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Contributing editors: Alexander Ehlers and Cord Willhöft

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# Switzerland

Frank Scherrer

Wenger & Vieli AG

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## Organisation and financing of health care

### 1 How is health care in your jurisdiction organised?

The Swiss health-care system is based to a great extent on a mandatory health insurance. Basic health insurance can be contracted with a health insurance company of one's choice and there is the possibility of contracting additional private insurance. Apart from health insurance, there are other types of social insurance. Social insurance pays or reimburses the costs of the health-care providers (hospitals, physicians, pharmacists, etc). The private health-care sector, which is not financed by social insurance, is also very important. The health-care system shows a federalist structure, and only certain areas are governed by federal law. Many competences and tasks have remained under the control of the 26 cantons (such as the running of public hospitals and to a large extent the exercise of health-care professions).

### 2 How is the health-care system financed in the outpatient and inpatient sectors?

The health-care system is mainly financed by social health insurance, private insurance, the Swiss Confederation, the cantons, the communities and the direct payments of patients. Public hospitals that provide mainly inpatient treatment are mainly financed by health insurance and the canton to which they belong. Outpatient treatment is mostly provided by private practitioners and is financed mainly by health insurance. The basic health insurance provides for a patient copayment of, in principle, 10 per cent with a maximum of 700 Swiss francs per year for adults. For both the outpatient and the inpatient sectors, private additional health insurance and direct payment of health-care services are possible.

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## Compliance – pharmaceutical manufacturers

### 3 Which legislation governs advertisement of medicinal products to the general public and health-care professionals?

Advertising for medicinal products is governed by:

- the Law on Therapeutic Products (LTP);
- the Ordinance on Advertising for Medicinal Products;
- the Ordinance on Health Insurance (article 65, paragraph 6);
- the Federal Act against Unfair Competition;
- the Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code), issued by the Swiss Society of Chemical Industries.

### 4 What are the main rules and principles applying to advertising aimed at health-care professionals?

Advertising aimed at health-care professionals is generally allowed for all medicinal products authorised in Switzerland. Advertising

must not be misleading, inaccurate, against public order or unethical, or incite excessive, abusive or inappropriate use of medicinal products.

Advertising aimed at health-care professionals must be in line with the latest product information approved by the Swiss regulatory agency (Swissmedic). Advertising must be accurate, balanced and provable. The claims must be based on and reflect the current state of scientific knowledge. They may only refer to clinical studies conducted in accordance with good clinical practice (GCP) that are published or accepted for publication. Publications must be quoted literally, completely and with the exact reference.

Advertisements must not:

- indicate that a medicinal product does not have adverse events or be riskless or harmless;
- appear to be an editorial;
- indicate that a human medicinal product does not create addiction.

### 5 What are the main rules and principles applying to advertising aimed at the general public?

Advertising aimed at the general public is not allowed for prescription-only medicinal products. It is furthermore not allowed for medicinal products that are reimbursed by the basic health insurance.

Advertising aimed at the general public must not be misleading, inaccurate, against public order or unethical, or incite excessive, abusive or inappropriate use of medicinal products. It must be in line with the latest Swissmedic-approved product information. It must be objective and without exaggeration and contain an invitation to consult the patient leaflet. Pharmaceutical products must be clearly presented as such. Quizzes, vouchers, testimonials and invitations to contact the marketing authorisation holder are not permitted.

Advertisements on radio and television must be submitted to Swissmedic for prior approval. Public advertisements in a printed form for analgesics, sedatives, sleeping tablets, laxatives and anorectics must also be submitted to Swissmedic for prior approval.

Swissmedic issued a communication in 2006 about internet marketing, which requires that access to advertising for prescription-only medicinal products on the internet must be limited to health-care professionals by means of password protection. This communication also contains rules about links and domain names. After the password requirement has been unsuccessfully challenged, Swissmedic now expects the pharmaceutical industry to comply with the communication from 1 January 2010 onwards.

### 6 What are the most common infringements committed by manufacturers with regard to the advertisement rules?

The most common infringements with regard to advertising rules are:

- the use of comparisons or superlatives without correct scientific basis;

- advertising for off-label use or medicinal products that have not yet been authorised;
- claims that are not correctly referenced;
- advertising that lacks the necessary minimum information;
- advertising that is not in accordance with the approved product information;
- advertising to the general public of prescription-only medicines; and
- in advertising to the general public, exaggerations, promises of therapeutic effect and advertising together with products other than medicinal products (cosmetics or food) are common.

It should be noted that the surveillance of advertising aimed at health-care professionals is mainly performed by a body instituted by the Pharma Code and not Swissmedic. If advertising endangers drug safety, however, Swissmedic must act.

- 7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

Advertising for products that have not yet been authorised in Switzerland, or for off-label use of authorised products, is not allowed. According to the Swiss Pharma Code, pharmaceutical companies are, however, allowed to inform health-care professionals and the media about products or new indications, fields of use, dosages, galenic forms or packages that have not yet been authorised in Switzerland. The trade name may be used, but always in connection with the international non-proprietary name of the active substances. The companies have to make it clear that the medicinal product, new indication, field of use, dosage, galenic form or package has not yet been authorised by Swissmedic in Switzerland.

The Swiss Federal Court has confirmed in a recent decision that the mentioning of the trade name of a medicinal product is not always to be regarded as advertising. However, the companies should be careful when mentioning off-label use because information and advertising are often difficult to distinguish.

- 8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals?

The rules governing the collaboration of the pharmaceutical industry with health-care professionals are located in various Acts and ordinances, mainly the following:

- the LTP, especially article 33 and the provisions on clinical trials and vigilance;
- the Ordinance on Advertising for Medicinal Products, especially article 11 on scientific congresses and promotional events;
- the Ordinance on Clinical Trials;
- the anti-bribery provisions of the Swiss Criminal Code, article 322ter to 322octies, and of the Act against Unfair Competition, article 4a;
- the rules governing the employment and function of health-care professionals; and
- the Federal Law on Academic Medicinal Professions.

- 9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

There are certain types of collaboration for which specific rules of best practice have been developed, and these are mainly set out in a publication of Swissmedic, the Pharma Code and a guideline of the Swiss Academy of Medical Sciences.

The main legal rule is article 33 of the LTP, which prohibits the offering of financial or other advantages to physicians, pharmacists, druggists or health-care establishments that employ such persons for prescribing or dispensing certain medicinal products; the rule also prohibits the acceptance of such advantages.

‘Advantages’ considered permissible are:

- gifts of a modest value, which are relevant for the professional activity of the recipient (eg, pens, calculators, prescription pads); according to practice, gifts are considered to be of a modest value if their total value is not more than 300 Swiss francs per year to each health-care professional; and
- discounts that are customary in the relevant field or that are justified on business grounds, for example, volume discounts; according to Swissmedic, such discounts must be passed on to the patient or insurer that pays for the product.

According to article 11 of the Ordinance on the Advertising for Medicinal Products, hospitality related to scientific congresses or promotional events must be justifiable and be subordinate to the main (scientific) purpose of the event. Accompanying persons must pay for their own costs.

With regard to the support for the participation of physicians in medical congresses, Swissmedic has issued a publication containing detailed rules. The basic rule is that physicians have to make a copayment of at least 33 per cent of the direct costs of their participation (ie, registration, accommodation, food and beverages, etc).

- 10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

Infringements committed by manufacturers with regard to collaboration with health-care professionals in general relate to undue financial advantages. Decisions of Swissmedic in this field are, however, not published and the number of decisions has diminished in recent years, pending a revision of article 33 LTP.

- 11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

The Swiss Pharma Code was revised on 1 July 2008 to incorporate the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations of 5 October 2007 (with a deadline for implementation by 31 March 2009).

The main rules and principles are as follows:

- Companies shall respect the independence of patient organisations with regard to their political position, their methodology and their activities.
- All partnerships between patient organisations and companies should be based on mutual respect.
- The companies shall neither ask patient organisations to promote certain medicinal products nor respond to corresponding requests by patient organisations.
- The aims, the scope and the agreement of support and partnerships should be transparent and documented in writing.
- It is expected that patient organisations will attempt to gain support from several companies. Companies in turn may not require that they are exclusive sponsors of patient organisations or of individual projects, financially, or with respect to any other form of support.

- 12 Are manufacturers’ infringements of competition law pursued by national authorities?

Infringements of the Act against Unfair Competition are usually brought forward in a civil procedure. Only in very limited circumstances will the authorities act ex officio.

The competence for the enforcement of the Cartel Act lies with the Swiss Competition Commission. Currently, an investigation on alleged resale price maintenance through the provision to pharmacists of recommended resale prices is pending against Pfizer, Eli Lilly and Bayer regarding their non-reimbursed medicinal products Viagra, Cialis and Levitra.

**13** Is follow-on private antitrust litigation against manufacturers possible?

The Swiss Cartel Act contains provisions on private lawsuits in case of breach of cartel law. Private antitrust litigation, however, only plays a very modest role in antitrust enforcement in Switzerland.

## Compliance – medical device manufacturers

**14** Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Advertising of medical devices is not as rigorously regulated as advertising for medicinal products. The Ordinance on Medical Devices contains one provision on advertising that sets the following rules (article 21):

- advertising for medical devices that are intended for the direct distribution to or use by the public must be limited to statements contained in the product information with respect to use, capabilities and efficacy;
- misleading claims of efficacy or capabilities are prohibited; and
- advertising to the general public is prohibited with regard to medical devices that are subject to prescription or are exclusively distributed for use by health-care professionals.

Collaboration between manufacturers of medical devices and health-care professionals and patient organisations is not as rigorously regulated as for pharmaceutical products. In particular, article 33 of the LTP on the prohibition of financial advantages in its current wording does not apply to medical devices. The industry association of medical device manufacturers and distributors FASMED has issued a code of conduct that provides for similar rules as article 33 of the LTP. Currently, a revision project of article 33 of the LTP is pending, which will extend article 33 of the LTP to encompass medical devices (with certain exceptions that are not yet defined).

## Pharmaceuticals regulation

**15** Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The rules regarding the granting of marketing authorisations and the placing of medicines on the market are set out in the LTP and various ordinances depending on it, in particular the Ordinance on the Requirements for Marketing Authorisation of Medicinal Products, the Ordinance on the Simplified Marketing Authorisation of Medicinal Products and Authorisation by Way of Notification, the Ordinance on the Simplified Marketing Authorisation of Complimentary and Herbal Medicinal Products, the Ordinance on Establishment Licenses and the Ordinance on Medicinal Products.

**16** Which authorities may grant marketing authorisation in your jurisdiction?

Marketing authorisation is granted by Swissmedic.

**17** What are the relevant procedures?

The relevant procedures are the ordinary, the fast-track and the simplified procedure. A marketing authorisation can only be granted to a company or person having its domicile, registered office or a branch office in Switzerland. The applicant must also have a manufacturing, import or wholesale licence.

**Ordinary procedure**

The application to Swissmedic for marketing authorisation must be made using standard forms and, for new active substances, the

common technical document (CTD) of the International Conference on Harmonisation. The required documents are listed in detail in the Ordinance on the Requirements for Marketing Authorisation of Medicinal Products and guidelines issued under it. Swissmedic supports submitting data electronically; it is planned that, starting on 1 January 2010, submissions can be made in the eCTD format.

The conditions for granting marketing authorisation are that the product is of high quality, safe and effective. If a drug or process has already been authorised in another country that has a similar system of marketing authorisation, the results of the examinations carried out for that purpose should be considered. There is, however, no automatic recognition of foreign marketing authorisations. Swissmedic has recently published a guideline on this subject.

The normal authorisation process takes about a year. Swissmedic has issued a guideline setting out its internal targeted time periods and milestones. If Swissmedic has queries or requests further information or documents, the internal targeted time periods are stopped ('clock stop') and the authorisation process can take longer.

**Fast-track procedure**

If there is no treatment, satisfactory or otherwise, against a perilous or heavily disabling disease, and if the medical preparation is of a high therapeutic value, a fast-track procedure is available at the applicant's request. The fast-track procedure must be requested at least three months before the application for the marketing authorisation is filed. It enables registration to be completed within about four months. If Swissmedic has queries, the proceedings may take longer.

**Simplified procedure**

A simplified marketing authorisation procedure is available for certain types of medicinal products, such as:

- complementary and alternative medicinal products;
- generics and other medicinal products with active substances that have already been authorised;
- parallel imports from a country with an equivalent marketing authorisation system; and
- orphan drugs.

The procedure is mainly governed by the Ordinance on the Simplified Marketing Authorisation of Medicinal Products and Authorisation by Way of Notification.

For certain medicinal products (eg, certain homoeopathic and anthroposophical products) authorisation by way of a mere notification procedure is possible.

**18** Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Current legislation does not stipulate that marketing authorisations become invalid if products are not marketed within a certain time. However, the LTP was revised on 13 June 2008 to provide for such a sunset clause. It is planned that the revision will come into effect in summer 2010. Article 16a of the LTP will state that Swissmedic will withdraw the marketing authorisation of any medicinal product if it is not effectively brought into circulation within three years from the grant of marketing authorisation or not marketed for three consecutive years. Ordinances that have not yet been published can provide for exceptions to this rule and also for shorter forfeiture periods for medicinal products combating serious disease, injury or handicap.

**19** Which medicines may be marketed without authorisation?

The following human medicines may be marketed without authorisation (article 9 of the LTP):

- medicinal products manufactured by hospitals or public pharmacies based on a prescription by a physician for a specific person or a specific circle of persons (magistral formula);

- medicinal products manufactured by hospitals, public pharmacies, drugstores or other establishments with a manufacturing license based on a special monograph of the pharmacopoeia or another recognised dispensatory in small quantities and for dispensation to their own clients (official formula);
- medicinal products manufactured by hospitals, public pharmacies, drugstores or other establishments with a manufacturing license based on their own formula and within their own dispensing competence in small quantities and for dispensation to their own clients;
- medicinal products for clinical trials; and
- medicinal products that can not be standardised.

The revision of the LTP of 13 June 2008 that is planned to come into effect in summer 2010 will extend these categories.

Swissmedic may authorise the distribution or dispensation for a limited period of medicinal products against life-threatening or seriously disabling diseases if this is compatible with the protection of health, a significant therapeutic benefit can be expected from the administration of these products and no equivalent medicinal product is available in Switzerland ('compassionate use', according to article 18 to 23 of the Ordinance on the Simplified Marketing Authorisation of Medicinal Products and Authorisation by Way of Notification).

Under certain conditions, physicians may furthermore import certain medicinal products that are not authorised for the treatment of named patients or in emergency situations (article 36 of the Ordinance on Establishment Licences).

- 20 What, according to the legislation and case law, constitute medicinal products?

Medicinal products are defined in article 4, paragraph 1(a) of the LTP as products of chemical or biological origin that are intended to have, or are presented as having, a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps; blood and blood products are also to be considered as medicinal products.

In May 2009, Swissmedic and the Federal Office of Public Health published criteria for the classification of medicinal products, food stuffs and objects of utility. Essentially, they suggest looking both at the composition of the product and its intended function, but to give priority to the composition.

#### Pricing and reimbursement of medicinal products

- 21 To what extent is the market price of a medicinal product governed by law or regulation?

Medicinal products that are reimbursed by the basic health insurance are subject to governmental price control. The prices of non-reimbursed products are free and not government-controlled.

This applies to medicinal products in the inpatient and outpatient sectors. The difference is made between reimbursed and non-reimbursed products. A finished medicinal product (whether prescription-only or non-prescription) must in principle be listed on the so-called speciality list (SL) established by the Federal Office of Public Health in order that it can be reimbursed in the basic health insurance. When deciding on the admission of a medicinal product to the SL, the Federal Office of Public Health determines its list price. This price is the maximum price that can be invoiced by health-care providers and that will be reimbursed by the health insurance companies. About 40 per cent of pharmaceutical products registered in Switzerland are listed on the SL.

A medicinal product is only admitted to the SL if the applicant can show its efficacy, usefulness and economy. The relevant criteria for fixing the SL price of an original product are: the prices of drugs having the same indication or a similar mode of action and

the average ex-factory price (without VAT) of the product in other countries. Since 1 October 2009, the prices in Germany, Denmark, England, the Netherlands, France and Austria are used for the comparison. If the medicinal product constitutes a therapeutic advancement, an innovation premium can be granted. For determining the SL price, the Federal Office of Public Health adds a distribution margin to the ex-factory price determined according to certain criteria.

The fulfilment of the conditions for admission to the SL is reviewed every three years. A review of the conditions for admission to the SL also takes place immediately after expiration of patent protection.

- 22 In which circumstances will the national health insurance system reimburse the cost of medicines?

In the basic health insurance the insurance companies pay or reimburse finished medicinal products prescribed by physicians (or under certain circumstances chiropractors) that are listed on the SL. In two exceptional situations, the costs of a product that is listed in the SL (without a limitation of reimbursement) but used off-label are taken over by the basic health insurance: in a compassionate use situation and in the situation of a 'treatment complex' (ie, when there is a very narrow connection between medical services that are reimbursed and services that are not or only partially reimbursed when the non-reimbursed services are a necessary condition for the treatment, or are of considerable importance for the success of the treatment).

Whether the health insurance company reimburses the costs to the patients after they have paid the health-care providers or directly pays their invoices depends primarily on the insurance system in place in the canton of the patient's domicile.

Optional additional private insurance also covers authorised medicinal products that are not listed in the SL.

#### Medicine quality and access to information

- 23 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

Swiss legislation provides for several means to combat the counterfeiting and illegal distribution of medicines. The LTP prohibits the distribution of medicinal products that are not authorised and provides for severe sanctions. The competences of Swissmedic and the customs authorities to block counterfeited or illegally traded medicinal products and to investigate breaches of the law are broad. Swissmedic has made combating the illegal trade of medicinal products a priority and is in close contact with foreign authorities.

Besides the LTP the legislation on intellectual property also offers means to counter the counterfeiting and illegal distribution of medicines.

- 24 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

Advertising for prescription-only medicines is prohibited in Switzerland. The Swiss Federal Court has confirmed this prohibition in recent decisions. In contrast, information on illnesses and treatment options is admissible. It has become clear that the product information for a prescription-only medicine (information for professionals and patient leaflet) is not to be regarded as advertising and can be made freely available, including on the internet. On the other hand, the Swiss Federal Administrative Court has recently confirmed that advertising for prescription-only medicinal products aimed at health-care practitioners must be password-protected if made available through the internet.

Pharmaceutical companies seem to intensify initiatives to make health-related information on illnesses and treatment options available to the general public and also to advertise themselves as companies.

### Update and trends

General trends in the Swiss regulation of medicinal products relate to international harmonisation, pressure on the prices for reimbursed products and a partial weakening of the rights of research-based industry (extension of parallel imports, restrictive grant of data protection). The following revisions of the LTP are also in progress.

A revision of the LTP is planned to come into effect in summer 2010, which provides for an extension of the categories of medicinal products that do not require a marketing authorisation what allows hospitals to manufacture more medicinal products themselves. The revision also provides for a sunset clause, which allows Swissmedic to withdraw the marketing authorisation if a medicinal product is not placed on the market within three years of the marketing authorisation being granted,

or if the medicinal product is not marketed for three consecutive years. Changes in the ordinances relate to medical devices (incorporation of EC Directive 2007/47/EC) and the facilitated marketing authorisation process of medicinal products that have been authorised in the EU centralised procedure. If implemented consistently, this latter point will facilitate Swiss marketing authorisation procedures.

A second revision of the LTP is being prepared by the Federal Council. Its aims are to facilitate the marketing authorisation process, to treat medicinal products for children more favourably (eg, with regard to data exclusivity) and to clarify certain disputed provisions. A preliminary draft has been published in October 2009 and the draft is scheduled to be submitted to parliament in summer 2011.

#### 25 Outline major developments to the regime relating to safety monitoring of medicines.

A major development to the regime relating to the safety monitoring of medicines has been the implementation of the ICH guideline on pharmacovigilance planning (E2E), as of 1 January 2007. Swissmedic released a publication in this respect in the Swissmedic Journal (May 2006).

In 2008 and 2009 Swissmedic has published additional supporting documentation clarifying certain aspects of pharmacovigilance requirements.

The preliminary draft for a revision project of the LTP that has been published in October 2009 provides for an extension of the reporting obligations, the implementation of 'good vigilance practice' and pharmacovigilance planning and for quality assurance measures in the medication process. The draft revision project is scheduled to be submitted to parliament in summer 2011.

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