

Code of Conduct

of the Pharmaceutical Industry in Switzerland (Pharma Code)

of 4 December 2003, last revised on 14 May 2020 (As per: 1 January 2021)

Please note: This is a translation for your convenience. Legal standard is the German or French version.

Preamble

The Associations of the Pharmaceutical Industry in Switzerland:

- **scienceindustries** (Business Association Chemistry Pharma Life Sciences)¹,
- **ASSGP** (Association of the Swiss Self-Medication Industry)²,
- **Intergenerika** (Swiss Association of Manufacturers and Importers of Generics and Biosimilars)³,
- **Interpharma** (Association of the Research-Based Pharmaceutical Companies in Switzerland)⁴ and
- **vips** (Association of Pharmaceutical Companies in Switzerland)⁵,

knowing that:

- Healthcare and the well-being of patients are the foremost priority for pharmaceutical companies;
- Successful research and development, especially in the areas of medicine and pharmaceutical sciences, is dependent on the support of the pharmaceutical companies. Nevertheless, in just such cases, conflicts of interest are possible. When these arise, they should be resolved in a transparent and fair manner that permits the promotion of research and development;
- The open exchange of scientific and professional information between the partners in research and development must be ensured; nevertheless, it is ethically indefensible to bias, or attempt to bias, the investigators with corresponding inducements;
- Postgraduate medical training and continuing medical education of those people entitled to prescribe, dispense and administer therapeutic medicinal products for humans are encouraged by the support of the pharmaceutical industry. However, conflicts of interest are possible, and these should be resolved in a transparent and fair manner that still ensures continued support;
- The products of pharmaceutical companies have to comply with high standards of quality, safety and efficacy laid down by the public authorities;
- Interactions between pharmaceutical companies and healthcare professionals must be ethical, appropriate and professional at all times;
- Pharmaceutical companies are responsible for providing accurate, balanced and scientifically based information about their products;

and considering, in this connection, the relevant laws, international codes of the pharmaceutical industry and guidelines from healthcare professional circles:

- Swiss laws and ordinances applicable in this connection;
- IFPMA Code of Practice 2019⁶, published by the International Federation of Pharmaceutical Manufac-

¹ <https://www.scienceindustries.ch>

² <https://www.assgp.ch/>

³ <https://www.intergenerika.ch/>

⁴ <https://www.interpharma.ch/de/index.asp>

⁵ <https://www.vips.ch/>

⁶ <https://www.ifpma.org/subtopics/new-ifpma-code-of-practice-2019/?parentid=264>

- turers and Associations, IFPMA;⁷
- EFPIA Code of Practice (adopted by the EFPIA Board on 22 March 2019, and ratified by the EFPIA Statutory General Assembly of 27 June 2019)⁸, published by the European Federation of Pharmaceutical Industries and Associations, EFPIA⁹;
 - "Collaboration between the medical profession and industry", Guidelines issued by the Swiss Academy of Medical Sciences (SAMS) of 29 November 2012¹⁰;

have adopted the following code of conduct which is recommended to their members.

This Code puts the above-mentioned codes of the international pharmaceutical industry associations into concrete terms for Switzerland.

This Code determines the accompanying rules for implementation of the relevant obligations by pharmaceutical companies, or anyone acting on their behalf, and for monitoring compliance with them.

The associations designated in the Preamble pledge to ensure that the pharmaceutical companies affiliated to them will comply with the following regulations which are based on the principles of ethics and integrity, and sign the following declaration.

The obligation to comply with State law applicable in this connection and which takes priority remains unaffected by compliance with this Code.

All terms referring to persons in this Code refer to persons of both genders.

Rules

1 General provisions

11 Scope

- 11.1 This Code applies to all matters regulated thereby, insofar as these principally take place, are organised or performed in Switzerland. With regard to continuing education support for healthcare professionals by way of participation in international events, the provisions of this Code apply if such healthcare professionals perform their professional activities in Switzerland. If conflicts of standards that seem unsolvable should nevertheless arise in the international context, the stricter provisions of the relevant national country codes will apply.
- 11.2 This Code applies to:
- 11.2.1 Professional promotion for medicinal products for humans: promotions directed at healthcare professionals by pharmaceutical companies, in particular in printed or electronic form (including via the Internet) as defined by section 2 of this Code;
- 11.2.2 Information about medicinal products for humans: communications addressed to healthcare professionals and corresponding reference material of pharmaceutical companies, in particular about new indications, possible applications, dosages, presentation forms or packages, notifications to the pharmaceutical security body and sales catalogues and price lists which do not contain any promotional statements about particular medicinal products for humans;
- 11.2.3 Events as defined by section 13.19 of this Code;
- 11.2.4 Cooperation of pharmaceutical companies with healthcare professionals, healthcare organisations and patient organisations;

⁷ <https://www.ifpma.org/>

⁸ <https://www.efpia.eu/relationships-code/the-efpia-code/>

⁹ <https://www.efpia.eu/>

¹⁰ <http://www.samw.ch/de/Publikationen/Richtlinien.html>

- 11.2.5 Support (sponsorship) by pharmaceutical companies for clinical trials with medicinal products for humans and for non-interventional studies in connection with medicinal products as defined by section 5 of this Code;
- 11.2.6 Activities pursuant to sections 11.2.1 to 11.2.5 of this Code, with whose preparation, implementation or organisation pharmaceutical companies entrust third parties (persons or organisations such as sales force organisations or market research companies, advertising, public relations or congress agencies) which act on behalf of pharmaceutical companies but not in their name.
- 11.3 This Code applies to pharmaceutical companies which have undertaken to comply with this Code by signing the declaration (Annex). Member companies of EFPIA (full and affiliate members) are obliged under EFPIA's rules to sign this Code for as long as they themselves or through third parties are responsible for the performance of the activities pursuant to section 11.2.1 to 11.2.5 of this Code in Switzerland.
- 11.4 Pharmaceutical companies which manufacture or distribute medicinal products for humans in Switzerland but do not belong to any of the associations named in the Preamble may likewise undertake to comply with this Code.

12 Delimitation

This Code does not apply to:

- 12.1 Information about medicinal products (information for healthcare professionals and leaflets), together with data and texts on the containers and packaging material for medicinal products which are prescribed by Swiss law on therapeutic products and approved by the Swiss Agency for Therapeutic Products (Swissmedic);
- 12.2 General information about health or illnesses of humans insofar as such information does not relate either directly or indirectly to specific medicinal products for humans;
- 12.3 Information from pharmaceutical companies about the medicinal products which they manufacture or distribute, provided in reports specifically for the economic media and for shareholders, investors and other persons who are not healthcare professionals;
- 12.4 Promotion by pharmaceutical companies of over-the-counter medicinal products for humans intended for a lay public (public advertising).

13 Terms

- 13.1 *Medicinal products*: medicinal products for humans as defined by the Swiss law on therapeutic products.
Prescription-only medicinal products: medicinal products which under the Swiss law on therapeutic products were classed in a prescription-only category by the competent authorities.
- 13.2 *Medical sales representatives of pharmaceutical companies*: persons who are employed by a pharmaceutical company or a third party mandated by a pharmaceutical company to interact with healthcare professionals or healthcare organisations concerning professional promotion for medicinal products.
- 13.3 *Third parties*: legal entities and/or natural persons who represent a pharmaceutical company or who interact with other third parties on behalf of a pharmaceutical company or in relation to a medicinal product on the instructions of a pharmaceutical company, such as congress organisers, contract sellers, market research companies, advertising agencies, providers of services in connection with events, PR services, management services for non-clinical trials and/or non-interventional studies.
- 13.4 *Healthcare professionals*: physicians, dentists and pharmacists who are working in particular in a practice or hospital together with pharmacists and druggists active in retail businesses and persons who are authorised by the Swiss law on therapeutic products to prescribe, deliver, use

or purchase medicinal products for humans. This definition also includes official representatives and persons with a public-law employment contract or mandate if they perform or are authorised to perform such activities. In case of doubt, the Confederation's provisions on therapeutic products must be taken into account.

- 13.5 *Professional promotion*: professional promotion of medicinal products that addresses healthcare professionals who are authorised to prescribe, deliver or professionally and independently administer medicinal products. It includes all measures for developing the market and creating incentives intended to promote the prescription, delivery, sale, use or application of medicinal products.
- 13.6 *Healthcare organisations*: legal entities under private and public law as well as companies, sole proprietorships or other entities that are not specifically regulated in legal terms who employ healthcare professionals. Under this Code, these in particular include institutions, organisations, associations or other groups of healthcare professionals who provide healthcare services or consultancy or other services in healthcare (e.g. hospitals, clinics, foundations, universities or other educational establishments, scientific societies or professional associations, community practices or networks, but not patient organisations).
- 13.7 *Host country principle*: this refers to the priority given to the limit for a meal (food and beverages) as determined by this Code. This amount applies only to events which are held in Switzerland. For events which are held abroad, the limits set out in the code which claims territorial validity for the host country apply to all the participants, regardless of where the supported healthcare professionals have their primary practice or definitive business address or their registered business headquarters or residential address.
- 13.8 *Information and training materials as well as objects provided for healthcare professionals*: materials and software of modest value which are only important to pharmaceutical and/or medical practice and have a cumulative benefit for patient care. These also include *objects of medical value*: objects and software of modest value that directly serve to promote the training of healthcare professionals and/or the provision of medical services while also improving patient care, but do not cover the usual practice requirements of a healthcare professional.
- 13.9 *Financial contribution with regard to events*: financial contribution to cover the costs of meals, travel, accommodation and/or registration costs. This should make it easier for a healthcare professional or a representative of a healthcare organisation or patient organisation to participate in an event that is organised or supported by a pharmaceutical company.
- 13.10 *Medical training*: postgraduate medical training and continuing medical education in human health and diseases as well as courses relating to medicinal products that are not intended to be promotional.
- 13.11 *Samples*: these are samples of medicinal products as described in Art. 10 of the Ordinance on Advertising for Medicinal Products (AWV), i.e. free sample packages of a medicinal product given to a healthcare professional. Such samples are a recognised method of advertising for medicinal products and allow a healthcare professional to become familiar with a new medicinal product and gain experience in its application. Samples therefore not only serve a promotional function, but also provide information.
- 13.12 *Non-interventional study*: scientific study where a medicinal product is prescribed in the usual manner in accordance with the conditions of the marketing authorisation. The allocation of the patient to a specific treatment strategy is not determined in advance in a trial protocol, but in practice by the prescription of the medicinal product, and has to be recorded separately from the decision to include the patient in the study. No additional diagnostic or monitoring procedures should be applied for the patient.
- 13.13 *Patient organisations*: not-for-profit organisations (including the organisations to which they are affiliated) based or active in Switzerland, which consist primarily of patients or their carers

and which represent or support the needs of patients or their carers.

This definition also includes persons who represent and/or formulate the collective concerns and interests of a patient organisation about a specific topic or a specific pathology.

- 13.14 *Personal health data*: All information relating to the physical, mental or hereditary health or inherited or acquired genetic characteristics of an identified or identifiable natural person, including the performance of health services containing information about their physiology or state of health.
- 13.15 *Pharmaceutical companies*: companies which manufacture or distribute medicinal products for humans by way of business in Switzerland.
Employees of a pharmaceutical company: persons who are employed by a pharmaceutical company or work through a third party on instructions of a pharmaceutical company, provided that they perform activities that fall under this Code.
- 13.16 *Donations and grants*: money, assets or services not intended as compensation for a contribution that is delivered in support of healthcare, scientific research or medical training. This does not include support contributions as defined by Art. 6 of the Ordinance on Integrity and Transparency in the Therapeutic Products Sector (VITH), because these may be agreed directly with healthcare professionals and paid to them directly (see section 15.5 of this Code).
- 13.17 *Sponsorship*: support made available by or on the instructions of a pharmaceutical company as compensation for an appropriate contribution in aid of an activity (including an event) that was executed, organised or prepared by a healthcare professional, healthcare organisation, patient organisation or third party, provided that this is permitted by law.
- 13.18 *Event venue*: actual venue where an event is organised and held (hotel, conference centre, etc.). This is different from the *location*, which refers to the geographic location (country, region, city, etc.).
- 13.19 *Events*: events which are organised by a pharmaceutical company or in its name or financially or otherwise supported by it, such as symposia or congresses, meetings of healthcare professionals, advisory bodies or bodies for the planning of clinical trials or non-interventional investigations or for the training of testers for clinical trials, visits and inspections of research and manufacturing establishments of pharmaceutical companies.

14 Principles of conduct

- 14.1 Pharmaceutical companies who undertake to comply with this Code acknowledge the rules for the enforcement of this Code if proceedings are taken for conduct in breach of the Code.
- 14.2 As long as relevant proceedings are pending, they will in principle not refer the matter at the same time to a State authority or to a court on grounds of breach of the Swiss legal order.
- 14.3 The safeguarding of rights which may be endangered or defeated by compliance with these principles of conduct is reserved.
- 14.4 Pharmaceutical companies may not answer requests from third parties (patients, their relatives, etc.) for advice in personal medical matters. They are obliged to instruct such persons to consult a healthcare professional.

15 Principles of integrity

- 15.1 Where pharmaceutical companies cooperate with healthcare professionals, healthcare organisations and/or patient organisations, such cooperation and the pecuniary benefits granted in return must not constitute an inducement to recommend, prescribe, acquire, supply, sell or administer specific medicinal products for humans.
- 15.2 Pharmaceutical companies may not accord any undue benefits to healthcare professionals, healthcare organisations and/or patient organisations; in particular, they may not offer, promise or grant any gifts (either in cash or non-cash considerations). This prohibition also applies

to any and all promotional items, except those that are explicitly excluded under section 15.3 below.

- 15.3 This does not include:
 - 15.3.1 Objects, information and training materials of modest value as defined by section 13.8 of this Code (maximum CHF 300 per healthcare professional and year) provided for healthcare professionals that are intended solely for a 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; these items can include the company name, but may not be product branded;
 - 15.3.2 Writing implements and pads of modest value, made available to participants at events by pharmaceutical companies; these writing implements and pads may not bear any references to the pharmaceutical company or to particular medicinal products;
 - 15.3.3 Financial contributions to support research, postgraduate medical training and continuing medical education, provided that the criteria set out in this Code are fulfilled;
 - 15.3.4 Appropriate compensation for contributions of equal value, in particular price discounts or rebates on orders, deliveries and purchases of medicinal products, provided that they have no influence on the choice of treatment;
 - 15.3.5 Delivery of free of charge samples of medicinal products to healthcare professionals.
- 15.4 Payment for meals (including beverages) on a reasonable and modest scale, subject to a maximum amount of CHF 100 per healthcare professional per meal is only permitted in the context of a technical discussion or in direct relation to an event. This amount applies only to discussions held with healthcare professionals working in Switzerland and/or representatives of healthcare organisations domiciled in Switzerland or events which are held in Switzerland. For events that are held abroad, the limits set out in the code which claims territorial validity for the host country apply to all the participants, regardless of where they have their primary practice or definitive business address or their registered office.
- 15.5 Donations and grants in whatever form may neither be offered nor promised nor given to healthcare professionals. Such donations and grants may only be offered, promised or given to healthcare organisations or patient organisations. This does not include support contributions as defined by Art. 6 VITH; these may be agreed directly with healthcare professionals.
- 15.6 Donations and grants are only admissible if:
 - 15.6.1 they are made in support of healthcare, research or medical education;
 - 15.6.2 they are documented and these documents are stored by the donor; and
 - 15.6.3 it cannot be interpreted as an incentive to recommend, prescribe, acquire, deliver, sell or distribute specific medicinal products.
- 15.7 Healthcare organisations or patient organisations may not be required by pharmaceutical companies to be exclusively supported by such pharmaceutical company. The same applies to support for events organised by healthcare professionals. The aim should be for such organisations and healthcare professionals to be supported by several pharmaceutical companies.
- 15.8 The laws and ordinances applicable in this connection are reserved, as is their enforcement by State authorities.

2 Professional promotion of and information about medicinal products

21 Principle

Pharmaceutical companies must at all times meet a high ethical standard in all their promotional and information activities. Professional promotion for medicinal products and infor-

mation for healthcare professionals may never discredit the pharmaceutical industry or erode the trust in the industry. They must always take account of the general perception of medicinal products and the professional standing of healthcare professionals, healthcare organisations and patient organisations.

22 Professional promotion

The term professional promotion covers:

- 22.1 Professional promotion arranged or supported by pharmaceutical companies which is directed specifically at healthcare professionals and intended for them, in particular promotion in professional journals and other printed matter, promotion on objects, at events or via other communication channels, including digital media of all kinds, in order to promote the prescription, recommendation, delivery, administration, use or purchase of particular medicinal products.
- 22.2 The activity of medical sales representatives of pharmaceutical companies in relation to healthcare professionals and/or healthcare organisations and that of persons or companies to whom the pharmaceutical company entrusts such activities.

23 General requirements for professional promotion

- 23.1 Professional promotion for a medicinal product may only be made after it has received marketing authorisation from Swissmedic.
- 23.2 The same applies to new indications, possible applications, dosages, pharmaceutical forms and packaging of a medicinal product.
- 23.3 The statements made in professional promotion must concur with the currently valid version of the professional information approved by Swissmedic or, should such not be required by Swissmedic, with that of the marketing authorisation decree.
- 23.4 As long as the professional information about the medicinal product has not been officially published, the version last approved by Swissmedic has to be appended to the promotion.
- 23.5 Printed promotion (advertisements, pamphlets, brochures, etc.) must be easily legible with respect to font size and layout.
- 23.6 Professional promotion may not veil or obscure the actual intention. In professional media, promotion must be clearly distinguishable from the contributions for which the editors of the professional medium are responsible. The same applies to information in the editorial part (PR texts, promotional reports and similar) which is either directly or indirectly related to professional promotion in the same medium.
- 23.7 In professional promotion for medicinal products or information about such products on the *Internet*, the following must also be provided:
 - 23.7.1 The name of the pharmaceutical company which operates or directly or indirectly sponsors the website,
 - 23.7.2 Which information on the website is intended for healthcare professionals and which for a lay public,
 - 23.7.3 A reference to the professional information about the medicinal product most recently approved by Swissmedic if a pharmaceutical company provides information about particular medicinal products for healthcare professionals on its website.
- 23.8 Moreover, the pharmaceutical companies must comply in their professional promotion and information on the Internet with the relevant provisions of the Swiss law on therapeutic products (in particular Art. 5a AWV) and the recommendations of the associations.

24 Requirements concerning the content of professional promotion

- 24.1 Professional promotion must be exact, balanced, fair, objective and sufficiently complete to allow healthcare professionals to form their own opinion about the therapeutic value of the medicinal product in question. It must be based on and clearly present a current assessment of all relevant evidence.
- 24.2 The statements made in professional promotion must be supported by evidence, which must be provided to healthcare professionals on request. They must not be misleading through distortion, inappropriate emphasis, omission or in any other way. Promotional statements about adverse reactions of medicinal products must in particular reflect the current state of knowledge or be evidenced by clinical experiences.
- 24.3 The following in particular are prohibited because they are misleading:
- 24.3.1 Use of the word “safe”, except in conjunction with an appropriate objective qualification;
- 24.3.2 The use of the word “new”, unless the following conditions are met: Medicinal products, indications, possible applications, dosages, pharmaceutical forms and packaging may only be described as new for the first 12 months after they have become available or have been advertised in Switzerland. As such, they may only be called “new” for 18 months after they were first authorised in Switzerland. The information must make clear on what this attribute is based.
- 24.3.3 Information to the effect that a medicinal product has no undesirable effects, does not cause habituation, is risk-free or harmless or other expressions which suggest that a substance is harmless.
- 24.4 Professional promotion must (subject to sections 24.6 and 24.7 of this Code) contain:
- 24.4.1 The brand name of the medicinal product or a corresponding unmistakable identifying description, e.g. the description of the active ingredient, together with the name of the manufacturing or distributing company;
- 24.4.2 The active ingredient(s) with the official abbreviated designation (DCI/INN), should such exist. If a medicinal product contains several active ingredients, then only the therapeutically more significant active ingredients must be cited with the official abbreviated designation or a Swissmedic-approved designation; the other ingredients may be listed in an informative, summarised form;
- 24.4.3 The category of the medicinal product determined by Swissmedic;
- 24.4.4 The name and the address of the pharmaceutical company that is responsible for the medicinal product in Switzerland (holder of the Swissmedic marketing authorisation); this information must be stated either in the promotion itself or be clearly seen in the professional medium in which the promotion appears;
- 24.4.5 The indication that comprehensive information can be found in the professional information for the medicinal product, with a reference to its official publication¹¹;
- 24.4.6 The date (month and year) on which the promotion is produced or, if it has been subsequently changed, the date (month and year) on which it was last changed.
- 24.5 The term *informative professional promotion* means promotion which contains statements about the application of a medicinal product. In addition to the statements according to section 24.4 of this Code, such professional promotion must at least include an indication or possible application that has been authorised by Swissmedic, the dosage, category of application as well as a summary of limitations to use, adverse reactions and interactions (so-called “succinct statement”).

¹¹ Publication on the Swissmedic website: <https://www.swissmedic.ch/swissmedic/en/home/services/medicinal-product-information.html>

- 24.6 The term *reminder promotion* means promotion which is intended to remind the reader of a well-established medicinal product. Such promotion lists only the indications or therapeutic category of the medicinal product; they contain no statements concerning the application of the product. Reminder promotion must satisfy the requirements of section 24.4 of this Code. The “succinct statement” (section 24.5 of this Code) is not required in reminder promotion.
- 24.7 The term *brand name promotion* means professional promotion in which the promotion is confined to the brand name of a medicinal product or the umbrella brand of a range of medicinal products. In brand promotion, apart from the particular brand of the medicinal product or the umbrella brand of a pharmaceutical range (as a sign, logo or both), only the official concise designation (DCI/INN) of the active substance or substance(s), the name of the pharmaceutical company (owner of the Swissmedic authorisation) and its logo may be used.
- 25 References and comparisons**
- 25.1 Should promotion to healthcare professionals refer to clinical trials, these trials must have been carried out in accordance with the Good Clinical Practice (GCP) guidelines that were valid at the time of the trials. The cited clinical trial reports must reflect the current state of scientific knowledge. Mention must be made of the fact that a copy of the full clinical trial report may be requested from the company by healthcare professionals.
- 25.2 Should promotion to healthcare professionals refer to clinical trials, the corresponding clinical trial reports must have been published in a recognised scientific medium.
- 25.3 The clinical trial reports must be cited with the full title, authors’ names, date and the scientific medium in which they were published; in addition, for scientific journals, the year or volume as well as the page number must be indicated.
- 25.4 Under the following conditions, promotion to healthcare professionals may refer to clinical trial reports which have not yet been published:
- 25.4.1 They must have been submitted to, and accepted by, a recognised scientific medium for publication;
- 25.4.2 These reports must be cited in the promotion to healthcare professionals with the full title, authors’ names and date; the corresponding scientific medium must also be indicated;
- 25.4.3 In the promotion to healthcare professionals, mention must be made of the fact that a copy of the full clinical trial report may be requested from the pharmaceutical company by healthcare professionals.
- 25.5 Citations from professional medical literature or from lectures by experts at scientific events may not distort or otherwise alter the results of the clinical trials or the opinion of the author.
- 25.6 All graphs, illustrations, photos and tables from published studies contained in promotional materials must clearly state the precise source of such illustrations and must be true to the original, unless a minor change or modification is unavoidable. In the latter case, it must be stated that the illustration was changed and/or modified. Special care should also be taken that the illustrations contained in the promotion do not make any misleading statements about the use of a medicinal product, or that incomplete and statistically irrelevant information or non-standard benchmarks lead to misleading statements or comparisons.
- 25.7 Should professional promotion refer to investigations such as meta-analyses, pharmacoeconomic studies or field reports from practice, these must have been published in a recognised scientific medium. These publications must be quoted verbatim, in full and with the exact source. Mention must be made of the fact that a copy of the full clinical trial report may be requested from the company by healthcare professionals. The requirements for the citation should also correspond to sections 25.1 to 25.6 of this Code.
- 25.8 Comparisons with other medicinal products must be scientifically correct and referenced, and may not be misleading. Possible references include the latest valid version of the professional

information about the medicinal product as approved by Swissmedic, or, should such not be required by Swissmedic, information from the marketing authorisation decree by Swissmedic, clinical trials or other studies that satisfy the requirements according to sections 25.1 to 25.7 of this Code, or citations from scientific statements marked and referenced as such, or guidelines issued by acknowledged scientific entities.

25.9 The same applies to qualifications such as “better”, “more effective”, “better tolerability” or similar expressions, as well as to superlatives (e.g. “the best”, “the most effective”, “the most prescribed”) or similar expressions and distinctive features (e.g. “unique”, “at the top of ...”, “the standard for ...”, “the number 1”, “the drug of choice”, “the gold standard”).

25.10 Should professional promotion be based on trials whose results are founded on in vitro experiments or make use of animals, this must be clearly evident from the citation.

26 Information about medicinal products that have not yet received marketing authorisation by Swissmedic

26.1 Information about medicinal products must always be precise, balanced, fair, objective and complete. It must be based on and clearly present a current assessment of all relevant evidence.

26.2 The pharmaceutical companies may inform healthcare professionals and the media about medicinal products that have not yet received marketing authorisation from Swissmedic; however, no promotion for these medicinal products is allowed. The same applies to new indications, possible applications, dosages, pharmaceutical forms and packaging of a medicinal product. The brand name may be used; however, it must always be accompanied by the official abbreviated designation of its active ingredients (DCI/INN¹²).

26.3 With such information, it must always be clearly stated that this medicinal product, or the new indication, possible application, dosage, pharmaceutical form or packaging for the medicinal product has not yet received marketing authorisation from Swissmedic.

27 Information materials used at events with international participation

27.1 Information materials that are given out in response to a request at events with international participation may refer to medicinal products that are authorised in other countries but not in Switzerland, or are authorised in Switzerland under different conditions.

27.2 Such information materials must be accompanied by the following declarations:

27.2.1 Reference to the 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 in Switzerland;

27.2.2 Reference to the possible differences in registration requirements and the government-approved professional information (indications, warnings, etc.) in the country or countries where the medicinal products concerned are authorised.

28 Samples

28.1 A limited number of samples may be provided to healthcare professionals so that they may become familiar with a medicinal product and gain experience with its use in practice.

28.2 Samples may not be given as an inducement to recommend, prescribe, acquire, deliver, sell or administer a particular medicinal product.

28.3 The dispensing of samples must otherwise comply with the relevant stipulations of the Swiss law on therapeutic products.

¹² <http://www.who.int/medicines/services/inn/en/>

29 Distribution of professional promotion

- 29.1 Professional promotion may only address those healthcare professionals or organisations who may be reasonably assumed to need or be interested in specific information in the performance of their activities.
- 29.2 All dispatch lists must be kept up to date. If a healthcare professional asks to be removed from a dispatch list, the pharmaceutical company in question must immediately meet this request.
- 29.3 Communication for promotional purposes by fax, e-mail, automated calling systems, text messages and other digital formats may only - whenever possible - be disseminated with the prior consent of the recipients.

210 Important notices

- 210.1.1 Should pharmaceutical companies urgently inform healthcare professionals of something that could affect the safety of a particular medicinal product which is urgent and decisive for healthcare professionals and patients' reactions to treatment, such as a market recall of a medicinal product, limitations to its distribution or use, or a suspension of a recall or limitations to distribution or use, this information must be marked as an "important notice". The same stipulation applies if pharmaceutical companies have to inform healthcare professionals of the interruption or cessation of supply of a medicinal product for other reasons.
- 210.1.2 The label "important notice" must be added in an easily visible and clearly legible manner, both on the envelope for the mailshot and on the information itself.
- 210.1.3 This label may only be used for such information. Labels that sound similar (e.g. "urgent information") should be avoided so that attention is not detracted from important notices.

3 Events for the professional promotion of and dissemination of information about medicinal products as well as postgraduate medical training and continuing medical education for healthcare professionals**31 Principles**

- 31.1 Postgraduate medical training and continuing medical education aim to promote the scientific knowledge and competence of healthcare professionals, and thereby improve medical practice and treatment outcomes for patients. Pharmaceutical companies may participate in different postgraduate medical training and continuing medical education programmes, provided that the following rules are observed:
- 31.1.1 Such activities may not count as promotion. Any promotional activities must be clearly separated from the further education and/or training event.
- 31.1.2 When funding postgraduate medical training and continuing medical education or organising activities pertaining to postgraduate medical training and continuing medical education (directly or in cooperation with third parties), pharmaceutical companies have to ensure that the recipient of the funding is in agreement with the type of cooperation and that this cooperation is transparent to third parties.
- 31.1.3 Where pharmaceutical companies submit their own contributions or participate in the presentation of contents when organising activities that promote postgraduate medical training and continuing medical education, they are responsible for making their activities known. Such contents must be fair, balanced and objective and allow conclusions about different theories and accepted opinions.
- 31.2 Events as defined by section 13.19 of this Code are recognised means of disseminating knowledge and experience about medicinal products and treatments and for further education and advanced training of healthcare professionals.
- 31.3 Events should be organised and executed in such a way that conflicts of interest and financial

dependencies are avoided.

- 31.4 Events which are organised or receive financial support from pharmaceutical companies with subsidiaries in Switzerland and which are aimed purely at participants from Switzerland should fundamentally be staged in Switzerland. The inducement to attend such an event should be derived from the specialist topic and, where appropriate, from the guest speakers who will talk on the subject rather than from the location of the event or within any associated tourist or hospitality-related framework.
- 31.5 Events which are organised or receive financial support from pharmaceutical companies with subsidiaries in Switzerland and which are aimed purely at participants from Switzerland can be staged abroad if the aim is to provide the participants with specialist information that is only available at this location (e.g. medical or pharmaceutical research facilities or projects).
- 31.6 Invitations to events which are staged abroad by the headquarters or regional centres of international pharmaceutical companies can be issued by the subsidiary to participants from Switzerland; such participants must make an appropriate contribution towards the costs.
- 31.7 The same applies to events of an international nature which are staged abroad by international medical or pharmaceutical professional societies and sponsored by pharmaceutical companies with registered offices or subsidiaries in Switzerland and within the framework of which events are also staged, if necessary, by pharmaceutical companies (e.g. satellite symposia).

32 General regulations

- 32.1 The events should impart to the participants knowledge, skills and abilities for patient care that are objective and balanced, useful and necessary.
- 32.2 The main purpose of these events is the communication of scientific or professional information as defined in section 31.2 of this Code. Financial support given by pharmaceutical companies in this context must therefore be limited to registration fees, direct travelling expenses, required meals and accommodation. These support payments must be appropriate and may not be extravagant in any way or manner.
- 32.3 The events should take place at appropriate venues conducive to the main purpose of the event (section 32.2 of this Code). Their choice should be guided primarily by the space and infrastructure availability, with a view to the appropriate performance of the main purpose. Locations which are famous for their entertainment facilities or regarded as extravagant should be avoided.
- 32.4 Refreshments or meals (including beverages) must accompany the main purpose of the event; they may be offered only to participants in the event and must be modest and reasonable in compliance with customary local standards as prescribed by section 15.4 of this Code.
- 32.5 The pharmaceutical companies may not offer or pay for any entertainment or other leisure or hospitality activities.
- 32.6 The financial expenditure for the event should correspond approximately to the amount which the average participant would be willing to spend should they have to pay for it themselves.
- 32.7 An invitation, either as a participant or a speaker, to healthcare professionals who do not work for the pharmaceutical company organising or financially supporting the event may not be made dependent upon the recommendation, prescription or dispensation of a specific medicinal product.
- 32.8 Speakers have to make their interests known in an appropriate manner to the event organiser, the professional society and, before beginning their presentations, also to the participants.
- 32.9 Speakers' fees must be appropriate to the extent of the work performed. Speakers may be additionally compensated for their expenses incurred for participating in the event, including travel costs.

32.10 Pharmaceutical companies may not pay travel, subsistence and accommodation expenses for persons who accompany healthcare professionals invited to the event.

32.11 Should pharmaceutical companies disseminate lectures or discussion contributions that were held at an event or reports about these, the pharmaceutical companies concerned must ensure that the information which is sent out correctly and accurately reproduces what was communicated at the event. The same applies if the pharmaceutical companies entrust other people, media or companies with the task of transmitting this information.

33 Financial support for events staged by healthcare organisations

Should pharmaceutical companies support events for postgraduate medical training or continuing medical education that are offered or carried out under the aegis of professional societies, universities, hospitals, healthcare professionals or other institutions, financially or otherwise, they have to respect the following provisions in particular:

33.1 When an event is announced, at this event itself, and in publications concerning this event, the fact that financial support was provided must be clearly recognisable, and the names of the pharmaceutical companies who supported the event must be disclosed.

33.2 The public use by a pharmaceutical company of a logo and/or materials protected by copyright of such an organisation requires the latter's prior written consent. When asking for this permission, the specific purpose for and the way and manner of using the logo and/or the materials protected by copyright must be clearly stated.

33.3 The financial support for the event has to be specified by the pharmaceutical company in a written contract with the event organiser.

33.4 Financial contributions for support provided by pharmaceutical companies should be transferred into an account of the event organiser that has been specifically opened for this purpose. The speakers as well as all expenditures for the organisation and implementation of the event have to be paid from this account.

33.5 The event organiser is charged with the responsibility of overseeing the finances. Upon request, the budget and bills have to be presented to the supporting pharmaceutical companies and professional societies.

33.6 The organiser determines the topics of the event. These should be treated in an objective manner based on the current state of scientific knowledge.

33.7 In principle, when medicinal products are mentioned in lectures, they should be referred to with the internationally acknowledged active ingredient description (DCI/INN). If several medicinal products, medical devices or processes are available for diagnosis or treatment, these should be mentioned.

34 Financial support for healthcare professionals attending events for further education or advanced training

34.1 Pharmaceutical companies may make financial contributions to healthcare professionals for their participation in further education and training events.

34.2 Pharmaceutical companies may not pay any financial compensation to healthcare professionals purely for the time they spend attending an event.

34.3 If a pharmaceutical company grants a healthcare professional financial support for taking part in an event with international participation, such financial support is subject to the regulations and legal practice in the country in which such healthcare professionals exercise their profession.

35 Financial contribution by participants

35.1 For the purpose of maintaining the independence of healthcare professionals who participate

in an event, pharmaceutical companies have to require as a matter of principle that these persons should make an appropriate financial contribution. When determining this contribution, they must in particular consider the applicable legal regulations and current legal practice.

- 35.2 A reduced financial contribution may be requested from healthcare professionals who are still in post-graduate medical training.
- 35.3 A financial contribution may be waived for events that are held in Switzerland and do not require the participating healthcare professionals to stay overnight at the venue and last for half a working day at most, excluding the time calculated for a meal following the professional part of the event.
- 35.4 These rules likewise apply to events that are financially supported by pharmaceutical companies. They must be respected when regulating the financial support in a contract (section 33.3 of this Code).
- 35.5 Should pharmaceutical companies invite healthcare professionals to an event that is offered or carried out by professional societies, universities, hospitals, healthcare professionals or other institutions, then, along the same lines, the pharmaceutical companies will also request an appropriate financial contribution from the healthcare professionals.
- 35.6 Pharmaceutical companies may not refund to the participants, or have someone else refund to them, either partially or totally, the financial contribution made by the participants.

36 Events by pharmaceutical companies

Should pharmaceutical companies carry out events for promotion and providing information about a medicinal product to healthcare professionals, or for the purposes of postgraduate medical training or continuing medical education, or should they retain someone else to carry out these events, such as congress organisers, then, in addition to sections 31, 32, 33 and 35 of this Code, the following provisions have to be observed in particular:

- 36.1 The responsible professional society decides whether a particular event carried out by one or more pharmaceutical companies should be recognised as postgraduate medical training or continuing medical education.
- 36.2 The costs of additional hotel stays, trips or other activities that have no connection with the subject of the event must be paid for in full by the participants and, where applicable, their accompanying persons.
- 36.3 Pharmaceutical companies may not, apart from events which have the primary purpose of imparting scientific or technical information, offer or pay for events or activities within the area of culture, sports, leisure activities or similar for healthcare professionals.

4 Cooperation with healthcare professionals, healthcare organisations and patient organisations

41 Consultancy or service contracts with healthcare professionals and healthcare organisations

- 41.1 Contracts between pharmaceutical companies and healthcare professionals or healthcare organisations are only permitted if these services are provided in support of healthcare, research, development or medical training and cannot be interpreted as an incentive to recommend, prescribe, acquire, sell, deliver or administer specific medicinal products.
- 41.2 Pharmaceutical companies may entrust healthcare professionals either in groups or individually with consultancy tasks or services, such as papers and the conduct of meetings, medical or scientific studies, clinical trials, non-interventional studies, training and participation in consultancy bodies.
- 41.3 Compensation for such services must be commensurate to the efforts expended and reflect the fair market value of the services that were provided.

- 41.4 Pharmaceutical companies must agree such mandates with healthcare professionals and healthcare organisations in writing before the work begins; in particular, the consultancy task or service to be provided and the compensation for it must be adequately specified.
- 41.5 In this connection, pharmaceutical companies have to respect the following principles:
- 41.5.1 There must be a justified need for the proposed consultancy task or service, which must be documented before the services are requested and the agreements are signed;
- 41.5.2 The criteria for the selection of healthcare professionals have to be directly related to the defined need, and the persons responsible for the selection of consultants must have the professional knowledge required to assess whether the healthcare professional in question meets these criteria;
- 41.5.3 The healthcare professional(s) retained for the task must be qualified to perform it;
- 41.5.4 No more healthcare professionals will be entrusted with a consultancy task or service than are needed to perform or provide it;
- 41.5.5 The commissioning pharmaceutical company has to document the consultancy tasks or services provided by one or more healthcare professionals and use the documents for their intended purpose.
- 41.5.6 Sham contracts of any kind designed to enable healthcare professionals or healthcare organisations to receive financial benefits without any obligation to perform a consultancy task or service are prohibited.
- 41.6 In the mandates issued by them, pharmaceutical companies must stipulate that the healthcare professionals and healthcare organisations have to disclose their mandate relationship if they write or speak in public about matters which are the subject of the mandate or otherwise related to the commissioning pharmaceutical company.
- 41.7 Pharmaceutical companies that employ practising healthcare professionals or representatives of healthcare organisations under a (part-time) employment contract have to stipulate in such contracts that these persons must disclose their employment relationship when they write or speak in public about matters which are the subject of the employment contract or otherwise related to this pharmaceutical company.
- 41.8 If a healthcare professional or representative of a healthcare organisation participates in an event in the context of a mandate relationship e.g. as speaker or consultant, the relevant legal and self-regulatory provisions also apply to these persons (see section 3 of this Code).
- 42 Support of events for professional promotion of and dissemination of information about medicinal products as well as postgraduate medical training and continuing medical education for healthcare professionals**
- 42.1 Pharmaceutical companies may support healthcare professionals and healthcare organisations insofar as such support is limited to research or other healthcare service areas.
- 42.2 The relevant legal and self-regulatory provisions (see section 3 above) must be observed without fail. Such support commitments must in particular always be regulated by a written agreement.
- 43 Principles for cooperation with patient organisations**
- 43.1 Pharmaceutical companies obliged to comply with this Code have to safeguard the independence of patient organisations with reference to their political attitude, their mode of action and their activity. They have to make sure that persons, pharmaceutical companies or organisations retained by them in this connection proceed in the same way.
- 43.2 All partnerships between patient organisations and pharmaceutical companies must be based upon mutual respect, whereby the views and decisions of both partners are of equal value.

- 43.3 Pharmaceutical companies may neither require patient organisations to promote certain specific prescription-only medicinal products, nor may they consider corresponding requests made by patient organisations.
- 43.4 The aims, scope and agreement on support and partnerships must be evidenced in writing and be transparent.
- 43.5 The aim is for patient organisations to be supported by more than one pharmaceutical company. Pharmaceutical companies may not require patient organisations to provide financial or other support for them as a sole pharmaceutical company, either overall or for their individual projects.

44 Consultancy or service contracts with patient organisations

- 44.1 Contracts between pharmaceutical companies and patient organisations by virtue of which the latter provide consultancy tasks or services of any kind for the pharmaceutical company are only permitted if such consultancy tasks or services are provided to support healthcare or research and cannot be interpreted as an incentive to recommend, prescribe, acquire, deliver, sell or administer specific medicinal products.
- 44.2 Pharmaceutical companies may retain representatives of patient organisations as experts for consultancy tasks or services, for instance to attend meetings of consultancy bodies or provide speaker services. Agreements relating to consultancy tasks or services must satisfy the following conditions:
- 44.2.1 A written contract must be signed in advance which stipulates the nature of the consultancy tasks or services to be provided and provides the basis for the payment of these consultancy tasks or services.
- 44.2.2 The need for the consultancy tasks or services must be justified and clearly designated and documented before the consultancy tasks or services are used or agreed.
- 44.2.3 The conditions for the selection of the consultancy tasks or services must correspond directly to the need specified for them. The persons responsible for the selection of the consultancy tasks or services must have the professional expertise needed to determine whether the proposed specialists from the patient organisations meet these conditions.
- 44.2.4 The number of consultants and the scope of the consultancy tasks or services must be no greater than is reasonably necessary to satisfy the specified requirement.
- 44.2.5 The contractually retained pharmaceutical company must record the consultancy tasks and services provided and make expedient use thereof.
- 44.2.6 Compensation for the consultancy tasks or services must be reasonable and may not exceed the normal market value of such consultancy tasks or services. In this connection, no sham contracts may be concluded to justify payments to patient organisations.
- 44.2.7 Pharmaceutical companies have to include provisions in their contracts with patient organisations stipulating that the patient organisation must disclose the fact that it has provided paid consultancy tasks or services to the pharmaceutical company whenever it writes or speaks in public on a topic which is the subject of the contract or on other matters which relate to the particular pharmaceutical company.

45 Support for patient organisations

- 45.1 Where pharmaceutical companies grant financial or other support on a significant scale to a patient organisation, they must agree such support in writing with the patient organisation before it begins.
- 45.2 The following points in particular must be included in the agreement which is to be signed with due legal validity by both parties:

- 45.2.1 names of the partner organisations: pharmaceutical company, patient organisation; where appropriate the retained persons, companies or organisations;
- 45.2.2 description of the nature and purpose of the support;
- 45.2.3 aims and activities within the framework of the support (events, publications, other);
- 45.2.4 tasks, rights and obligations of the pharmaceutical company and patient organisation;
- 45.2.5 if financial support is provided: its amount;
- 45.2.6 in the case of other kinds of support: nature (payment of the costs of a public relations agency working for the patient organisations, training courses provided free of charge, etc.);
- 45.2.7 date and duration of the agreement.

45.3 Pharmaceutical companies have to ensure that third parties can clearly recognise that they have provided financial or practical support to one or more patient organisations.

45.4 Pharmaceutical companies must make arrangements for the internal approval of such agreements.

46 Events and hospitality in dealing with patient organisations

46.1 The events should take place at appropriate venues conducive to the main purpose of the event. They should be chosen with regard to the desired achievement of the main objectives, mainly according to the suitability of the location and infrastructure of the venue. Locations which are renowned for their entertainment facilities or are considered extravagant should be avoided.

46.2 All forms of hospitality granted to patient organisations by pharmaceutical companies must be of an appropriate level and subordinated to the main purpose of the event, regardless whether the event is organised by patient organisations or by pharmaceutical companies.

46.3 Hospitality in connection with events must be confined to the journey, meals (including beverages), accommodation and participation fees.

46.4 Hospitality may only be granted to persons who are entitled to it as participants. In exceptional cases, i.e. in instances where clear health grounds so justify (e.g. handicapped persons), the travel, subsistence, accommodation and participation fees may be paid for an accompanying person who provides care.

46.5 Hospitality may not include the support or organisation of entertainment (e.g. sport or leisure activities).

46.6 Pharmaceutical companies may not organise or sponsor events which are held outside Switzerland, except in the following cases:

46.6.1 most of the guests come from other countries, making it more appropriate for logistic reasons to hold the event in a different country; or

46.6.2 the determining resources or professional knowledge which constitute the objective or personal reason for an event are available in another country, making it more appropriate for logistic reasons to organise the event there.

47 Use of logos - documents of healthcare professionals, healthcare organisations and patient organisations

47.1 Pharmaceutical companies wanting to use logos or other legally protected documents of healthcare professionals, healthcare organisations and patient organisations in publications must obtain their prior written consent.

47.2 When asking for this consent, the pharmaceutical company must clearly describe the specific purpose and the publication for which they will be used, and explain how it wants to use the logo or the legally protected documents.

47.3 Pharmaceutical companies may not, in their own commercial interests, attempt to influence the texts in documents of professionals, health care organisations and patient organisations to whom they provide financial or other support; the correction of factual errors, however, is reserved. Pharmaceutical companies may only make a contribution to a text from a fair and balanced scientific perspective if specifically asked to do so by a patient organisation.

5 Sponsoring of clinical trials with medicinal products and execution of non-interventional studies

51 Principle

Through all of the clinical trials or scientific research sponsored or otherwise supported by them, pharmaceutical companies intend to contribute to knowledge which is in the interest of patients' well-being and advances the cause of science and medicine. Pharmaceutical companies are required to assure the transparency of the clinical trials sponsored by them. By following the rules and regulations cited below, pharmaceutical companies that sponsor clinical trials with medicinal products help to ensure that the most objective trial results will be obtained, that the collaboration between sponsors and investigators is as transparent as possible, and will help avoid conflicts of interest and financial dependencies. They respect the protection of the privacy and personal data of patients.

52 Respecting Good Clinical Practice

Clinical trials of medicinal products must be prepared, conducted and assessed according to the relevant laws and ordinances and the rules of Good Clinical Practice (GCP).

53 Contractual regulation

53.1 Financial support for clinical trials by pharmaceutical companies has to be specified in a written contract. These contracts must be signed, in a legally binding manner, by the pharmaceutical company or companies that finance(s) the clinical trial as the sponsor, the healthcare professional primarily responsible for carrying out the clinical trial (investigator), and the institution (university, faculty or department, hospital, foundation, research organisation, etc.) in which or with which the clinical trial is conducted.

53.2 The contract has to stipulate the parameters that define the clinical trial, specifically:

53.2.1 The clinical trial that is the subject of the contract;

53.2.2 The relationship between the service rendered and the compensation regarding the execution and financing of the clinical trial;

53.2.3 The compensation of the responsible investigator that should be commensurate with the services rendered;

53.2.4 Access of the investigator responsible to all data that are relevant to the conduct of the clinical trial and for the safety of the trial subjects, as well as to all data that are acquired as part of the trial;

53.2.5 The right to publish, or to make publicly available, within a practical time period, the trial results in a medium that is appropriate for such publications, and is accessible for healthcare professionals with a reasonable amount of effort.

53.3 Remuneration for clinical trials that are carried out within the framework of institutions must be transferred to an account of the institution at which the clinical trial is carried out. The account must be audited by a neutral party.

54 Independence of investigators

Pharmaceutical companies that sponsor clinical trials with medicinal products must make sure that the responsible investigator and their staff conduct the trials independently of the interests of the sponsoring pharmaceutical company and have no financial interest in the results of

the trial.

55 Independence of research projects and product procurement

- 55.1 Pharmaceutical companies that sponsor clinical trials with medicinal products may not make them dependent, either directly or indirectly, upon a purchase, or purchasing conditions, of any medicinal product which they either manufacture or distribute, or other products for the therapeutic needs of the institution in which the trial takes place.
- 55.2 Likewise, pharmaceutical companies may not acquiesce to the wishes of those institutions that seek to make the purchase or the purchasing conditions of the pharmaceutical company's products dependent on the clinical trials, either directly or indirectly.

56 Publication

- 56.1 The results of clinical trials must in principle be published in compliance with the applicable laws and ordinances. Upon publication, the relevance of the results has to be assessed considering the significance of the disease as well as the clinical effort involved and the associated financial costs of the procedure or measure investigated. The publication should indicate that this was a pharmaceutical company sponsored clinical trial and the name of the sponsor has to be mentioned.
- 56.2 When publishing the results of a clinical trial, a statement or a footnote that clearly indicates the name of the sponsor of the clinical trial must be included. When presenting the results of the clinical trial during lectures, congresses and the like, the sponsorship must be mentioned; likewise, any possible financial interest of the authors must be disclosed.
- 56.3 The interpretation of the results of a clinical trial must be independent from the interests of the sponsor.
- 56.4 Clinical assessment, monitoring and experience programmes and post-authorisation studies (including retrospective studies) may not serve as hidden promotion. Such assessments, programmes and studies must primarily be carried out for scientific or teaching purposes and investigate valid scientific concerns.

57 Non-interventional studies using authorised medicinal products

- 57.1 Scientific studies exhibiting the following features qualify as non-interventional studies using authorised medicinal products:
- 57.1.1 an authorised medicinal product is prescribed, dispensed or applied by the healthcare professionals taking part in the study in the usual way, complying with the currently valid professional information;
- 57.1.2 the involvement of patients in such a study 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 a patient in the investigation;
- 57.1.3 no additional diagnosis or control measures are provided for patients; recognised methods are used to analyse the collected data.
- 57.2 The following regulations apply to non-interventional studies that are prospective in nature, including individuals or groups of healthcare professionals where patient data is collected specially for the study:
- 57.2.1 There is a written study plan (observation plan/protocol);
- 57.2.2 The competent ethics commission must be consulted in advance;
- 57.2.3 The study plan must be approved by the pharmaceutical company's scientific service and the execution of the study must be supervised by this service;
- 57.2.4 The study results must be analysed by or on the instructions of the contracting pharmaceutical company and summaries of the result must be prepared and made available to the relevant

departments of the pharmaceutical company within a reasonable period; the competent department of the pharmaceutical company must keep copies of such reports for an appropriate period of time; it is generally recommended to publish the study results in a recognised register or professional medium;

- 57.2.5 The pharmaceutical company must provide interested healthcare professionals and the Code Secretariat with a summary of the study results in an appropriate form upon request.
- 57.2.6 If the study results are important for assessing the risk-benefit profile, the competent authorities (usually Swissmedic) must be informed without delay;
- 57.2.7 The pharmaceutical company's medical sales representatives may only participate in such studies under the supervision of the scientific service and only in an administrative capacity; the scientific service has to ensure that the medical sales representatives are adequately trained; their participation may also not be related to the promotion of such a medicinal product.
- 57.3 Pharmaceutical companies also have to comply for all other studies/investigations, including epidemiological and other retrospective studies/investigations, with section 57.2 of this Code.

6 Obligations of pharmaceutical companies when implementing this Code

61 Personnel of pharmaceutical companies

- 61.1 Pharmaceutical companies have to ensure that their personnel who are responsible for the preparation, supervision and approval as well as for the performance of the activities governed by this Code are familiar and comply with the international codes (IFPMA and EFPIA), this Code and the relevant provisions of Swiss law relating to this Code.
- 61.2 Every pharmaceutical company must also appoint at least one senior employee who is responsible for supervising the pharmaceutical company and its associated group companies to ensure compliance with the rules of this Code and the relevant provisions of Swiss law.
- 61.3 Pharmaceutical companies must ensure that their medical sales representatives at all times perform their tasks in a responsible and ethically correct manner. They must be suitably trained and have sufficient knowledge of the Code to be able to correctly inform others about their pharmaceutical company's medicinal products.
- 61.4 Pharmaceutical companies have to ensure that their medical sales representatives continue to satisfy these requirements and that their training is continuously updated.
- 61.5 Medical sales representatives are obliged to inform their pharmaceutical company, on a continuous basis, of any specialised information they learn through their activities, especially about reports of adverse reactions of medicinal products.
- 61.6 When visiting healthcare professionals, medical sales representatives must provide or keep ready a summary of the product features for each of the medicinal products represented by them, subject to the applicable laws and regulations.
- 61.7 Medical sales representatives must ensure that the frequency, time, duration and manner of performance of visits to healthcare professionals, pharmacies, hospitals and other healthcare organisations are appropriate.
- 61.8 Medical sales representatives may not promise incentives or use ploys to get a consultation appointment. When asking for an appointment and during the discussion itself, they have to ensure full transparency from the outset about their own identity and the identity of the pharmaceutical company represented by them.
- 61.9 The type of compensation may not entice medical sales representatives to mislead healthcare professionals to incorrect prescribing or dispensation practices of medicinal products.

62 Scientific service of pharmaceutical companies

- 62.1 Pharmaceutical companies have to set up a scientific service which is responsible for the information about their medicinal products and their promotion and also for the approval and control of clinical trials and non-interventional studies.
- 62.2 Pharmaceutical companies are free to choose whether this service is responsible for both tasks or whether different services perform the named tasks separately.
- 62.3 The scientific service has to include a doctor or, if suitable, a pharmacist or scientist who is responsible for ensuring the conformity of all promotional and information materials with this Code before they are deployed. This person must confirm to the person responsible according to section 63 of this Code for the decision to release, that this final version of the promotional material has been checked and that it complies as far as they can tell with this Code and Swiss legislation on therapeutic products.
- 62.4 The scientific service also has to include a physician or, if suitable, a pharmacist, who can supervise the clinical trials and non-interventional studies and monitor responsibility for such investigations and the collaboration of the medical sales representatives.
- 62.5 This person has to confirm that they have checked the protocol of a clinical trial or a non-interventional study that is prospective in nature and that the latter complies with the valid regulations.

63 Responsible persons at pharmaceutical companies

- 63.1 Pharmaceutical companies have to ensure that the activities regulated by this Code are approved prior to their practical implementation by an expert (responsible person) employed by the pharmaceutical company or instructed by it, who is designated for this purpose.
- 63.2 Participation by the pharmaceutical company in international events, at which this Code and appropriately applicable foreign codes are to be observed, is also included in the area of its responsibility.
- 63.3 Pharmaceutical companies may entrust this responsibility to different persons, organised according to the subject matter pursuant to sections 1 to 5. The responsible person(s) take(s) their decisions independently of the marketing and sales interests of the pharmaceutical company.
- 63.4 Pharmaceutical companies have to provide the names of this (these) person(s) to the Code Secretariat.

64 Specimen copies as documentation for Code Secretariat

- 64.1 Pharmaceutical companies have to deliver as quickly as possible to the Code Secretariat a complete sample copy of all professional promotional materials or information about their medicinal products that they issue to healthcare professionals. The same applies to mailshots and information from specialists in connection with sections 2 and 3 of this Code. To this end, they have to include the Code Secretariat on their mailing lists.
- 64.2 Pharmaceutical companies normally have to communicate these sample copies to the Code Secretariat in electronic form, or if that is not possible, by post.

65 Dispatch lists

- 65.1 Pharmaceutical companies have to keep their dispatch lists up to date. If healthcare professionals ask for their address to be deleted from such a dispatch list, their request must be acted upon.
- 65.2 Communication for promotional purposes by fax, e-mail, automated calling systems, text messages and other digital formats may only - whenever possible - be disseminated with the prior consent of the recipients.

7 Supervision of compliance with the Pharma Code

71 Code Secretariat

- 71.1 scienceindustries entrusts an appropriate healthcare professional (as a rule a physician) who is independent from the pharmaceutical companies to direct the Code Secretariat¹³. It also appoints a person with comparable qualifications as their substitute.
- 71.2 The Code Secretariat is attached to the scienceindustries secretariat for administrative purposes.
- 71.3 The Code Secretariat must ensure the objective and impartial supervision of the work and activities subject to this Code that are performed or arranged by the pharmaceutical companies and their duties as prescribed in section 6 of this Code.
- 71.4 In particular, the Code Secretariat has to ensure that:
- 71.4.1 Pharmaceutical companies which have demonstrably acted in breach of the Code cease such conduct or, if that is impossible in view of the concrete circumstances, give a guarantee that conduct in breach of the Code will cease in future;
- 71.4.2 Differences of opinion between the participants involved in a procedure are settled by joint agreement through mediation.
- 71.5 The Code Secretariat performs the administrative activities necessary for supervision, supported by the scienceindustries secretariat.
- 71.6 It will inform the pharmaceutical companies periodically about rulings handed down by it (without naming the pharmaceutical company or specific medicinal product) as well as about experiences gained in connection with the practical implementation of the Code that are of general interest.
- 71.7 It publishes an annual report on its activities¹⁴.
- 71.8 scienceindustries provides the necessary secretariat infrastructure for the appointed person.

72 Notifications

- 72.1 The Code Secretariat investigates, either on its own initiative or upon receiving notification, alleged breaches of the Code.
- 72.2 Anyone may notify the Code Secretariat of circumstances which are suspected to be in breach of the Code.
- 72.3 The Code Secretariat acts upon notifications if they are made in writing and the charge is founded. If necessary, it may ask the notifying person or unit to supplement or document their substantiation and set an appropriate deadline for doing so.
- 72.4 The Code Secretariat will not respond to anonymous or manifestly unfounded notifications. It cannot respond to complaints that primarily or mostly pursue a commercial interest.
- 72.5 To clarify notifications, the Code Secretariat may request documents from the relevant pharmaceutical companies and set an appropriate deadline for them to comply; it may also put questions to their staff or appointed agents.

73 Procedure adopted by the Code Secretariat

- 73.1 If the Code Secretariat itself opens a case, it has to inform the pharmaceutical company concerned in writing of the conduct found to be in breach of the Code, stating its reasons.

¹³The Code Secretariat is also responsible for supervision of the Code of Conduct of the Pharmaceutical Industry in Switzerland on Cooperation with Healthcare Professional Circles and Patient Organisations (Pharma Cooperation Code).

¹⁴ <https://www.scienceindustries.ch/en/article/12674/annual-reports-of-the-codes-secretariat>

- 73.2 If a suspected breach of the Code is notified to the Code Secretariat, it forwards a complete copy of the notification to the pharmaceutical company concerned at the earliest opportunity.
- 73.3 The Code Secretariat gives the pharmaceutical company concerned the opportunity to state a written opinion, setting a reasonable deadline for it to do so.
- 73.4 If the procedure cannot be settled by consensus in writing, the Code Secretariat may invite the parties to verbal negotiations.
- 73.5 The Code Secretariat sets down the outcome of the negotiations, together with a summary of the arguments, in writing for the attention of the parties.
- 73.6 If the pharmaceutical company concerned acknowledges the conduct in breach of the Code, it has to desist from such conduct and confirm that fact in writing to the Code Secretariat.
- 73.7 The Code Secretariat sets deadlines for the remedial measures to be taken and for their written confirmation. These deadlines have to be commensurate with the severity of the breach of the Code.

74 Serious breaches of the Code

- 74.1 Should the Code Secretariat consider a breach to be patent and serious, it has to, as soon as possible, issue a written summons to the pharmaceutical company to discontinue the conduct contrary to the Code and to guarantee that it will desist from such conduct in future. It sets the pharmaceutical company concerned a short deadline for these remedial measures to be undertaken and for a written confirmation that this has been done.
- 74.2 Should the pharmaceutical company concerned provide credible evidence within the stipulated deadline that there has been no breach or no serious breach of the Code, the Code Secretariat will review the matter as appropriate.

75 Procedure for unresolved cases

- 75.1 Should the pharmaceutical company concerned fail to comply within the set period with the ruling of the Code Secretariat, or should it decline to do so or fail to comply with its confirmation pursuant to sections 73.6 or 74.1 of this Code, the Code Secretariat may refer the matter to the appropriate State authority for a judgement after a warning to comply has not been respected.
- 75.2 At the same time, the Code Secretariat will inform the pharmaceutical company or the person who reported the breach of the Code to the Code Secretariat in writing.

76 Duration of the proceedings

- 76.1 Proceedings according to this Code have to be completed within the shortest possible deadline. They may not last for more than one month.
- 76.2 In justified cases, the Code Secretariat may extend the duration of the proceedings by a reasonable length of time.
- 76.3 The proceedings commence on the date when the Code Secretariat receives notification of a charge, or on the date when a case is opened by the Code Secretariat.
- 76.4 The duration of the procedure ends upon the date of receipt of timely confirmation by the pharmaceutical company concerned that it will comply with the request of the Code Secretariat or the outcome of the consensus settlement to the proceedings recorded by the Code Secretariat and will cease in a timely manner its conduct in breach of the Code and guarantee that it will desist from such conduct in future.
- 76.5 If cessation of the breach of the Code is not possible in light of the concrete circumstances, the pharmaceutical company must guarantee in writing to the Code Secretariat that it will desist from such conduct in future.

- 76.6 The Code Secretariat and the parties to the proceedings will use their best endeavours to ensure that the proceedings can be brought to a speedy conclusion.
- 76.7 If the proceedings cannot be concluded by the specified time limit, the case will be deemed to be unresolved (section 75 of this Code).
- 77 Proceedings before State authorities or courts**
- 77.1 If pharmaceutical companies refer conduct which they deem to be in breach of the scope of this Code or suspect in this connection to constitute a breach of State law to a State authority or to a court, the Code Secretariat will suspend any proceedings which have already been opened for as long as none of the participating pharmaceutical companies ask for the proceedings to be terminated.
- 77.2 The Code Secretariat will refrain from any participation in proceedings which pharmaceutical companies bring before a State authority or a court.
- 77.3 scienceindustries and Swissmedic will reach an understanding in a written agreement on cooperation about the supervision, in particular of professional promotion, insofar as the latter is governed both by this Code and by the Swiss law on therapeutic products.
- 8 Consultative activity of the Code Secretariat**
- 81 To safeguard its independence in the assessment of notifications of suspected breaches of the Code, the Code Secretariat will not assess any forms of conduct, documents or publications governed by this Code before they have been implemented or circulated by the pharmaceutical companies. In doing so, it will consider the recommendations of the international pharmaceutical associations (IFPMA and EFPIA) as far as possible.
- 82 On request, it will provide information about the interpretation of provisions of this Code, without determining the accuracy of certain statements made in the documents or publications of a pharmaceutical company.
- 9 Code Committee**
- 91 Formation and membership**
- 91.1 In consultation with the associations designated in the Preamble, the scienceindustries secretariat appoints a committee to advise the Code Secretariat (Code Committee).
- 91.2 The Code Committee consists of a maximum of fifteen professionals who are competent and experienced in the scope of this code (especially medicine, pharmacy, marketing, promotion and law).
- 91.3 At least three members of the Code Committee may not be employees or representatives of pharmaceutical companies.
- 91.4 A member of the scienceindustries secretariat will be appointed to chair the Code Committee. The scienceindustries secretariat handles the administrative matters of the Code Committee.
- 91.5 In all other respects, the Code Committee constitutes itself at its own discretion.
- 92 Activities**
- 92.1 The Chairman convenes a meeting of the Code Committee at least once every year.
- 92.2 Based on the Code Secretariat's annual report and other reports concerning its enforcement activity and questions of interpretation of this Code, the Code Committee advises the Code Secretariat.
- 92.3 Comprehensive revisions of this Code must always be submitted to the Code Committee pursuant to section 101.1 of this Code before being adopted.

10 Final provisions**101 Amendments**

- 101.1 Where Swiss State law undergoes changes which have an immediate impact on this Code, or if IFPMA or EFPIA change particular provisions of their codes which are referred to in the Preamble to this Code as the basis for the latter in a manner which is binding for the national associations affiliated to them, scienceindustries will reach agreement with the partner associations referred to in the Preamble on a suitable amendment to this Code.
- 101.2 Prior to the enactment of such changes, the associations cited above will hold a consultation of the pharmaceutical companies that have signed the declaration of compliance with this Code.
- 101.3 Should the international pharmaceutical associations (IFPMA and EFPIA) adopt annexes to their codes and explicitly declare these to be binding, these will have to be considered in the implementation of this Code, which may lead to changes that have to be integrated into this Code without any further consultations.
- 101.4 scienceindustries determines in agreement with the partner associations referred to in the Preamble the date on which such amendments will enter into force.

102 Entry into force, replacement of existing law and transitional provisions

- 102.1 The Pharma Code entered into force on 1 January 2004.
- 102.2 The version of this Code revised on 14 May 2020 shall enter into force on 1 January 2021.

103 List of obligated pharmaceutical companies

scienceindustries publishes a list of the pharmaceutical companies¹⁵ that have undertaken to comply with this Code by signing the declaration (Annex).

¹⁵ <https://www.scienceindustries.ch/en/article/12556/pharma-code-signatories>

Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code)

Declaration

The pharmaceutical company cited below hereby declares, independently of its membership of any of the associations named in the Preamble, that it will comply with the rules of this Code and respect the instructions given by the Code Secretariat.

Name of the pharmaceutical company:

Address:

Date:

Stamp and legally binding signature(s)

– Chief Executive Officer:

– Responsible person(s) (section 63 of the Pharma Code):