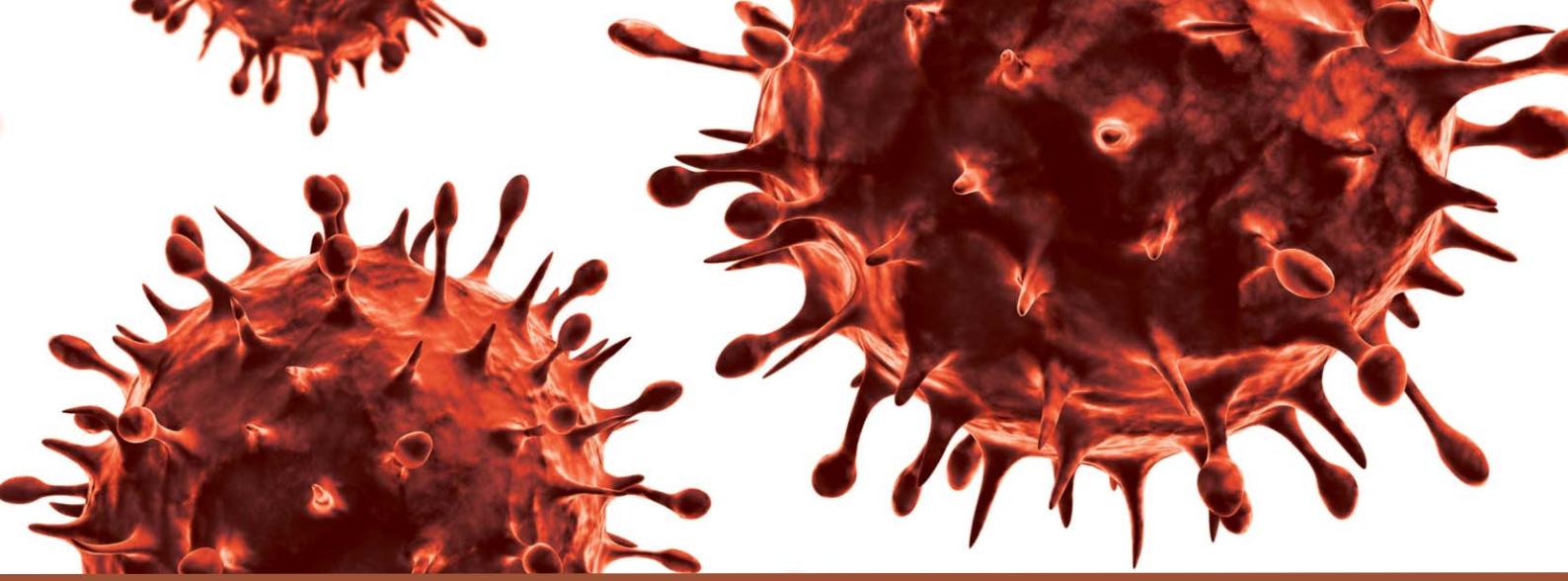


ICLG

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2014

11th Edition

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group, with contributions from:

A. Lopes Muniz Advogados Associados
Adams & Adams
Advokatfirmaet Grette DA
Arnold & Porter LLP
Arthur Cox
Biolato Longo Ridola & Mori
Boga & Associates
Clayton Utz
Clifford Chance
CMS Cameron McKenna
CMS, Russia
Debarliev, Dameski & Kelesoska Attorneys at Law
Edwards Wildman Palmer LLP
Faus & Moliner
Herbst Kinsky Rechtsanwälte GmbH
Hwang Mok Park P.C.
Jones Day
Jusmedico Advokatanpartsselskab
Life Sciences Legal Advocaten
Mannheimer Swartling Advokatbyrå
Mehmet Gün & Partners
Nishimura & Asahi
OLIVARES
PDG Avocats
Roschier, Attorneys Ltd.
Schellenberg Wittmer Ltd
Sołtysiński Kawecki & Szlęzak
Subramaniam & Associates (SNA)
Tilleke & Gibbins
Van Innis & Delarue
Vieira de Almeida & Associados

GLG
Global Legal Group

The International Comparative Legal Guide to: Pharmaceutical Advertising 2014

GLG
Global Legal Group

Contributing Editor
Ian Dodds-Smith,
Arnold & Porter (UK) LLP

Account Managers
Assel Ashirbayeva,
Edmond Atta, Beth Bassett,
Antony Dine, Dror Levy,
Maria Lopez, Florjan
Osmani, Paul Regan,
Gordon Sambrooks,
Oliver Smith, Rory Smith

Sales Support Manager
Toni Wyatt

Sub Editors
Nicholas Catlin
Amy Hirst

Editors
Beatriz Arroyo
Gemma Bridge

Senior Editor
Suzie Kidd

Group Consulting Editor
Alan Falach

Group Publisher
Richard Firth

Published by
Global Legal Group Ltd.
59 Tanner Street
London SE1 3PL, UK
Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

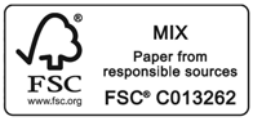
GLG Cover Design
F&F Studio Design

GLG Cover Image Source
iStockphoto

Printed by
Information Press Ltd
June 2014

ISBN 978-1-910083-03-1
ISSN 1743-3363

Strategic Partners



Preface:

General Chapter:

Country Question and Answer Chapters:

Further copies of this book and others in the series can be ordered from the publisher. Please call +44 20 7367 0720

Chapter 33

Switzerland

Andrea Mondini

Christine Beusch-Liggenstorfer

Schellenberg Wittmer Ltd

1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in Switzerland?

Advertising of medicinal products is governed by the Federal Law on Medicinal Products and Medical Devices of 15 December 2000 (in short: Law on Therapeutic Products), the Ordinance on Advertising for Medicinal Products of 17 October 2001 and, with regard to advertising to healthcare professionals, the Code of Conduct of the Pharmaceutical Industry in Switzerland of 4 December 2003 (revised in 2006, 2008, 2010, 2011, 2012 and 2013), issued by the Business Association Chemistry Pharma Biotech (in short: scienceindustries) together with all other important associations of the Swiss pharmaceutical industry (in short: Pharma Code). In 2013, scienceindustries, together with other important associations of the Swiss pharmaceutical industry, also issued the Code of Conduct of the Pharmaceutical Industry in Switzerland on Cooperation with Healthcare Professional Circles and Patient Organizations (in short: Pharma Cooperation Code). These two codes take into account, in particular, the codes issued by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), as well as the Guidelines issued by the Swiss Academy of Medical Sciences relating to collaboration between the medical profession and the industry which have been enacted in close cooperation with the FMH Swiss Medical Association (in short: SAMS/FMH Guidelines). Furthermore, the provisions of the Federal Law against Unfair Competition of 19 December 1986 must be observed.

The Pharma Code and the Pharma Cooperation Code, as well as the SAMS/FMH Guidelines, have no legal force, but are considered to be self-regulatory instruments for the pharmaceutical industry and the medical profession, respectively, providing the minimum standards to be observed.

1.2 How is "advertising" defined?

The Ordinance on Advertising for Medicinal Products defines the term "advertising for medicinal products" fairly broadly. All information, marketing and incentive measures that are aimed at encouraging the prescribing, dispensing, selling, using and administering of medicinal products fall into the category of advertising for medicinal products.

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?

As a rule, companies are not required to have specific arrangements in place to ensure compliance with the various laws and codes of practice on advertising. An advance "sign off" of promotional material is only mandatory in specific cases (with regard thereto, see question 1.5 below).

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

Pharmaceutical companies must have internal control measures in place ensuring the compliance of all advertising activities with the pertinent legislation. In particular, they must appoint a qualified person who assumes responsibility for the advertising activities and has, in particular, the following obligations: ensuring that the advertising activities comply with the legal provisions; ensuring that the requests of Swissmedic (as defined in question 1.5 below) are followed; providing Swissmedic upon request with all pertinent documents and information; retaining copies of all advertising material for a period of six months calculated from the last use of the material; and keeping a record of all recipients of advertising materials, as well as the form of publication and the date of first publication.

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?

As mentioned above, in principle, advertisements do not need to be approved in advance.

Advance approval is only mandatory for advertisements for medicinal products of categories C and D on the radio, television and in cinemas, as well as for advertisements to the general public in print media and through the use of audio-visual aids and other information media using pictures, sound, and data, as well as data transmission systems (including the Internet) for certain categories of medicinal products (analgesics, sleeping pills, sedatives and laxatives, as well as appetite suppressants). The approval body is the Swiss Agency for Therapeutic Products (in

short: Swissmedic). In principle, Swissmedic provides for a two-phase procedure: first, the applicant submits a project of the proposed advertisement in the form of a storyboard/script or of a draft, respectively, of the advertisement. The documents submitted must give a clear impression of the proposed advertisement (text in all language versions; a detailed description of action, picture and sound). If the project complies with legal requirements, Swissmedic will then invite the applicant to submit the final advertising tool produced in accordance with the documents submitted for final approval. Should the project not comply with the pertinent requirements, Swissmedic will inform the applicant accordingly, offering the chance to submit a new project.

Furthermore, in cases of severe or repeated violations of the pertinent rules governing the advertising of medicinal products, advanced approval of all proposed advertisements may be ordered by Swissmedic for a predefined period of time.

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, as the supervising body exercising control over advertising activities, may take all administrative measures necessary to enforce the law. In particular, 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 or even sentence the responsible parties to send a rectification statement to all recipients of previously received illegal or incorrect advertising media. Swissmedic may also file penal complaints with the competent cantonal public prosecutor. Decisions of Swissmedic may be appealed to the Federal Administrative Court. Decisions on the appeal may in turn be challenged before the Swiss Federal Supreme Court in Lausanne.

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? To what extent may competitors take direct action through the courts?

The criminal sanction for violating the rules on the advertising of medicinal products is a fine of up to CHF 50,000 if the perpetrator acted intentionally. If the person in question was acting in his/her professional capacity, the penalty is a fine of up to CHF 540,000. If the perpetrator acted negligently, the penalty is a fine of up to CHF 10,000.

Swissmedic is responsible for enforcement of the law. In the area of advertising to healthcare professionals, Swissmedic is supported by scienceindustries as far as the violations of the rules on the advertising of medicinal products have no impact on or do not endanger human health (see also question 1.8 below). Thus, Swissmedic and scienceindustries focus on quite different aspects of advertising of medicinal products.

Given the fact that each person or organisation has the right to notify Swissmedic and scienceindustries, respectively, of facts which might violate the pertinent rules governing the advertising of medicinal products, and that Swissmedic and, to the extent applicable, scienceindustries observe the market situation very carefully, the rules are very strictly enforced.

As a rule, the details of any action taken are not published. An exception to this rule may, however, be given if decisions of Swissmedic are appealed. In this connection it may be referred to a decision of the Swiss Federal Supreme Court in Lausanne rendered in August 2006 with which the court confirmed an earlier administrative measure issued by Swissmedic against Pfizer AG. The measure included the prohibition to the pharmaceutical company to distribute a deceptive brochure on headaches and migraines and sentenced the company to send a rectification statement to some 940,000 addressees, i.e., all persons who previously had received that brochure (with regard thereto, as well as comparable recent examples, see also question 9.3 below).

Competitors may take action directly through the courts and/or file a penal complaint in cases where the violation of the rules on the advertising of medicinal products also qualifies as an act of unfair competition (with regard thereto, see also question 1.9 below).

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?

As referred to above, there is only a limited area where the self-regulatory process goes in parallel with the enforcement competence of the competent authorities. Based on an agreement reached between Swissmedic and scienceindustries, the latter primarily investigates matters relating to advertising activities addressed to healthcare professionals under the angle of unfair competition and ethical considerations. All other cases, particularly where the violations of the rules have an impact on or endanger human health, are dealt with exclusively by Swissmedic. To the extent scienceindustries becomes active, it does so in an exclusive manner by issuing directives to the pharmaceutical company in question or requesting a commitment with regard to its future practice. Only in cases where the company does not comply with its commitments or where no agreement with regard to its future practice can be reached, scienceindustries immediately dispatches the affair to Swissmedic for evaluation and further procedures, if it considers the violation of the Pharma Code to be a possible health risk. In cases where matters are drawn to the attention of both scienceindustries and Swissmedic, the latter will only become active where it is obliged to do so by law. In this connection it should be noted that pharmaceutical companies that have pledged to the observance of the Pharma Code and/or the Pharma Cooperation Code undertake for as long as the corresponding proceedings with scienceindustries are pending to refrain from notifying Swissmedic of any violation of the legislation on Therapeutic Products, and from filing unfair competition claims before a court. Swissmedic does not take up matters dealt with by scienceindustries, except in cases where the matter in dispute is assigned to it.

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?

To the extent that the violation of the rules on the advertising of medicinal products also qualifies as an act of unfair competition, it is possible to take action directly through the courts and to seek to obtain injunctive relief and the seizure of illegal advertising media. Furthermore, it is possible to request that either a corrective statement or the judgment itself be communicated to third parties, or published. A claimant can also sue for damages and compensation, and can petition for disgorgement of profit. Such actions through the courts may be taken by anyone whose clientele, credit, professional standing, business or other economic interests are threatened or injured by unfair competition. Customers whose economic interests are threatened or injured by unfair competition may also bring such actions. Under certain conditions, actions may also be brought by trade and business associations and consumer protection organisations, as well as by the Swiss government.

Anyone who is entitled to file a civil action, as referred to above, may also file a penal complaint. The criminal sanctions for committing acts of unfair competition are imprisonment for up to three years or a fine of up to CHF 1,080,000.

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)?

The Pharma Code distinguishes between the advertising of a medicinal product, on the one hand, and providing information on such product, on the other. Whereas any advertising activity concerning a medicinal product is permissible only if Swissmedic has registered the product in question, the exchange of medical and scientific information during the development or registration procedure of a medicinal product is, in principle, permissible. Therefore, information on medicinal products not yet registered in Switzerland may be made available at scientific meetings, so long as no advertising occurs. In principle, it does not make a difference whether a meeting is sponsored or co-sponsored by the company responsible for the product (with regard to the conditions of participation at sponsored meetings, see also question 5.2 below). The brand name may be used in this connection, though only in connection with the approved non-proprietary name of the active ingredient(s) (DCI/INN). The addressees of the information must be made aware of the fact that Swissmedic has not yet registered the new medicinal product. The position is the same with regard to the provision of off-label information. With regard to restrictions on marketing activities imposed by the Federal Law on Patents for Inventions of 25 June 1954, see the reference to two recent decisions rendered by the Swiss Federal Patent Court under question 9.3 below.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Under the rules referred to in question 2.1 above, information on not yet registered medicines, as well as off-label information, may also be referred to in scientific reports.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

According to the Pharma Code, it is permissible under the rules referred to in question 2.1 above to inform the media about medicinal products that have not yet been authorised. Thus, it is possible to issue press releases in order to enable the media to, for example, publish an article on the product in question. It is, however, not permissible to pay or to, directly or indirectly, grant any other incentives for the publication of the press release itself or for an article written on the basis of the press release. The press release must be drafted in such a way that it contains only information and cannot, in any way, be characterised as an advertising tool.

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

To the extent that sending healthcare professionals medical and scientific information (which complies with the rules referred to in question 2.1 above) on as yet unauthorised medicinal products is clearly only informational, to the exclusion of any advertising/promotion purpose, it is permissible, even if the healthcare professionals in question did not request the information. If, however, healthcare professionals request that their addresses be deleted from the respective mailing lists, then this request must be complied with.

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 Switzerland?

So far, the ECJ judgment in the *Ludwigs* case, Case C-143/06, has neither been reflected in the legislation, nor in the practical guidance in Switzerland. It is also not planned to reflect the above-mentioned judgment in the current Ordinary Revision of the Law on Therapeutic Products (see also question 9.2 below). In this connection it should, however, be mentioned that Swiss authorities or courts have not yet ruled on a case similar to the *Ludwigs* case. Therefore, it may not be excluded that the judgment might, under certain circumstances, have an impact on the definition of the term "advertising" by the courts. In this context it should be noted that although Swiss courts are not bound by decisions of the European Court of Justice, they nevertheless often consider the case law of the ECJ and the relevant EC Directive in their decision-making process.

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?

To the extent the rules referred to in questions 2.1 and 2.4 above are observed, healthcare professionals working in institutions may be provided with such information.

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

So far, no specific guidelines have been issued on market research exercises concerning possible launch materials for medicinal products as yet unauthorised. The rules of the Pharma Code and the Pharma Cooperation Code, as well as those of the SAMS/FMH Guidelines applicable with regard to the involvement of healthcare professionals to provide consultancy services in connection with, e.g., market research, as laid down in question 5.4, would apply by analogy which do not set any specific limitations with regard to cases in which medicinal products as yet unauthorised are involved. With regard to market research for authorised medicinal products, the specific rules of the Pharma Code governing non-interventional studies using authorised medicinal products as laid down in question 5.5 need to be further complied with.

3 Advertisements to Healthcare Professionals

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

Advertisements, including claims for the use of a medicinal product directed to healthcare professionals, must contain the following information, which must be consistent with the product information for healthcare professionals approved by Swissmedic or, if this is not required, the marketing authorisation issued by Swissmedic:

a) the name of the medicinal product (usually brand name);

b) the active ingredient(s) listed by their approved non-proprietary name if available (DCI/INN);

c) the sales category approved by Swissmedic;

d) the name and address of the company responsible for marketing the product in Switzerland (this information must be either contained in the advertisement itself or be obvious from the media in which the advertisement is published);

e) an indication that comprehensive information can be found in the packaging insert or the product information for healthcare professionals, with precise reference to the source of such information; and

f) at least one approved indication or utilisation, the recommended dosage and mode of administration, as well as a summary of the contraindications, precautions, and side effects of the product ("succinct statement").

According to the Pharma Code, the advertisements should also contain the date on which the advertisement was produced or, if it has subsequently been changed, the date on which it was last changed. In connection with reminder advertisements, i.e., advertisements that remind the customer of a known medicinal product and thus contain no more than a simple statement of indication(s) or of the therapeutic category of the medicinal product, the information as per clause f) above may be omitted. Brand name advertisements intended to serve only as a reminder of the brand name must not contain any information other than the brand name (character, logo or both) and the approved non-proprietary name (DCI/INN) of the active ingredient(s), as well as the name and logo of the company responsible for marketing the product in Switzerland.

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

There are no specific restrictions on information that may appear in an advertisement. According to the Pharma Code, advertising to healthcare professionals for, and information about, medicinal products must be accurate, balanced, objective and fair. The statements must be substantiated. They may not be misleading due to misrepresentation, unsuitable emphasis, omission or other distortions. Inadmissible, because they are deemed to be misleading, are specifically: (i) the use of the expression "safe", except when used in connection with an appropriate qualification; and (ii) statements indicating that a medicinal product has no adverse effects, does not cause addiction, is harmless or risk-free, or other statements or expressions that downplay the possible risks.

There are no specific restrictions to refer in advertisements to studies not in the SmPC. There is, however, a requirement that advertisements to healthcare professionals may only refer to clinical trials which have been carried out in accordance with the Good Clinical Practice guidelines and which are published in a reputable scientific medium or accepted for publication. The clinical trial report must be cited in particular, with the full title and authors' names and dates, as well as indicate the corresponding scientific medium. In the advertisement, it must be mentioned that a copy of the full clinical trial report may be requested from the company. The same rules apply with regard to references in advertisements to investigations such as meta-analyses, pharmaco-economic studies or field reports.

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

In connection with the inclusion of endorsements by healthcare professionals in promotional material, the general principles governing the advertising of medicinal products as laid down in question 3.2 must be complied with. Citations from professional medical literature or from lectures by experts at scientific events shall not distort or in any other manner alter the results of the clinical trials or the intention or opinion of the authors. To the extent the endorsements by healthcare professionals are included in advertisements published in professional media, such advertisements need to be clearly distinguishable from the contributions for which the editors of the professional medium are responsible.

Please note that no testimonials or recommendations by healthcare professionals are permitted in connection with advertisements to the general public.

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 are made?

No, this is not a requirement. With regard to the rules governing comparator advertisements, see question 3.5.

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 which had not yet been authorised in Switzerland?

Comparisons with the medicinal products of other companies in connection with advertisements to healthcare professionals are permissible only if they are scientifically sound and if they refer either to the latest version of the product information for healthcare professionals approved by Swissmedic, or, if this is not required, the market authorisation issued by Swissmedic, clinical trials, or the results of controlled studies. If the advertisement refers to results of *in vitro* experiments or animal studies, a clear statement to that effect must be given in the citation. Advertisements comparing prices of medicinal products are not permissible.

Under the rules of the Federal Law against Unfair Competition, even a comparison based on correct data may be misleading, and therefore unfair, if it is based on irrelevant or incomplete facts while omitting other relevant facts. If a comparison is limited to certain parameters or products, this should be indicated to the public. Claims of superiority, such as "better", "more effective", and "the most effective" must be verifiable, otherwise they are deemed to be unfair.

An advertisement claiming that a competitor's product that has not yet been registered in Switzerland is under all parameters inferior to the advertiser's registered product should, in principle, be permissible, provided that all the requirements for the admissibility of comparative advertisements described above have been fulfilled. However, it is not permissible to claim that a product not registered in Switzerland is superior to a registered product.

To the extent that the rules of the Federal Law against Unfair Competition are observed, another company's brand name may be used as part of a comparison. Such comparison should not, however, feature the competitor's logos, and should not contain disparaging statements about the competitor.

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

For providing information to healthcare professionals about medicinal products in scientific papers and/or proceedings of congresses, accuracy, balance, objectiveness and fairness are to be considered generally valid principles. According to the Pharma Code, advertising and information materials which are offered or given away at events with international participation may refer to medicinal products which are authorised in other countries, but not in Switzerland or are authorised there subject to different conditions. Such specialist advertising and information material must, however, be accompanied by a reference (i) to countries where the medicinal products concerned are authorised, and to the fact that the medicinal products concerned are not authorised in Switzerland or are subject to different conditions there, and (ii) to the possible differences in the registration requirements and the government-approved professional information (indications, warnings, etc.) in the country or countries where the medicinal products are authorised. Please also note that any financial interest of the authors of the information must be clearly disclosed.

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

To the extent that "teaser" advertisements comply with the general principles governing the advertising of, and providing of information on, medicinal products, it might be expected for such advertisements to be admissible. According to these principles, advertising and information must be accurate, balanced, objective, and fair. It must not be misleading, i.e., should not contain any distortion, undue emphasis, omission, or other misinformation. Further, all statements must be provable by documentation. Each "teaser" advertisement would thus have to be examined individually.

4 Gifts and Financial Incentives

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

Healthcare professionals may be provided with samples of products, but only in small numbers and upon their written request. The supply of samples must be recorded with the company responsible for the marketing of the product in Switzerland. Only the smallest commercial packages or specially manufactured sample packages approved by Swissmedic with even smaller contents are permissible as samples. Samples must be clearly identified as free samples by readily visible, obvious, and permanent labelling. They must, in addition, contain the necessary product information and text on the container and packaging material and (if the medicinal product may only be marketed with a packaging insert) on the approved insert. The sample must also be accompanied by medical information relating to the product last approved by Swissmedic or a reference to the official publication of such information on the Swissmedic website (www.swissmedicinfo.ch). Samples must not be sold. According to a publication issued by Swissmedic in January 2010 setting forth detailed rules relating to the provision of healthcare professionals with samples of products, it is not permissible to systematically provide healthcare professionals with such samples in connection with symposia and similar events, even if the healthcare professionals sign a request form on the spot.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply?

Subject to the exceptional rules with regard to promotional gifts of modest value (see question 4.6 below), it is only possible to grant, offer or provide material benefits (e.g., gifts, donations of money, other advantages) to healthcare professionals if one can exclude the possibility that such incentives, directly or indirectly, might influence them in their prescribing and dispensing practice,

or might serve as a reward for previously prescribed or dispensed medicinal products. The issue of whether or not the granting of a financial incentive influences healthcare professionals is a delicate one and can only be dealt with by analysing the circumstances in question on a case-by-case basis.

The Pharma Cooperation Code stipulates detailed guidelines with regard to disclosure of pecuniary benefits granted to healthcare professionals. According thereto, pharmaceutical companies must satisfy their obligation of disclosure on their corporate website, which is accessible to the public, either in Switzerland or internationally. The pecuniary benefits are to be disclosed within six months of the end of a reporting period. The information must remain accessible to the public for at least three years after its disclosure. The Pharma Cooperation Code contains a list of benefits that are excluded from the obligation of disclosure and which includes, e.g., (i) the delivery of free of charge samples of medicinal products, (ii) objects intended for healthcare professionals, information and training materials of moderate value which are intended exclusively for the medical or pharmaceutical activity or used for post-graduate or continuing education in medicine or pharmacy and which, in both cases, are also of benefit to patients, (iii) items of modest value, such as writing implements or folders, made available to participants at events by pharmaceutical companies, as well as (iv) payment for meals (including beverages).

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?

In principle, the same rules apply as with regard to the offering of gifts and other incentives to healthcare professionals (see question 4.2 above). It is, however, acknowledged that the risk of influencing healthcare professionals in prescribing or applying specific medicinal products might be less critical in big hospitals where the gifts or donations are to the hospital as such and not to a specific department of the hospital. In this connection it has been acknowledged that it might be possible for a company to, e.g., fund the cost of a nurse if the company pays the amount to a central account within the hospital, thus funding the hospital's nursing costs in general. The SAMS/FMH Guidelines stipulate, in line with the above restrictions, that an institution such as a hospital should issue a policy governing the accepting of gifts or donations of money. In connection with important purchases or mandates, joint-signing authority is required (four-eyes principle). Further, the organisational body accepting gifts or donations of money must clearly be separate from the hospital's procurement department. All agreements on the acceptance of gifts and donations of money above a certain limit established for the institution in question must, furthermore, be concluded in writing. The respective agreement must also define the permitted purpose for which the moneys paid to the donation account may be used.

As in the case of pecuniary benefits granted to healthcare professionals, all pecuniary benefits granted to healthcare organisations must be made transparent to the public (for further information see question 4.2 above).

In this connection, it should be mentioned that, with regard to gifts granted or donations made to hospitals owned or subsidised by public entities, the rules of the pertinent Articles of the Swiss Penal Code against corruption must also be observed. In connection with gifts granted or donations made to privately held institutions, the pertinent provisions of the Federal Law against Unfair Competition against corruption in the private sector must be observed.

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?

No, it is not possible to provide goods or services to healthcare professionals that could lead to changes in prescribing patterns (see also question 4.2).

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?

It is permitted to grant commercially or economically justified discounts that directly reflect in the price. In the past, the general understanding of Swissmedic in this respect was that, in order to comply with this requirement, it is, in principle, sufficient if the discounts are passed on to the patient or the paying insurer. In April 2012, the Swiss Federal Supreme Court ruled that the requirement of discounts to directly reflect in the price does not *per se* stipulate an obligation to pass on the discounts to the patient or the paying insurer, but does rather require that discounts be granted in a transparent way thus enabling the examination that they are, in fact, commercially or economically justified (decision of 12 April 2012). As a consequence of this decision, the interpretation of the regulations on discounts has become rather difficult and unpredictable. It should also be noted that neither Swissmedic, nor the Swiss Federal Supreme Court have published guidelines or criteria that help determine what is to be considered commercially or economically justified. Swissmedic has, however, confirmed that straight volume-related discounts would not be permissible, as they would enable circumventing the restrictions relating to the granting of samples of products. It should be noted that, in connection with the pending revision of the Law on Therapeutic Products, new provisions are supposed to be introduced which are aimed at clarifying the legal situation regarding permissibility of such discounts (see also question 9.2 in this regard).

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?

As already referred to in question 4.2 above, it is not possible to grant, offer or provide material benefits (e.g., gifts, donations of money, other advantages) to healthcare professionals if this is contingent on the prescribing and dispensing of medicinal

products. In connection with the purchase of medicinal products, it is only permitted to offer healthcare professionals/institutions objects, information and training materials of moderate value, which are intended exclusively for the medical or pharmaceutical activity or are used for post-graduate or continuing education in medicine or pharmacy and which, in both cases, are also beneficial to patients. As a rule of thumb, such gifts must not exceed the value of approx. CHF 300 per year and per healthcare professional/institution.

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?

No, this is neither possible with regard to prescription-only medicine, nor with regard to over-the-counter medicine.

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

In principle, it is possible for pharmaceutical companies to sponsor continuing medical education, if and to the extent any conflicts of interest can thereby be avoided. Thus basically the same rules apply as with regard to the offering of gifts and other incentives to healthcare professionals (see question 4.2 above). In this connection, it has been acknowledged that it might be possible for a company to, e.g., sponsor the continuing education of healthcare professionals working in a hospital if the company pays the amount to a central account within the hospital, and not to a specific department or even to an individual healthcare professional. The same applies in connection with funding the cost of a professor at a university/institute. Furthermore, in the case of continuing medical education events, it must be ensured that the sponsor has no influence on the admission of participants. With regard to the conditions of participation at sponsored meetings, see also question 5.2. In case the sponsoring of continuing medical education comprises the providing of, i.e., scientific literature, the rules referred to in questions 4.2 and 4.6 apply.

According to the Pharma Cooperation Code, it is possible for pharmaceutical companies to support institutions, organisations or associations of healthcare professionals performing research in the healthcare sector or providing other services, either financially or in some other way, insofar as such support is restricted to research and other services in the area of healthcare and is confirmed in writing and the relevant documents are available to the pharmaceutical company. The pharmaceutical companies must disclose, in particular, the pecuniary benefit granted and the recipient, as well as the basis on which the benefit has been granted.

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? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

Companies may not offer any undue financial incentives, including hospitality, to healthcare professionals and their auxiliary personnel, to influence their prescribing and dispensing practices, or to reward them for medicinal products that have already been prescribed or dispensed. The rules referred to in connection with the granting of gifts (see question 4.2 above) apply, regardless of whether the hospitality offered takes place in Switzerland or abroad. The Pharma Code has issued some guidelines with regard to the question as to where hospitality may be offered. According thereto, events for the advertisement or provision of information about medicinal products to healthcare professionals (e.g., symposia, congresses and similar, even smaller events) which are organised or receive financial support from companies with subsidiaries in Switzerland and which are aimed purely at participants from Switzerland, should as a rule take place in Switzerland. An exception to this rule is only admitted if the aim is to provide participants with specific information that is only available outside of Switzerland, e.g., medical or pharmaceutical research facilities or projects. Swiss subsidiaries of international companies may invite healthcare professionals to events organised abroad by the headquarters or regional centres of their group companies, if the participant makes an appropriate contribution towards the costs.

The Pharma Code provides that the financial expenditure for the event should correspond approximately to the amount which the average participant would be willing to spend should he/she have to pay for it himself/herself. In general, it is required that participants make an appropriate financial contribution to the costs (for further details and exceptions to this rule, see also question 5.2 below). With regard to the costs for meals (including beverages), the Pharma Code sets the limit at CHF 150 per healthcare professional and per meal.

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?

It is possible to pay for the healthcare professional's expenses in connection with attending a scientific meeting, if (i) the duration of the meeting lasts less than one day, and/or (ii) the costs of hospitality are reasonable, i.e., do not exceed the costs of a simple meal. In case these conditions are not met, paying for the healthcare professional's expenses is only possible if the healthcare professional makes an appropriate contribution to the costs. In connection with determining the amount to be paid, factors such as the duration and location of the event, its subject matter and scientific content, the amount of the costs directly linked to the participation, the interdependence between the institution organising the scientific meeting and the sponsor of the meeting, and the personal situation of the participant must be taken into account. According to the principles stipulated by Swissmedic, healthcare professionals are supposed to pay at least one third of the direct costs, i.e., the participation fee, as well as the cost of travel, meals and accommodation directly linked to the meeting. In case of doctors-in-training, the contribution may be reduced to one-fifth. scienceindustries approves of this practice and further recommends that a reduced contribution only may be requested from healthcare professionals who are still in post-graduate medical training. Active participants, i.e., participants who give a presentation or render another reasonable service in connection with the meeting, may be released from paying a contribution to the cost (and may even be appropriately remunerated). The Pharma Code clearly stipulates that hospitality may only be extended to persons who qualify as

participants in their own right. According to the Pharma Code, hospitality shall not include sponsoring or organising entertainment.

The Pharma Code explicitly states that companies must not grant attendees any financial compensation purely for the time they spend attending an event. In this connection, the Pharma Code specifies that if a company does grant a healthcare professional financial support for taking part in an event with international participation, such financial support is subject to the rules of the jurisdiction where such healthcare professional carries out his/her profession.

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 a pharmaceutical company violates the rules referred to under questions 5.1 and 5.2, Swissmedic will, as a rule, raise objections, pronounce admonition or fix an appropriate period for the reestablishment of the state of the law, such measures being ordered within the scope of an administrative procedure. Only in severe cases, in particular, in cases where the violation of the rules has an impact on or endangers human health, will Swissmedic file penal complaints with the competent cantonal public prosecutor.

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 possible to appoint healthcare professionals as consultants, in groups or individually, to undertake expert services and reimburse them appropriately for the associated expenditure according to the usual standards. Both the Pharma Cooperation Code and the SAMS/FMH Guidelines stipulate in this connection that the details of the arrangement, in particular, the specification of the services to be rendered and the remuneration, shall be adequately specified in a written agreement prior to the commencement of the assignment. In this connection the Pharma Cooperation Code provides that the companies shall adhere to the following principles: (i) there is a justified need for the proposed consultancy service to be rendered; (ii) the healthcare professional(s) assigned is/are suitably qualified; (iii) the number of healthcare professionals appointed to perform a service should not be excessive to deliver the desired results; (iv) the contracting company shall document the services rendered by the healthcare professional(s) and use the documents according to their purpose; and (v) token consultancy arrangements to allow healthcare professionals to receive financial remuneration without having a duty to provide a service are not permitted. It is further required that healthcare professionals disclose their consultant status if they write or talk publicly about matters which are the object of the consultancy contract or are otherwise connected with the companies making the contracts. Finally, the Pharma Cooperation Code stipulates that the cooperation with healthcare professionals must be made transparent to the public.

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

To the extent healthcare professionals take part in post-marketing surveillance studies as consultants, the rules laid down in question 5.4 apply. According to these rules it is, in principle, possible to pay healthcare professionals for the services rendered, whereby it must, in particular, be made sure that the involvement of consultants and the benefits granted to them do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer certain medicinal products. The Pharma Code further provides for specific rules relating to non-interventional studies using authorised medicinal products, i.e., studies in which an authorised medicinal product is prescribed, dispensed or applied by the healthcare professional taking part in the investigations in the usual way, complying with the currently valid professional information, and where the involvement of patients in such an investigation is not determined in advance by an investigation protocol and the prescription, dispensing or use of medicines is clearly separate from the decision to include the patient in the investigation. No additional diagnosis or control measures must be provided in such studies for patients; epidemiological methods are used for analysing the collected data. Also in connection with non-interventional studies, it must be made sure that they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a certain medicinal product.

Again, according to the Pharma Cooperation Code, the cooperation has to be made transparent to the public.

In this connection, it should also be noted that, according to the SAMS/FMH Guidelines, scientists who participate in the trial or examination of a medicinal product must not be involved in the marketing of said product.

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

The rules laid down in question 5.5 above apply.

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?

Subject to the exceptions referred to below, non-prescription medicines (i.e., medicinal products of sales categories C, D and E; in short: over-the-counter (OTC) drugs) may be advertised to the general public. Advertisements must reflect the approved medical information relating to the product and must not be misleading, untrue or unethical. Advertisements that could cause an excessive, abusive or improper use of drugs are prohibited. Advertisements must be clearly separated and distinct from the editorial part of a publication. In advertisements for medicinal products of sales categories C and D, medicinal products must clearly be described as such. Advertisements for such products must contain the brand name of the medicinal product, the name of the company responsible for the marketing of the product in Switzerland and at least one approved indication, as well as an explicit and clearly legible invitation to read the packaging insert or the text on the package (which must comply with the specific requirements set forth in respective guidelines issued by Swissmedic). In connection with advertisements for medicinal

products of categories C and D in electronic media, a special warning fulfilling the requirements stipulated by the law must be faded in.

Should the advertisements be intended to serve only as reminders of the brand name, the advertisements must not contain any information other than the brand name and, if so desired, the name of the company responsible for marketing the product in Switzerland. No brand name advertising is permitted in connection with advertisements in cinemas and on the radio and television.

Advertising to the general public is not permitted for finished medicinal products that must by law be reimbursed by health insurance. Restrictions also apply to advertisements on the radio or television for drugs that are taken orally and that contain alcohol. No advertising to the general public is permitted for medicinal products that contain narcotic or psychotropic substances.

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

The law prohibits advertising prescription-only medicines to the general public.

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?

Whereas it is, in principle, possible to inform the general public of a particular disease, it is not possible in this connection to make any direct or indirect link to a particular prescription-only medicine. Reference in this connection to the approved non-proprietary name of the active ingredient(s) (DCI/INN) of prescription-only medicines might already be considered as an indirect illegal link to prescription-only medicines (with regard thereto, see also question 9.3 below). In connection with arranging disease awareness campaigns, it should also be taken into consideration that the law explicitly prohibits advertisements which could trigger fear or panic that the condition of a healthy person might worsen without the use of a particular drug.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply?

It is possible to issue such press releases to non-scientific journals in order to enable them to, e.g., publish an article on the issue in question. It is, however, not possible to pay for or to grant, directly or indirectly, any other incentives for the publication of the press release itself or for an article written on the basis of the press release. It is important in this connection that the press release be drafted in such a way that it contains information only and does not appear in any way to be an advertising tool.

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

Generally, Annual Reports are not considered to be marketing tools. Thus it is, as a rule, possible to describe in such documents products and research initiatives. It would, however, not be allowed to use extracts of Annual Reports containing the above-mentioned descriptions in a way that would characterise them as marketing tools. The same also applies, in principle, with regard to corporate brochures, whereby it would have to be examined on a case-by-case basis, to which extent such brochures qualify as marketing tools.

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

According to the Pharma Cooperation Code, in particular, the following rules must be complied with in connection with the support of patient organisations: regardless of any support, the independence of the patient organisations must be respected. In line with this, all partnerships between patient organisations and companies should be based on mutual respect. Pharmaceutical companies shall neither ask patient organisations to promote certain medicinal products, nor respond to corresponding requests of patient organisations. Companies may not ask patient organisations to be their sole company support overall or for individual projects, financially or in any other form. Companies must accept that patient organisations will strive for support from several sources.

If companies which have undertaken to adhere to the Pharma Cooperation Code grant a patient organisation substantial support, be it financial or other, they shall agree this support in writing with the patient group prior to commencement. This written document shall, in particular, contain a description of the nature (e.g., amount of financial support or description of benefit in kind) and purpose of the support. As a further requirement, companies must not try to influence in their own commercial interests the text of documents of patient organisations to which they are granting financial or other support.

The Pharma Cooperation Code also states that contracts between companies and patient organisations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research. In this connection, the Pharma Cooperation Code also lists the criteria that must be fulfilled in connection with the engagement of patient organisations as experts and advisors for services such as participations at advisory board meetings and speaker services.

The Pharma Cooperation Code stipulates disclosure obligations with regard to the support of patient organisations. According thereto, companies must publish (e.g., on their websites addressed to the Swiss market) a list of the patient organisations which they support financially or otherwise to any significant extent. The list must contain a short description of the nature of the support in sufficient detail and must be complete in the sense that the average reader can recognise the scale of the support. The description must include the pecuniary value of financial support and of invoiced costs. If significant non-financial support is provided, for which no meaningful pecuniary value can be determined, a clear description of the non-pecuniary benefit that the patient organisation receives is necessary. The list must be updated at least once a year.

Pharmaceutical companies are also required to publish information with regard to significant contracted services provided to patient organisations. The information must include a short description of the nature of the services provided without the necessity to reveal confidential information.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, what information should be disclosed, and when and how?

According to the Ordinance on Clinical Trials in Human Research of 20 September 2013 (in short: Clinical Trials Ordinance), all clinical trials need to be registered in a registry officially recognised by the World Health Organization (in short: WHO) or in the registry of the US National Library of Medicine. Clinical trials must, in principle, be registered prior to their start-date. Clinical trials of Phase I may be registered within one year after the completion of the clinical trial. The information registered must include at least the data required by the WHO. The registration must be updated on an on-going basis, however – at least once per year.

In addition, further information on the clinical trials must be registered in a national registry administered by the Federal Office of Public Health (in short: National Registry). The information that must be registered with the National Registry includes (i) the name of the international register, as described above, where the clinical trial has been registered as well as the date of the registration and the identification number allocated by the international register, (ii) the designation of the clinical trial as well as a short description of the clinical study protocol in such language that an average person not familiar with clinical trials may understand, (iii) the health-related intervention to be researched, (iv) the disease under examination or health state, (v) the scope of the clinical trial, and finally (vi) the location(s) where the clinical trial is conducted.

The information submitted to the National Registry must either be in German, Italian or French. The National Registry is accessible to the public.

7.2 Has your national code been amended in order to implement the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and, if so, does the change go beyond the requirements of the EFPIA Disclosure Code or simply implement them without variation?

By an amendment of the Pharma Code and the issue of the new Pharma Code scienceindustries has implemented the EFPIA Disclosure Code. The provisions of the Pharma Code and the Pharma Cooperation Code do not go beyond the requirements of the EFPIA Disclosure Code.

7.3 If the EFPIA Disclosure Code has not been implemented in Switzerland, is there a requirement in law and/or 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 information should be disclosed, from what date and how?

The EFPIA Disclosure Code has been implemented in Switzerland. Please refer to question 7.2 for further information.

8 The Internet

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

The law permits Internet advertising in connection with advertisements to healthcare professionals, as well as to the general public. The rules referred to in questions 3.1 and 6.1 above apply analogously. With regard to certain categories of medicinal products, an advance approval of Internet advertising to the general public is necessary (see question 1.5). Swissmedic has issued detailed guidelines relating to Internet advertising and, in particular, as to the selection of admissible domain names. As far as advertising to healthcare professionals is concerned, the Pharma Code stipulates additional rules. In particular, an Internet presentation must clearly indicate which company operates or sponsors, whether directly or indirectly, the website. Furthermore, it must be clear what information on the website is addressed to the general public and what information is aimed only at healthcare professionals.

With regard to the bodies that exercise control and the success of such control, reference is made to the statements made in question 1.7 above.

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?

In connection with Internet advertising directed at healthcare professionals, Swissmedic requires companies to ensure by password that only authorised healthcare professionals have access to such sites.

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?

In its guidelines relating to Internet advertising, Swissmedic confirms that, as a rule, no objection may be made to setting a link from a company-sponsored website to an independent website. Such linking, however, must not be used to circumvent the law, in particular, to avoid the limitations set by the Law on Therapeutic Products with regard to advertisements. In principle, the owner of a website is responsible for its content. There are, however, exceptions, in particular, in case of a so-called framing, i.e., if the visitor of a website is "led" to a third party website without leaving the initially visited website. A further exception may, e.g., be given in case the company setting the link, partly or totally, finances the third party website and influences the contents and design of such website. In these cases, the owner of the website having set the link might be liable for the content of the independent site. In order to reduce the risk of being liable for the content of a third party website, Swissmedic recommends clearly setting a warning notice, if by clicking a link the visitors leave the initially visited website and switch to a third party website. Under this condition, Swissmedic also considers it admissible for a Swiss company to set a link from its webpage to, e.g., its US parent company's website, even if on such website no distinction is made between information and advertisements addressed to the general public and to healthcare professionals,

respectively. It would, however, not be admissible to set such link abusively, i.e., in order to circumvent the Swiss access restrictions.

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

On its website that may be accessed by the public a pharmaceutical company may, in principle, place all information relating to its products and the company, as well as general information relating to health and diseases, with the exception of information which directly or indirectly qualifies as advertisements for prescription-only medicine. Thus it is possible to place on the website information such as advertisements for non-prescription-only medicines (fulfilling the requirements referred to in questions 1.5 and 6.1) and the medical information relating to the product approved by Swissmedic (information addressed to patients, as well as to healthcare professionals) if not used as a marketing tool, as well as information for investors and patients.

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

There are no specific rules, laws or guidance governing the controlling of the use of social media by companies. So far, it may also not be expected that, in connection with the Ordinary Revision of the Law on Therapeutic Products, provisions on the controlling of the use of social media by companies should be implemented in the Law on Therapeutic Products (for more information in this regard, see also question 9.2).

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?

In September 2013, scienceindustries adopted an amended version of the Pharma Code in order to reflect, in particular, the changes imposed by the amendment of the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals. Also in September 2013, scienceindustries issued the new Pharma Cooperation Code incorporating the guidelines set out by the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations. The new Pharma Cooperation Code, as well as the amended version of the Pharma Code, entered into effect on 1 January 2014.

In January 2014, scienceindustries issued updated versions of several of its internal Recommendations in order to facilitate the proper application of the Pharma Code and the Pharma Cooperation Code.

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

In October 2009, the Swiss Federal Council opened the consultation process regarding the Ordinary Revision of the Law on Therapeutic Products. By a decision of 7 November 2012, the Swiss Federal Council submitted the bill to the Swiss parliament. The proposed amendments focus on, among other things, an increase in the transparency of information on medicinal products and on new rules relating to the granting of material benefits (including the granting of discounts). Furthermore, the enforcement of the rules on the grant of financial advantages to healthcare professionals shall no longer be enforced by Swissmedic, but by the Federal Office for Public Health. The proposal will now have to be discussed by the two chambers of parliament and, once finally adopted, might be subject to a referendum. The new legislation may not be expected to enter into force before 2016.

In March 2014, the second of the two chambers of Swiss parliament adopted a motion submitted by a member of the Council of States in June 2013 that mandates the Swiss Federal Council to amend the Ordinance on Advertising for Medicinal Products by a provision permitting pharmaceutical companies and other holders of marketing licences to state in connection with advertising to the public that a non-prescription medicine has been approved by Swissmedic. The purpose of such provision is to enable consumers to better distinguish between medicinal products, on the one hand, and functional food and medical devices, on the other.

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

Over the last few years, the Swiss Federal Supreme Court confirmed its practice relating to illegal indirect advertising to the public for prescription-only medicine in a number of cases (e.g., decision of 10 August 2006 re "*Migräneinformation*", decision of 9 May 2007 re "*Love Card*", and decision of 13 June 2007 re "*Migräne und Sport*"). In a decision of 1 October 2008, the Swiss Federal Supreme Court dealt again with the distinction between information on, and advertising for, a medicine. In the case at hand, the pharmaceutical company distributed material on a registered prescription-only medicine containing information on new indications not yet approved by Swissmedic. The court confirmed that it is admissible to distribute information on new indications, as there is an interest therefore given the fact that off-label use is, in principle, not prohibited. In the case at hand, the court, however, held that the information material had to be considered as an advertising tool. Advertising, however, is only admissible for approved indications.

In October 2011, the Federal Administrative Court rendered a leading decision relating to advertising activities of healthcare professionals for their services by mentioning names of pharmaceutical products. In the case at hand, a medical practice advertised "medical treatment with Botox" to the public. The Court confirmed a previous decision by Swissmedic, according to which the advertising activities did not only relate to the treatment as such, but also to the prescription-only medicines Botox and Vistabel. As a consequence, the Court ruled that the advertising activities to the public for the treatment with Botox qualify as an illegal advertising of prescription-only medicines (decision of 17 October 2011 re "*Botox*", C-1795/2009, confirmed again in a decision of 14 October 2013, C-546/2010). In March 2012, Swissmedic issued detailed guidelines on the restrictions imposed on healthcare professionals in connection with information relating to aesthetically motivated medical treatments with botulinum toxin (in particular, Botox and Vistabel) in order to avoid illegal advertising activities for the prescription-only medicine in question.

In two recent decisions rendered on 27 February 2014 and 31 March 2014, respectively, the Swiss Federal Patent Court *ex parte* enjoined two generic companies from marketing a new, already authorised generic product by providing demand inquiry forms or purchase order forms to healthcare professionals before the expiration of the patent (or supplemental protection certificate) on the original product, even if such generic product would actually be delivered only after the patent expiration date.

9.4 Has your national code been amended in order to implement the 2013 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (the EFPIA HCP Code) and, if so, does the change go beyond the new requirements of the EFPIA HCP Code or simply implement it without variation?

In September 2013, the Pharma Code was amended in order to implement the amended version of the EFPIA HCP Code. Basically, the amendments made reflect the new provisions of the EFPIA HCP Code and do not go beyond the requirements of said Code.

In this connection it should, however, be mentioned that the regulations already contained in the previous version of the EFPIA HCP Code imposing concrete restrictions on the quantity of medical samples that may be distributed (i.e., the so-called 4x2 standard) have not yet been implemented in the Pharma Code. In its statement addressed to EFPIA, scienceindustries justified this situation by the fact that the Pharma Code already regulates the distribution of samples in a manner compatible with Swiss law, in particular, the Ordinance on Advertising for Medicinal Products, on the one hand, and that the proposed 4x2 standard is likely to be in conflict with Swiss competition law which forbids agreements concerning the limitation of production, procurement or supply quantities, on the other.

Andrea Mondini

Schellenberg Wittmer Ltd
Loewenstrasse 19, P.O. Box 1876
CH-8021 Zurich
Switzerland

Tel: *+41 44 215 5279*
Fax: *+41 44 215 5200*
Email: *andrea.mondini@swlegal.ch*
URL: *www.swlegal.ch*

Andrea Mondini is a partner in Schellenberg Wittmer's intellectual property and information technology group in Zurich. He was admitted to the Bar in Switzerland in 1991. He graduated from the School of Law of the University of Zurich in 1987 and obtained a Master of Laws from Georgetown University in 1995. Andrea Mondini joined Schellenberg Wittmer as an associate in 1992 and also worked as a foreign associate with Finnegan, Henderson, Farabow, Garrett & Dunner in Washington, D.C. He became a partner of Schellenberg Wittmer in 2000 and currently heads the firm's IP/IT practice group. His main areas of practice include intellectual property, information technology and unfair competition, with a particular focus on the pharmaceutical field. He advises clients on contractual matters such as distribution, franchising, licensing and technology transfer. He also handles litigation and arbitration in these fields. Andrea Mondini is a panelist with the World Intellectual Property Organization Arbitration and Mediation Center for Internet domain names and is a member of INTA, LES and AIPPI.

Christine Beusch-Liggenstorfer

Schellenberg Wittmer Ltd
Loewenstrasse 19, P.O. Box 1876
CH-8021 Zurich
Switzerland

Tel: *+41 44 215 5272*
Fax: *+41 44 215 5200*
Email: *christine.beusch@swlegal.ch*
URL: *www.swlegal.ch*

Christine Beusch-Liggenstorfer is of counsel in Schellenberg Wittmer's banking and finance group and corporate and commercial group in Zurich. She was admitted to the Bar in Switzerland in 1983. She graduated as a Doctor of Law from the School of Law of the University of Bern in 1982. Christine Beusch-Liggenstorfer joined Schellenberg Wittmer in 1982 and became a partner in 1990. She has been of counsel since 2000. In addition to contract law, her practice focuses on various aspects of public and administrative law and compliance issues (in particular, medicinal regulation law, data protection law, immigration law and work permits, lottery law, and anti-money laundering regulations). Christine Beusch-Liggenstorfer has published in the fields of public and administrative law, including a doctorate thesis on constitutional law and banking law.

SCHELLENBERG WITTMER

Schellenberg Wittmer Ltd is one of the leading business law firms in Switzerland. More than 140 lawyers in Zurich and Geneva advise both domestic and international clients on all aspects of business law. We offer a comprehensive range of services, from focused advice to project management, to local or foreign companies and high net worth individuals.

The firm's areas of expertise include: corporate and commercial law; dispute resolution and international arbitration; intellectual property (with a strong focus on the pharmaceutical industry); information technology; mergers and acquisitions; private equity and venture capital; competition and antitrust; banking and finance; private clients; trusts and estates; foundations; real estate and construction; restructuring and insolvency; taxation; and white-collar crime and compliance.

Schellenberg Wittmer has long-standing international experience in all of the above practice areas. The firm advises on large-scale international M&A and finance transactions and handles international litigation and arbitration, notably in the pharmaceutical field. It has recently advised international clients on various cross-border acquisitions and recapitalisations, debt and equity capital market transactions and in the structuring of relocations of corporate world-headquarters to Switzerland.

Other titles in the ICLG series include:

- Alternative Investment Funds
- Aviation Law
- Business Crime
- Cartels & Leniency
- Class & Group Actions
- Competition Litigation
- Construction & Engineering Law
- Copyright
- Corporate Governance
- Corporate Immigration
- Corporate Recovery & Insolvency
- Corporate Tax
- Data Protection
- Employment & Labour Law
- Environment & Climate Change Law
- Franchise
- Insurance & Reinsurance
- International Arbitration
- Lending & Secured Finance
- Litigation & Dispute Resolution
- Merger Control
- Mergers & Acquisitions
- Mining Law
- Oil & Gas Regulation
- Patents
- Private Client
- Product Liability
- Project Finance
- Public Procurement
- Real Estate
- Securitisation
- Shipping Law
- Telecoms, Media & Internet
- Trade Marks

GLG
Global Legal Group

59 Tanner Street, London SE1 3PL, United Kingdom
Tel: +44 20 7367 0720 / Fax: +44 20 7407 5255
Email: sales@glgroup.co.uk

www.iclg.co.uk