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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2018

15th Edition

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group, with contributions from:

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Published by
Global Legal Group Ltd.
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London SE1 3PL, UK
Tel: +44 20 7367 0720
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Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

GLG Cover Design
F&F Studio Design

GLG Cover Image Source
iStockphoto

Printed by
Stephens & George Print Group
June 2018

ISBN 978-1-912509-16-4
ISSN 1743-3363

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Country Question and Answer Chapters:

Switzerland

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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 Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, hereinafter "**TPA**", https://www.admin.ch/opc/en/classified-compilation/20002716/index.html) is the main statute regulating advertising of medicinal products and medical devices. The TPA sets forth the requirements for the manufacture, marketing authorisation, wholesale, distribution, dispensing and advertising of medicinal products. The Federal Ordinance on the Advertisement of Medicinal Products also provides for rules on advertising of medicinal products (hereinafter "**AWV**", https://www.admin.ch/opc/de/classified-compilation/20011778/index.html, no translation in English available).

Moreover, there are several guidelines enacted by Swissmedic, the agency responsible for the authorisation and supervision of therapeutic products, ruling specific forms of advertising of medicinal products and published in the Swissmedic Journal (www.swissmedic.ch).

Among the guidelines on the interaction between industry and healthcare professionals (hereinafter "**HCPs**") enacted by the industry, the Pharma Code and the Pharma Cooperation Code by Sciencesindustries (https://en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code) based on private law and binding the vast majority of pharmaceutical companies operating in Switzerland, shall be mentioned.

1.2 How is "advertising" defined?

The advertising of medicinal products is defined as all measures of information and promotional purposes, for cultivating marketing and for creating incentives with the goal of promoting additional dispensing, sales, consumption or use of medicinal products (article 2(a) AWV). Advertising includes both advertising to HCPs and advertising to the general public, as well as the offers of material benefits to professionals.

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 is required to elect a person who is responsible for the advertising of the medicinal products it distributes in Switzerland (article 25 AWV). He or she must ensure that the advertising materials are compliant with the statutory regulations, 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 the enforcement of Swissmedic's requests.

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 marketing authorisation holder by law has to elect a person who is responsible for compliance of the advertising of the medicinal products. This person must have a scientific, medical or similar formation or experience. In addition, the Pharma Code requests pharmaceutical companies set up a scientific service which is responsible for information about their medicinal products and for ensuring the conformity of all promotional and information materials with the Pharma Code and applicable laws (rule 53 Pharma Code). Despite this, no specific SOPs have been enacted yet.

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?

Any advertising to the general public – regardless of the medium used (aired on radio, TV or cinemas, or published in printed or electronic media) – for preparations of the so-called sensitive groups (analgesics, sleep-inducing products, sedatives, laxatives and anorexics) with a potential for dependence or abuse mentioned in the medicinal product information must be submitted to Swissmedic for prior written approval (article 15(a) and (c) and 23(1) AWV, *cf.* Swissmedic Journal 8/2016, p. 644 *et seqq.*). The procedure for approval is divided into two stages. First, the intended project is assessed based on a script or storyboard and approved or rejected by a preliminary decision. In a second stage, the final advertising product must be submitted to Swissmedic for final approval.

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 has the authority to enforce the TPA and the AWV through different administrative measures (article 66 TPA). It may seize, hold in official storage, destroy or prohibit the use of illegal advertising media, and publish the prohibition at the expense of the responsible parties. Moreover, it may temporarily or permanently stop the advertising of a specific medicinal product in the event of serious or repeated infringements of the TPA and AWV provisions, and publish the prohibition at the expense of the responsible parties (article 66(2)(f) and (g) TPA). Generally, Swissmedic may inform the general public about medicinal products that endanger health, in particular regarding authorisation and revocation decisions as well as about amendments to professional and patient information (article 67(1) TPA). Administrative measures ordered by Swissmedic can be appealed with the Federal Administrative Court or the Swiss 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?

Any person who contravenes the regulation on the advertising of medicinal products shall be liable to a fine of up to CHF 50,000 (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 that person acts in a professional capacity, the penalty shall be a custodial sentence of up to three years or a monetary penalty (article 87(2) TPA and article 333(2) and (5) SCC).

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, e.g. when the non-compliant advertising is displayed at a professional congress only, the penal cantonal authorities are responsible (article 90 TPA).

The rules are strictly enforced. An important and contentious example was the prosecution of Pfizer for the distribution of a brochure on migraines and their medical treatment, in which Swissmedic recognised a non-permitted promotion of the medicinal product Relpax (decision of the Swiss Supreme Court 2A.63/2006).

The TPA does not provide rules for civil claims. Therefore, competitors have to base civil claims on alternative statutory provisions to file an action with a court such as potentially under tort law or the Federal Act against Unfair Competition (Unfair Competition Act, hereinafter "**UCA**", https://www.admin.ch/opc/de/classified-compilation/19860391/index.html#a3, no translation in English available).

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 very active in marketing surveillance and does not tolerate the infringement of advertising statutory provisions. Accordingly, competitors often contact Swissmedic and require its intervention when they become aware of the infringement of advertising provisions. Swissmedic may also take up matters based on an adverse finding of a self-regulatory body. Often used as a first choice by competitors is, however, also the filing of a complaint with the Pharma Code Secretariat (self-regulatory body), which is responsible for the implementation of the Pharma Code and also indirectly verifies the compliance of advertising with TPA and AWV regulations. By choosing the Pharma Code Secretariat, pharmaceutical companies avoid being exposed to penal administrative proceedings, which may be effort- and time-consuming.

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?

Any incorrect or misleading statements about its own products (article 3(1)(b) UCA) or about the products of competitors (article 3(1)(a) UCA), as well as any measures that may cause confusion with competitors' products or business (article 3(1)(d) UCA), can be challenged in civil or penal unfair competition proceedings by competitors. Cantonal courts have exclusive jurisdiction and their decisions can be appealed with the Swiss Supreme Court. Within civil proceedings, provisional measures may be obtained quickly 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)?

Scientific information can be made available to HCPs before the medicinal product has obtained marketing authorisation under specific circumstances, e.g. at scientific meetings, but advertising of such medicinal products remains strictly prohibited (article 32(1)(c) TPA). In any case, it must always be clearly stated that the medicine is not yet authorised by Swissmedic (rule 242 Pharma Code). The

same rules basically apply to off-label information. Advertisements for off-label use of a medicine are unlawful (article 5(1) AWV), but not information on off-label use of a medicinal product, namely in scientific articles or congress reports.

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

Such information may be published as long as it does not qualify as advertisement (e.g. scientific articles).

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. main stream public media) please specify.

Pharmaceutical companies may issue press releases about unauthorised medicines and off-label information. It is legal to use the brand name; however, the International Nonproprietary Name ("**INN**") of the compound has to be used as well. Nevertheless, companies should make sure that press releases are not interpreted as unlawful advertising acts (rule 241 Pharma Code). For this, press releases should not be published in mainstream public media but only in specialised medical or scientific media.

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

It is permitted for pharmaceutical companies to send off-label information to HCPs. They may also inform HCPs about new indications, possible applications, dosages, pharmaceutical forms and packing of medicinal products (rule 241 Pharma Code). In any event, it must always be clearly stated that this medicinal product has not yet received marketing authorisation from Swissmedic (rule 242 Pharma Code).

It is not required that a single HCP requests information. However, it is unlawful to send unrequested mass mailing to HCPs (article 3(1)(o) UCA).

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?

The *Ludwigs* case has not yet been reflected in the Swiss legislation or in practical guidance in Switzerland. Independently of the above judgment, since 2002, the AWV states in article 1(2)(b) that its rules on advertisement do not apply to price lists. As a consequence, it is likely that the availability of price lists for non-approved medicinal products to pharmacists are not to be considered non-permitted off-label advertisements.

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?

Considering that most medicinal products are listed for reimbursement by healthcare insurers and that the prices for such products are determined by regulatory authorities only after the new medical indications are approved and immediately before the products are distributed on the Swiss market, there is no reason for a pharmaceutical company to disclose information on unauthorised medicines just for budget proposals. Under these circumstances, it is likely that such information would qualify as an unlawful advertisement.

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?

In principle, it is not prohibited for pharmaceutical companies to engage with HCPs for consultancy services (rule 211 Pharma Cooperation Code). Essentially, HCPs' involvement needs to be transparently disclosed by the pharmaceutical company. As market research is conducted with the purpose of advertising off-label indications to HCPs only (e.g. for non-scientific publications), engagement with HCPs is to be considered an unlawful advertising measure.

3 Advertisements to Healthcare Professionals

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

Any advertisement to HCPs must be recognised as such and editorial contributions must be clearly separated from advertisements (article 5(4) AWV). The content of the advertisement must comply with the product information approved by Swissmedic, in particular with regard to the indications and contraindications (article 5(1) AWV). In order to be comprehensive, the following information must be contained in advertisements: (i) drug name (brand); (ii) INN of the compound; (iii) name and address of the marketing authorisation holder; (iv) at least one indication or use of the medicine, as well as the dosage and the method of application; (v) a summary of the restricted use, contraindication 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).

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?

Advertisement is limited to the authorised indications and use of the medicine (article 5(1) AWV). In addition, the advertisement 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). Moreover, statements must be accurate, truthful, well-balanced, provable by up-to-date scientific findings, and must not be misleading. All statements in the advertisement have to comply with the medicinal product information authorised by Swissmedic (which in Switzerland corresponds to the SmPC (summary of product characteristics)). Reference to studies is only allowed if they fulfil the requirements of good clinical practice and have been published or accepted for publication (article 5(5) AWV). In addition, statements based on findings of new studies which do not correspond with the approved product information may not be used for advertisement (*cf.* decision of the Federal Administrative Court C-5490/2015).

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

Endorsements by HCPs are permitted in advertisements. In any event, their content must be well-balanced, not misleading and the endorsing HCPs must be 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?

Comparative advertisements must be based on at least one study. The study has to fulfil the requirements of good clinical practice and must have been published or been accepted for publication (article 7(1) AWV). As long as 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 advertising is permitted in Switzerland (article 7 AWV). However, the comparison has to be scientifically correct and must be based on at least one scientific study. It is also possible to expressly mention the brand names of competitors. Since Swiss law prohibits advertisement for unauthorised medicines or indications, no reference to such medicinal product or indication is permitted.

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

The general advertising rules apply. In particular, advertisements may not be disguised as scientific papers and/or proceedings of congresses (article 5(4) AWV) and then be distributed to HCPs.

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?

Advertisements directed to HCPs have to be informative (article 6 AWV). So far, it is likely that a teaser advertisement to alert HCPs that something new will follow without any additional information does not comply with this requirement.

4 Gifts and Financial Incentives

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

Pharmaceutical companies may provide material benefits of modest value to HCPs or healthcare institutions (article 33(3)(a) TPA). Such material benefits include product samples.

Free product samples can be handed over to HCPs under the following limitations: (i) sample packs must not be bigger than the smallest packs available for sale on the market (article 10(2)(c) AWV); (ii) they must be clearly and permanently labelled as "sample for free" (article 10(2)(a) AWV); and (iii) they must contain the approved patient information leaflet (article 10(2)(a) AWV). Moreover, product samples may only be distributed to HCPs who have expressly, and in writing, requested them (article 10(1) AWV) and only in small quantities (such quantities vary depending on the medicinal products (article 10(1) and (4) AWV)). According to Swissmedic, permitted quantities are (i) five sample packs per year and per medicinal product for each HCP in the first two years since the product launch, and (ii) two sample packs per year and per medicinal product for each HCP as of the third year from the product launch). Specific rules apply to narcotics and psychotropics (*cf.* article 56(3) on the Federal Ordinance on the Control of Narcotics, https://www.admin.ch/opc/de/classified-compilation/20101221/index.html, no translation in English available). The owner of the marketing authorisation is obliged to keep a record of all distributed product samples (article 10(5) AWV).

Please note, also with regard to the answers to the other questions below, that the revision of the TPA, which should soon come into force, will lead to some changes regarding the rules on material benefits (*cf.* the answer to question 9.2).

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.

Swiss law allows the grant of promotional gifts and other material benefits of modest value to HCPs if such benefits are relevant to the medical practice (article 33(3)(a) TPA). Federal authorities have determined that such material benefits may not exceed CHF 300 per year and individual recipient. Irrespective of its value, gifts without relevance to the medical practice (e.g. concert tickets or a bottle of wine) are prohibited.

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.

Any free contributions to healthcare organisations for the development of new products and for research activities in the form of equipment donations, funding of medical and technical services or in cash, are permitted. The same rules apply to donations to (public and private) institutions employing HCPs. Any donation in kind or in cash must be based on a written agreement and openly disclosed to the public in detail by the donating manufacturer of medicinal products (*cf.* rules 221–293 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?

Objects, information and training materials of moderate value can be provided to HCPs if they are used for post-graduate or continuing education and are beneficial to patients. Such goods and services are not covered by the obligation of disclosure (rule 233.3 Pharma Cooperation Code).

Against it, any other pecuniary benefits that constitute an inducement to recommend, prescribe, acquire, supply, sell or administer specific medicinal products are generally prohibited (article 33 TPA).

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?

Commercially and economically justified discounts which directly reflect on the price are permitted (article 33(3)(b) TPA). Reasons for economically justified rebates may be rebates on volume, if and as far as they reduce storage and other costs of the supplier. Other than rebates granted based on economic reasons, usual commercial discounts do not need to be justified by cost saving, but may be given for the introduction of a new product or for the maintenance of a customer. Usual commercial rebates can also be volume related.

The permissible range for rebates is not mentioned in the TPA. According to case law, (i) a rebate of 33% during one month to introduce a new product has been considered to be exceptionally high, and (ii) a discount of 1–25% may be seen as economically and commercially justifiable. According to Swissmedic, even rebates of 90% might qualify as usual commercial discounts if they are granted within a regular procurement process (*cf.* Swissmedic Journal 11/2012, p. 1054). In any case, rebates need to be transparent in a way that allows the assessment of their commercial and/or economic justifications and, eventually, their benefit to healthcare insurers and patients (article 56(3) of the Health Care Insurance Act, hereinafter "**KVG**", https://www.admin.ch/opc/de/classified-compilation/19940073/index.html, no translation in English available). In that sense, rebates have to be mentioned in receipts and invoices, as well as in the accounting records of the suppliers.

Because they reflect economic consideration, volume rebates are permitted in the following forms: (i) linear rebates or scale (for each defined of quantity) rebates; (ii) rebates on an estimated (and not on the actual) turnover; and (iii) rebates corresponding to the actual cost savings, always provided that no customer discrimination takes place.

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?

Under Swiss law, it is possible to offer additional contingent medical or technical services upon separate remuneration or as part of the original purchase price (as a "package deal"), provided that such material benefits (i) are not bound to a minimum order quantity for the medicinal products, (ii) are clearly disclosed in receipts and invoices as well as in the accounting records of the supplier, and (iii) can be forwarded to healthcare insurers, where healthcare insurance pays for such additional medical or technical services (article 56(3) KVG).

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?

Even if not expressly prohibited, in most constellations refund schemes are likely not to be permitted. A refund retained by HCPs is a pecuniary benefit that should be forwarded to patients or their healthcare insurers (article 56(3) KVG). Even if forwarded to patients and healthcare insurers, refund offers may be seen as an inducement to prescribe non-appropriate medicinal products (against the principle stated in article 56 KVG). With regard to over-the-counter medicines, and taking into account the guidelines for free samples (article 19 AWV), refund schemes may be permitted, provided that they do not unnecessarily increase the use of medicinal products, if they are strictly limited in time and amount (article 32(1)(b) TPA).

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

The grant of financial contributions to the continuing medical education of HCPs is permitted to the extent that (i) there is no (direct or indirect) connection with the prescription or provision of medicinal products, and (ii) participating HCPs pay a substantial contribution to the educational costs (at least 20% (for HCPs in formation) or 33% (for all other HCPs) of all costs, including participating fees). The supporting programme shall not exceed 20% of the duration of medical educational events and of the costs thereof (see Swissmedic Journal 1/2006, p. 20 *et seqq*.). Most healthcare organisations also request that the grant of sponsoring continuing medical education does not favour individual HCPs. Finally, objects, information and training materials of moderate value used for continuing education may be provided by pharmaceutical companies (rule 143.3 Pharma Cooperation Code).

4.9 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 33 TPA contains specific rules on bribery in relation to interactions between pharmaceutical companies and HCPs or HCIs. In addition to these provisions, the general anti-bribery rules stated in the Swiss Criminal Code are applicable to cases of bribery in the healthcare sector (*cf.* article 322*ter et seqq*. SCC). Swissmedic

has the statutory mandate to ensure compliance with pharmaceutical advertising as well as the specific rules on bribery. Swissmedic may therefore act as prosecuting authority in this area. At the same time, also the cantonal criminal authorities have to prosecute bribery cases. The delimitation of competence between the authorities has to be assessed on a case-by-case basis.

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?

Rules on permitted hospitality to HCPs are set off both in statutory regulations (article 33 TPA, article 56 KVG) and in the codes of conduct (rule 37 Pharma Cooperation Code). HCPs may accept hospitality contributions to their continual education and participation in scientific conferences, provided that the sponsoring relationships are kept transparent and do not qualify as granting material benefits.

If scientific conferences and events take place outside Switzerland, 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 logistic reasons to hold the event outside Switzerland (rule 376 Pharma Cooperation Code). The arrangements should be approved by the company affiliate organising and being responsible for the event, irrespective of the place where the hospitality takes place.

Also, regardless of where the scientific and educational events take place, HCPs that dispense medicinal products in Switzerland must pay a substantial contribution to the educational costs (*cf.* the answer to question 4.8). Payment for meals (including beverages) must remain on a reasonable and modest scale, subject to a maximum of CHF 150 per healthcare professional per meal for events that take place in Switzerland (rule 143.5 Pharma Cooperation Code).

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?

Hospitality contributions may be offered to HCPs in connection with their participation in scientific congresses. Such contributions must be confined to the journey, subsistence, accommodation and participation fees of the participating HCP. Hospitality must not include the support (sponsorship) or organisation of entertainment (e.g. sport or leisure activities) or the costs of accompanying persons (article 11(2) AWV). Also, indirect costs, such as loss of working time, cannot be compensated. A direct payment is only permitted if, and to the extent, the HCP assumes an active task during the scientific meeting (e.g. as speaker).

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?

Pharmaceutical companies are permitted to organise or carry out scientific congresses. In respect of such congresses, pharmaceutical companies may also be held responsible for the content. However, pharmaceutical companies cannot be held responsible for the content of scientific meetings they sponsor but do not organise – as they do not influence the content.

In any case, pharmaceutical companies remain liable for infringement of the advertising regulations, e.g. through non-permitted hospitality arrangements, during scientific meetings (article 87(1)(b) TPA).

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

Pharmaceutical companies may entrust HCPs with consultancy tasks or services, such as papers and the conduct of meetings, medical or scientific studies, clinical trials, training and participation in advisory boards, and provide reasonable compensation, according to the usual standards. Such expert services are permitted insofar as they do not result in material benefits granted to HCPs. The following requirements must also be complied with: (i) there must be a justified need for the proposed consultancy task or service; (ii) the retained HCPs must be qualified to perform the tasks; (iii) no more HCPs will be entrusted than needed; and (iv) consultancy tasks or services must be documented (rule 213 Pharma Cooperation Code). In this regard, the recommendations of the SAMW "Collaboration between the medical profession and industry" guidelines (http://www.samw.ch/en/Publications/Medical-ethical-Guidelines.html) should be taken into consideration.

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

HCPs are generally permitted to take part in clinical research, including post-marketing surveillance studies. Such studies must be carried out according to legal regulations and strict principles of good practices and based on a written agreement; the researchers and their co-workers must not have personal financial interest in the results of the clinical research. The recommendations of the SAMW "Collaboration between the medical profession and industry" guidelines should also be taken into consideration here.

If the researchers work for a healthcare institution (hospital, university, etc.), the clinical research has to be transparently disclosed to this institution. In addition, compensations are to be paid out on institutional separate accounts of the receiving institution. 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 possible to engage HCPs in promotional activities. However, HCPs who write or speak in public about matters which are the subject matter of research agreements concluded with a pharmaceutical company must clearly disclose their relationship (rule 214 Pharma Cooperation Code). Researchers responsible for or involved in a trial must not undermine their independence by participating in marketing campaigns for the product or procedure investigated.

More generally, advertisements to the public must not contain recommendations by HCPs or references to clinical research performed by them (article 22(g) AWV).

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?

Non-prescription medicines can be advertised to the general public (article 31(1)(b) TPA and article 14 AWV). However, no advertisement is permitted for medicines 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 doctor for the necessary diagnosis, prescription or treatment; or (iii) are frequently the object of abuse or lead to an addiction or dependence (article 32(2)(b) to (d) TPA). In addition, an advertisement to the general public for medicines with a recommended dosage of more than 0.5g of pure alcohol cannot be made on radio and television (article 20 AWV).

Advertisements to the 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?

Prescription-only medicines cannot be advertised 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?

Disease awareness campaigns encouraging patients with a particular medical condition to consult their doctor are permitted. However, if medical campaigns directly or indirectly refer to a specific prescription-only medicine (*cf.* decision of the Swiss Supreme Court 2A.63/2006, please see the answer to question 1.7), they amount to unpermitted advertisements towards the general public.

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?

Swiss law limits the advertisement for prescription-only medicines in journals to the ones directed to HCPs (article 4(a) AWV). In line with that, press releases for developments in relation to as yet unauthorised medicines and/or indications are not allowed.

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

Factual background information about the manufacture and research activities of pharmaceutical companies published in corporate brochures is not considered to be of an advertising nature, provided that no specific (prescription) medicinal products, indications or contraindications are described in detail. Detailed descriptions of medicinal products in an information brochure would circumvent the limitations on advertisement for medicines.

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

Any direct or indirect advertisements for prescription-only medicine through meetings or the funding of patient organisations are generally prohibited. In addition, pharmaceutical companies must not require patient organisations to promote specific products. Besides that, it is lawful to meet and to fund patient organisations. Where pharmaceutical companies grant financial or other support on a significant scale to a patient organisation, they must agree such support in writing and accurately describe the nature and the purpose of such support (rule 3 Pharma Cooperation Code).

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?

As such, it is not prohibited to provide items to or for the benefit of patients for free, as far as the patient is aware of the offer's gratuity and the healthcare insurance is not charged. As far as companies provide items for the benefit of patients to HCP, the limitations described in answer to question 4.1 apply. With regard to items provided directly to the patient, the rules of the UCA also have to be observed. In particular, it is illegal (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 free medicinal product samples provided to patients. Medicinal product samples can be distributed to patients under the following limitations: (i) they must be clearly and permanently labelled as "sample for free"; (ii) they must contain the approved information and texts on the containers and packing materials; and (iii) they must contain only the recommended dose for one day (article 19(1) and (2) AWV). Furthermore, medicinal products of certain categories can only be distributed by persons entitled to dispend them and not offered at self-service places (article 19(3) AWV). Finally, it is prohibited to sell samples for free (article 19(4) AWV).

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?

Switzerland has adopted transparency in clinical research with the enactment of the Federal Act on Research involving Human Beings (Human Research Act, hereinafter "**HRA**", https://www.admin.ch/opc/en/classified-compilation/20061313/index.html) and its ordinances in January 2014. All approved clinical trials must now be registered in a public registry and the results published after the trial's closure (article 56 HRA). The sponsor must register approved trials in a WHO primary registry or in the registry of the US National Library of Medicine (www.clinicaltrials.gov). Additionally, specific trial information must be made publicly available in the national language in the database of the Federal Council (article 64 *et seqq*. Clinical Trials Ordinance, https://www.admin.ch/opc/en/classified-compilation/20121176/index.html). Public access to information on clinical trials conducted in Switzerland is guaranteed by the SNCTP Portal (http://kofam.ch/en/swiss-clinical-trials-portal/). Trial information shall be registered before the start of the clinical trial.

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?

Swiss legislation does not oblige pharmaceutical companies to disclose information about the material benefits granted to HCPs or healthcare organisations. However, article 56(3) KVG requires transparency in the grant of rebates and of other material benefits in connection with prescription medicinal products, in order to allow a proper forwarding of the same to healthcare insurers and patients.

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?

Rule 23 *et seqq*. Pharma Cooperation Code requires the full disclosure of pecuniary benefits granted to HCPs or healthcare organisations. Pharmaceutical companies shall, in each case, disclose the pecuniary benefits annually and this information must remain accessible to the public for at least three years. Disclosure shall take place wherever possible and legally permitted, on an individual basis, to clearly identifiable HCPs with the relevant amounts paid; the remuneration for the agreed service or consultancy tasks and the compensation for the related costs of the service providers are to be disclosed separately. Companies are not obliged to disclose via a central platform but disclosure shall be done on their corporate website. The duty of disclosure applies to all pharmaceutical companies which are required to comply with the Pharma Cooperation Code. It may apply to companies that have not yet been granted a marketing authorisation. Foreign companies (apart from the Principality of Liechtenstein) cannot become members of the Pharma Cooperation Code and therefore do not need to respect these rules.

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?

According to rule 231 of the Pharma Cooperation Code, pharmaceutical companies shall disclose pecuniary benefits, which they grant to HCPs. The Pharma Cooperation Code also states that pharmaceutical companies shall stipulate in agreements with HCPs that the recipients of pecuniary benefits agree to disclose (rule 232). Without prior consent of the HCP, however, the pharmaceutical company would regularly breach the statutory data protection rights of that HCP by disclosing granted pecuniary benefits. The Pharma Cooperation Code is not a statute, which would allow the pharmaceutical company to justify the disclosure of the HCP's personal data without his/her prior consent. Accordingly, the Pharma Cooperation Code states that disclosure is not required if it is incompatible with the provision of data protection law (rule 234). Having said this, however, a pharmaceutical company should, whenever possible, disclose granted pecuniary benefits on an individual basis (rule 272 Pharma Cooperation Code).

8 The Internet

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

Advertisements on the internet directed to the general public are governed by the rules applicable to print advertisements. As all advertisements directed to the general public, advertisements on the internet for preparations of the sensitive groups with a potential for dependence or abuse mentioned in the medicinal product information must be submitted to Swissmedic for prior written approval (*cf*. the answer to question 1.5).

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?

Swissmedic requires that pharmaceutical companies must ensure that advertisements for HCPs are accessible only by them, e.g. by providing password-protected access (Swissmedic Journal 8/2006, p. 796 *et seqq*.).

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?

Pharmaceutical companies do not have the obligation to control the content of independent websites linked to their own website. However, this general rule may not apply where the linked webpage is part, or appears to be part, of a company's own website or where

the company is aware of the illegal content of the other webpage, but still provides a link on its own website.

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

On their publicly accessible websites, pharmaceutical companies may only place information that does not directly or indirectly qualify as an advertisement for prescription medicines.

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

The use of social media by pharmaceutical companies is not subject to specific rules. The prohibition for advertising of prescription medicines and the advertising rules set off in the TPA and AWV also apply to commercial information of pharmaceutical companies in social media.

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?

With effect from 1 January 2017, Swissmedic has changed its practice regarding the mandatory prior control of advertising directed to the general public: It is no longer necessary to submit any advertising that is going to be aired on radio, TV or shown in cinemas to Swissmedic but only advertising for preparations of the so-called sensitive groups (analgesics, sleep-inducing products, sedatives, laxatives and anorexics) if potential for dependence or abuse is mentioned in the medicinal product information (*cf.* answer to question 1.5). Thus, greater personal responsibility is placed with the originators of public advertising.

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

The TPA and its implementing ordinances are currently under revision and the new provisions will most likely come into force as per 1 January 2019.

As part of this revision, some provisions of the AWV will be amended. This concerns mostly only minor amendments which clarify the current wording or implement already existing practice. It should be noted, however, that the prior control of advertisings by Swissmedic shall be abolished completely.

More importantly, the current rule on pecuniary benefits (article 33 TPA) will be replaced by two new provisions (article 55 and 56 revTPA) and a newly created Ordinance on Integrity and Transparency in the Field of Therapeutic Products.

Unlike the current rule, the prohibition of granting undue material benefits will apply only to HCPs prescribing, dispensing, using or buying prescription-only medicines (article 55 revTPA). The list of exemptions to this *per se* prohibition will be amended. The exemption of granting material benefits of modest value to HCPs remains unaltered. Rebates and refunds, on the other hand, will be allowed under the revised rule if they do not affect the choice of treatment, which is primarily the case when discounts are forwarded to healthcare insurers and patients.

As principal novelty, the revised TPA provides for an explicit transparency obligation (article 56 revTPA). All parties involved in the purchase and sale of therapeutic products (including non-prescription products and medical devices) will have to fully disclose any discounts and refunds in their receipts, invoices and accounting records. In addition, the Federal Office of Public Health will have the competence to require the disclosure of these documents at any time.

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

The number of applications for prior control of advertisings has decreased in recent years, which is primarily due to changes in Swissmedic's practice on the necessity for prior approval. However, Swissmedic remains very active in enforcing advertising rules, mostly upon notifications of third parties.

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