cooperation between pharmaceutical companies and health insurance companies are more limited than outside of this area. There are various possibilities of cooperation in joint projects between pharmaceutical companies and HCPs and HCOs.

**4.10 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

According to article 55(2)(b) TPA and article 5 VITH, pharmaceutical companies may offer HCOs grants for continuing medical education, provided that the contributions: (i) are not offered, promised or granted to a single HCP, but to the organisation employing the HCP; (ii) are based on a written agreement stating the intended use; (iii) are used exclusively for the intended purpose; (iv) are not subject to conditions or requirements concerning the prescription, dispensing, use or purchase of certain prescription-only medicines; (v) are transferred to a designated account of the organisation to which HCPs do not have access individually; and (vi) are shown in the accounts of the organisation. Moreover, it must be ensured that the organisation providing the continuing medical education can decide independently on the type and content of the education and on the participating HCPs.

According to article 55(2)(b) TPA and article 6 VITH, pharmaceutical companies may also support individual HCPs for their participation at continuing medical education under certain conditions. The main condition is that the HCP pays at least one-third of the costs himself.

**4.11 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Article 55 TPA and the VITH contain rules on bribery related to prescription-only medicinal products and transparency related to medicinal products and medical devices. The FOPH has the statutory mandate to ensure compliance with article 55 TPA and the VITH. Therefore, the FOPH acts as the prosecuting authority in this area.

The general anti-bribery rules regarding public officials are stated in the SCC (*cf.* article 322*ter et seq.* SCC) and the general anti-bribery rules regarding private parties in the UCA. They are based on international conventions of the OECD, the Council of Europe and the United Nations. These rules also apply to the healthcare sector. The cantonal criminal authorities are the responsible prosecuting authority in this area.

The relationship between the rules of the TPA and the general anti-bribery provisions is not yet clear in all respects. In relation to the granting of advantages (as opposed to a specific corrupt agreement), it seems that the provisions of the TPA are *lex specialis* to the general rules.

Insofar as the FOPH has assessed and punished matters that constitute a breach of article 55 TPA, the criminal prosecution authorities may not investigate and punish these again. However, this question has not yet been decided by the courts. It requires an examination of the circumstances of the individual case to determine how the proceedings are coordinated between the FOPH and the authorities competent for anti-bribery.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Cost contributions, including hospitality, in connection with an educational event are permissible, provided they are agreed in writing and the participating HCP or the organisation employing him/her make an appropriate contribution to the costs of the event (article 55(2)(b) TPA and article 6(1) VITH). The cost contribution must amount to at least one-fifth for HCPs in further education and one-third for all other HCPs of the following costs: (i) participation fees; (ii) travel cost; (iii) accommodation and meals; and (iv) offers that are not necessary for participation in the event (supporting programmes) and which are of clearly subordinate importance (article 6(2) VITH).

A cost contribution may be waived if (i) the participating HCP provides an equivalent service in return during the event, and (ii) an event does not require the participating HCP to stay overnight on site and lasts no longer than half a working day without any catering following the scientific part (article 6(3) VITH).

Not permitted are: (i) the full or partial reimbursement of the cost contribution; (ii) the reimbursement of indirect participation costs such as loss of work or income; (iii) the reimbursement of costs for supporting programmes which are not of clearly subordinate importance with regard to the scientific part of the event; and (iv) the reimbursement of the costs of travel, accommodation, meals or supporting programmes of accompanying persons of the participating HCP, even if the accompanying persons are HCPs themselves (article 6(4) VITH).

These rules apply irrespective of the place where the event takes place.

In the context of a scientific discussion, the reimbursement of the costs for a meal of up to a maximum of CHF 100 is permitted in accordance with article 7(2) VITH. Article 7(2) VITH is stricter than rule 143.5 Pharma Cooperation Code, which states that payments for meals (including beverages) must remain at

a reasonable and modest scale, subject to a maximum of CHF 150 per HCP per meal for events that take place in Switzerland.

If scientific conferences and events take place outside Switzerland, according to the Pharma Code (rule 376), pharmaceutical companies may contribute to the hospitality costs only where most of the guests or the professional knowledge comes from other countries, making it more appropriate, for logistical reasons, to hold the event outside Switzerland. The arrangements should be approved by the company affiliate which organises and is responsible for the event, irrespective of the place where the hospitality takes place.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Cost contributions, including hospitality, in connection with an educational event are permissible under certain conditions (*cf.* answer to question 5.1). It is not permissible to pay a HCP for his time only. For the compensation of expert services, *cf.* answer to question 5.4.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

If pharmaceutical companies organise scientific congresses, they are liable for the organisation of such congresses and may become liable for its content (e.g. infringement of the advertising regulations). They are also responsible for ensuring that their hospitality arrangements comply with the law.

In case pharmaceutical companies only sponsor but do not organise the congress, they generally state in the contract with the event organiser that the organiser is responsible for the organisation and content of the congress and that the organiser has to comply with the applicable laws and codes. Therefore, the sponsoring company usually cannot be held responsible for the content of the congress and the hospitality arrangements, as they do not influence them.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

It is permissible to pay HCPs to provide expert services (e.g. participating in advisory boards), provided that this payment is based on a written agreement stating the nature and scope of the payment and service, and provided that the payment is equivalent to the service (article 55(2) TPA and article 7 VITH).

According to the Pharma Code, there must be: (i) a justified need for the proposed consultancy task or service; (ii) the engaged HCPs must be qualified to perform the tasks; and (iii) no more HCPs will be entrusted than needed.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Compensation for equivalent services provided by HCPs or HCOs (e.g. for carrying out scientific studies and clinical trials) is permissible if: (i) the compensation is based on a written agreement stating the nature and scope of the compensation and service; and (ii) the compensation is equivalent to the service provided (article 55(2)(c) TPA and article 7(1) VITH). No compensation may be paid for services which HCPs: (i) provide for themselves; (ii) provide in fulfilment of legal obligations (e.g. reporting of adverse events); or (iii) for which HCPs are otherwise compensated (article 7(2) VITH).

Under these conditions, it is admissible to pay HCPs for their services in post-marketing surveillance studies. In any event, the performance of post-marketing surveillance and clinical studies must remain independent from the purchase of medicinal products by the researchers and their employers.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

It is in our view permissible to pay HCPs to take part in market research involving promotional materials, provided that the requirements of article 55(2)(c) TPA and article 7(1) VITH are met (*cf.* answer to question 5.5).

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

It is possible to advertise non-prescription medicines to the general public (article 31(1)(b) TPA and article 14 AWV). However, no advertisement is allowed for medicinal products that: (i) contain narcotic or psychotropic substances; (ii) may not, on account of their composition and their intended use, be used without the intervention of a physician for the necessary diagnosis, prescription or treatment; or (iii) are frequently the object of abuse or lead to addiction or dependence (article 32(2)(b) to (d) TPA). Moreover, radio and television advertising addressed to the general public for medicinal products containing alcohol and intended for oral administration are only permitted if they contain less than 0.5g of pure alcohol in the maximum single dose according to the recommended dosage (article 20 AWV).

Advertisements addressed to the general public must not be misleading, incite abusive, excessive or inappropriate use of medicinal products, or be contrary to public morality and order (article 32(1) TPA). Exaggerations are prohibited, statements have to be in line with approved product information and advertisements must be recognisable as such (article 16 AWV). Specific advertisement elements that are not allowed to be used are listed in article 22 AWV.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

It is prohibited to advertise prescriptions-only medicines to the general public (article 32(2)(a) TPA and article 14 AWV).

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Information of a general nature concerning health or diseases,

provided that this information does not relate directly or indirectly to specific medicinal products, are not regarded as medicinal product advertising (article 1(2)(c) AWV). Therefore, disease awareness campaigns without references to a medicinal product encouraging patients with a particular medical condition to consult their physician are allowed.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Press dossiers and press releases which refer directly or indirectly to a specific prescription-only medicinal product may also be made accessible to media professionals of non-scientific journals. In the case of presentations of new medicinal products or active substances under development as well as the future perspective and focus of the company's research and development activities, only the name of the medicinal product, the name of the active substance and the therapeutic area or the area of application should be mentioned.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

It is permissible to describe research initiatives as background information in corporate brochures and annual reports. Describing manufacturing and research activities is also allowed. However, advertising specific prescription-only medicinal products, indications or contraindications is prohibited.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Pharmaceutical companies must respect the independence of patient organisations. Advertising prescription-only medicines through patient organisations is generally prohibited. Pharmaceutical companies must not require patient organisations to promote specific prescription-only products.

Besides that, it is lawful to support patient organisations. If the organisation must be defined as a HCO, in the meaning of the VITH, support contributions for education, research, teaching or infrastructure are permissible if they are: (i) not offered, promised or granted to a single HCP, but to the organisation employing the HCP; (ii) based on a written agreement stating the intended use; (iii) used exclusively for the intended purpose; (iv) not subject to conditions or requirements concerning the prescription, dispensing, use or purchase of certain prescription-only medicines; (v) transferred to a designated account of the organisation to which HCPs do not have access individually; and (vi) shown in the accounts of the organisation (article 55 (2) (b) TPA and article 4 VITH).

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Pharmaceutical companies may provide items to or for the benefit of patients for free. With regard to items provided directly to patients, the rules of the UCA also have to be taken into account. In particular, it is illicit (i) to deceive the patient by means of gifts about the actual value of the offer, and (ii) to impair the patient's freedom of decision by using particularly aggressive sales methods (article 3(g) and (h) UCA).

Specific rules apply to the distribution of free medicinal product samples by retailers to patients. Medicinal product samples only can be distributed to patients under the following conditions: (i) they must be clearly and permanently labelled as "sample for free"; and (ii) they must contain only the recommended dose for one day (article 19(1–3) AWV). Furthermore, samples can only be distributed by persons entitled to dispense them (article 19(4) AWV).

If pharmaceutical companies provide items for the benefit of patients to HCPs, the limitations described in the answer to question 4.2 apply.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

The Federal Act on Research involving Human Beings (Human Research Act, hereinafter "**HRA**", https://www.admin.ch/opc/en/classified-compilation/20061313/index.html) requires transparency in clinical research. All approved clinical trials must be registered in a public registry and the results must be published after the trial's closure (article 56 HRA). The sponsor must register approved trials in a World Health Organization ("**WHO**") primary registry or in the registry of the US National Library of Medicine. Additionally, specific trial information must be published in the database of the Federal Council (article 64 *et seq*. Clinical Trial Ordinance, hereinafter "**ClinO**", https://www.admin.ch/opc/en/classified-compilation/20121176/index.html). Public access to information on clinical trials conducted in Switzerland are available on the SNCTP Portal (https://www.kofam.ch/de/studienportal). Trial information must be registered before the clinical trial starts.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There is no such requirement.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

The Pharma Cooperation Code requires disclosure of monetary benefits granted by pharmaceutical companies to HCPs or HCOs. Pharmaceutical companies have to disclose the transfers of value annually and this information must remain accessible

to the public for at least three years. Disclosure shall be done wherever possible and legally permitted, on an individual basis, to clearly identifiable HCPs, HCOs or patient organisations with the relevant amounts paid. The compensation for the service or consultancy tasks and the reimbursement for the related costs of the service providers have to be disclosed separately. Pharmaceutical companies are not obliged to disclose via a central platform but disclosures shall take place on their corporate website. The disclosure duty applies to all pharmaceutical companies which are bound by the Pharma Cooperation Code. It may apply to pharmaceutical companies that have not yet been granted a marketing authorisation. Companies located outside Switzerland (apart from the Principality of Liechtenstein) cannot become members of the Pharma Cooperation Code, but they may be subject to transparency rules of their country.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

A pharmaceutical company should, whenever possible, disclose pecuniary benefits on an individual basis (rule 272 Pharma Cooperation Code). If the HCP refused to give consent, the disclosure has to be made in aggregated form without mentioning the identity of the HCP. The pharmaceutical company may consider not to conclude contracts with the HCP anymore.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Swissmedic has issued various guidelines concerning the advertising of medicinal products on the Internet, but there are no specific legal rules regarding Internet advertising. The general rules apply. In particular, no advertisement for prescription-only medicinal products may be made freely accessible on the Internet (on a domain ending on .ch or addressed to the Swiss market). Advertising for prescription-only medicinal products on the Internet must be password-protected and only accessible to HCPs.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

Pharmaceutical companies must ensure that advertisements for prescription-only medical products are accessible only to HCPs, e.g. by providing password-protected access. The Federal Administrative Court has confirmed that the password protection requirement requested by Swissmedic is the mildest suitable measure to enforce the ban on public advertising for prescription-only medical products (decision of the Federal Administrative Court of 24 April 2009, C-4173/2007). A self-declaration of the visitor is not sufficient.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

The placement of a link to a third-party website is permitted; however, such links may not be used to circumvent the advertising provisions. In principle, the provider of a website bears sole responsibility for the content of its website. However, the context and the thematic reference in which a link has been set, as well as the technical method used, can sometimes establish responsibility of the provider of a website for the content on the linked website. For example, in the case of so-called framing, Internet users are led to different (including third-party) websites without leaving the originally selected website. This enables the author of a website using this technique to incorporate the content of external websites into his own website. Swissmedic recommends that a warning notice be switched on if the website is left by clicking on a link. The warning notice should clearly express that by clicking of the link to the website of a foreign third party the user leaves the website and conformity with the requirements of Swiss legislation cannot be guaranteed (Swissmedic Journal 08/2006, p. 798).

In case of linking to a company website on a third-party website, the company will normally only be liable for its own website.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Pharmaceutical companies may publish information about the company itself, its activities, its therapeutic fields, its projects and investor information. No advertising for prescription-only medicinal products may be freely accessible on the Internet.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

There are no specific legal provisions regarding the use of social media by pharmaceutical companies. However, Swissmedic issued some recommendations concerning this aspect. The prohibition of advertising of prescription-only medicines and the advertising rules set out in the TPA and AWV also apply to social media.

In particular, it should be taken into account that advertising addressed to the general public may not contain recommendations by laypersons or medical experts (article 22(g) AWV). The publication of feedback of patients with regard to their experiences with specific medicinal products is therefore not permitted. It should also be mentioned that the use of the "Share" or "Like" functions on community tools, such as Facebook or YouTube, are considered as prohibited lay recommendations by Swissmedic.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

The TPA and its implementing ordinances have been revised. The revised AWV came into force on 1 January 2019. Furthermore, on 1 January 2020, new rules on pecuniary benefits came into effect. The former article 33 TPA was replaced by articles 55–56 TPA and the VITH. Unlike the former rule, the prohibition of granting undue material benefits in its present version applies only to HCPs prescribing, dispensing, using or

buying prescription-only medicines and HCOs employing such HCPs (article 55 TPA). As principal novelty, the revised TPA contains an explicit transparency obligation (article 56 TPA): All parties involved in the purchase and sale of therapeutic products have to fully disclose any discounts and refunds in their receipts, invoices and accounting records upon request to FOPH.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

Revision works on the Pharma Code and Pharma Cooperation Code are currently underway. The revised versions should enter into force in July 2020 at the earliest and in January 2021 at the latest. In the field of integrity and transparency, FOPH has become responsible for implementing the new provisions of articles 55 and 56 TPA on 1 January 2020. It may be expected that decisions of the FOPH will provide more clarity regarding its interpretation of the new legal provisions. In particular, decisions on the admissibility or inadmissibility of discounts respectively on the question of when discounts may influence the choice of therapy are expected. Due to the newly created competences of the FOPH with regard to the enforcement of the TPA, it may be expected that the ban of undue benefits will be more actively enforced.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

In recent years, Swissmedic has been the main enforcement authority for violations of the TPA. Since 2020, the FOPH and the Federal Customs Administration have also been given authorisation to enforce certain rules of the TPA (article 90 TPA). It is likely that this will strengthen the enforcement of the law.

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