

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

of 4 December 2003, revised on 6 September 2013 (As per: 1 November 2014)

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 Biotech)¹,
- **ASSGP** (Association of the Swiss Self-Medication Industry)²,
- **Intergenerika** (Association of the Generic Medicines Manufacturers in Switzerland)³,
- **Interpharma** (Association of the Research Based Pharmaceutical Companies in Switzerland)⁴ and
- **vips** (Association of Pharmaceutical Companies in Switzerland)⁵,

Knowing that:

- o Healthcare and the wellbeing of patients are the foremost priority for the pharmaceutical companies;
- o Successful research and development, especially in the areas of medicine and pharmaceutical sciences, is dependent upon 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;
- o 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;
- o Postgraduate medical training and continuing medical education of those people (hereafter referred to as healthcare professionals) entitled to prescribe, dispense and administer therapeutic medicinal products for humans (hereafter called medicinal products) is encouraged by the support of the pharmaceutical industry. However, conflicts of interest are possible, and these are to be resolved in a transparent and fair manner that still ensures continued support;
- o The products of the pharmaceutical companies have to comply with high standards of quality, safety and efficacy laid down by the public authorities;
- o Interactions between the pharmaceutical companies and healthcare professionals must be ethical, appropriate and professional at all times;
- o The pharmaceutical companies are responsible for providing accurate, balanced and scientifically based information about their products;

¹<http://www.en.scienceindustries.ch>

²http://www.assgp.ch/xml_1/internet/en/intro.cfm

³<http://www.intergenerika.ch/>

⁴<http://www.interpharma.ch/de/index.asp>; <http://www.interpharma.ch/fr/index.asp>

⁵<http://www.vips.ch/>

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 2012⁶, published by the International Federation of Pharmaceutical Manufacturers and Associations, IFPMA⁷;
- EFPIA Code of Practice on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals (amended following Statutory General Assembly approval of 24 June 2013)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.

The associations designated in the preamble pledge to ensure that the pharmaceutical branch 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.

To make the text easier to read, the male gender is used throughout the Pharmaceutical Code. However, the corresponding texts likewise always apply to females of the groups of persons referred to.

Regulations

1 General provisions

11 Scope

111 This Code applies to:

111.1 Professional promotion for medicinal products for humans: promotion directed at healthcare professionals by pharmaceutical companies, in particular in printed or electronic form (including via the Internet) within the meaning of Section 2 of this Code;

111.2 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;

111.3 Events within the meaning of Section 135 of this Code;

111.4 Support (sponsorship) by pharmaceutical companies for clinical trials with medicinal products for humans and for non-interventional examinations in connection with medicinal products within the meaning of Section 4 of this Code;

111.5 Activities pursuant to Sections 111.1 to 111.4, with whose preparation, implementation or organization pharmaceutical companies entrust third parties (persons or organizations 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.

⁶ <http://www.ifpma.org/ethics/ifpma-code-of-practice/about-ifpma-code-of-practice.html>

⁷ <http://www.ifpma.org/>

⁸ <http://transparency.efpia.eu/uploads/Modules/Documents/efpia-hcp-code---2013-consolidated-final-2.pdf>

⁹ <http://www.efpia.eu/>

¹⁰ <http://www.samw.ch/en/Ethics/Guidelines/Currently-valid-guidelines.html>

112 This Code applies to pharmaceutical companies which have undertaken to comply with this Code by signing the declaration (Annex).

113 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:

121 Information about medicinal products (information for healthcare professionals and patient information), 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);

122 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;

123 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;

124 Promotion by pharmaceutical companies of over-the-counter medicinal products for humans intended for a lay public (public advertising).

13 Terms

131 *Medicinal products*: medicinal products for humans within the meaning of Swiss law on therapeutic products.

132 *Pharmaceutical companies*: companies which manufacture or distribute medicinal products for humans by way of business in Switzerland.

133 *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 Swiss law on therapeutic products to prescribe, deliver or use medicinal products for humans.

134 *Healthcare organisations*: institutions, organisations, associations or other groups of healthcare professionals which 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).

135 *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 integrity

141 Where pharmaceutical companies cooperate with healthcare professionals or healthcare 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.

142 Pharmaceutical companies may not accord any undue benefits to healthcare professionals or healthcare organisations; in particular, they may not offer, promise or grant any gifts (either in cash or non-cash considerations).

143 The following are reserved:

143.1 Usual remuneration for healthcare professionals in connection with orders and deliveries of

- medicinal products;
- 143.2 Delivery of free of charge samples of medicinal products to healthcare professionals;
- 143.3 Objects, information and training materials of moderate value provided for healthcare professionals which are intended solely for the medical or pharmaceutical activity or are used for post-graduate or continuing education in medicine or pharmacy and which, in both cases, are also beneficial to patients;
- 143.4 Items of modest value, such as writing instruments or folders, which are made available by pharmaceutical companies to the participants in events; these items may bear the name of the pharmaceutical company but must not display any references to specific medicinal products;
- 143.5 Payment for meals (including beverages) on a reasonable and modest scale, subject to a maximum amount of CHF 150 per healthcare professional per meal. 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 they have their primary practice or definitive business address or their registered business headquarters.
- 144 The laws and ordinances applicable in this connection are reserved as is their enforcement by the State authorities.

15 Principles of conduct

- 151 Pharmaceutical companies which undertake to comply with this Code acknowledge the rules of enforcement of this Code if proceedings are taken for breach of the Code.
- 152 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.
- 153 The safeguarding of rights which may be endangered or defeated by compliance with these principles of conduct is reserved.

2 Professional promotion of medicinal products and information about such products for healthcare professionals

21 Principle

In the professional promotion of medicinal products and information about such products, ethics, accuracy, topicality, balance, fairness and the absence of misleading information are to be regarded as generally valid principles. The material used for professional promotion and information must facilitate the correct assessment of the benefits and risks of a medicinal product and its correct application.

22 Professional promotion

The term professional promotion covers:

- 221 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 the Internet, in order to promote the prescription, recommendation, delivery, administration or use of particular medicinal substances;
- 222 The activity of medical sales representatives of pharmaceutical companies (pharmaceutical advisors) in relation to healthcare professionals and that of persons or companies to whom the pharmaceutical company entrusts such activities;

23 General requirements for promotion to healthcare professionals

- 231 Promotion to healthcare professionals for a specific medicinal product can only be commenced after it has received marketing authorization from Swissmedic.
- 232 The same applies to new indications, possible applications, dosages, pharmaceutical forms and

- packings of a medicinal product.
- 233 The statements made in promotion to healthcare professionals 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 authorization decree.
- 234 As long as the professional information about the medicinal product has not been officially published¹¹, the version last approved by Swissmedic is to be appended to the promotion.
- 235 Printed promotion (advertisements, pamphlets, brochures etc.) to healthcare professionals must be easily legible with respect to font size and layout.
- 236 Promotion to healthcare professionals may not veil or obscure the actual intention. In professional media, promotion is to 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 e.g. to promotion in the same medium.
- 237 Medicinal products, indications, possible applications, dosages, pharmaceutical forms and packings may be described as *new* only within one year of their marketing authorization in Switzerland. It must be obvious from the information to what the term *new* refers.
- 238 In professional promotion for medicinal products or information about such products on the *Internet* the following information must also be provided:
- 238.1 The name of the pharmaceutical company which operates or directly or indirectly sponsors the website;
- 238.2 Which information on the website is intended for healthcare professionals and which for a lay public;
- 238.3 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.
- 239 Moreover, the pharmaceutical companies must comply in their professional promotion and information on the Internet with the relevant prescriptions of the Swiss law on therapeutic products and the EFPIA recommendations.
- 24 Information about medicinal products that have not yet received marketing authorisation by Swissmedic**
- 241 The pharmaceutical companies may inform healthcare professionals and the media about medicinal products that have not yet received marketing authorization from Swissmedic; however, no promotion for these medicinal products is allowed. The same applies for new indications, possible applications, dosages, pharmaceutical forms and packings 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).
- 242 With such information, it must always be clearly stated that this medicinal product, or the new indication, possible application, dosage, pharmaceutical form or packing for the medicinal product has not yet received marketing authorization from Swissmedic.
- 25 Requirements concerning the content of professional promotion**
- 251 The statements made in professional promotion must be proven.
- 252 They must not be misleading through distortion, inappropriate emphasis, omission or in any other way.
- 253 The following in particular are prohibited because they are misleading:

¹¹ Publication on the Swissmedic website: <http://www.swissmedicinfo.ch/>

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

- 253.1 Use of the word “safe” except in conjunction with an appropriate objective qualification;
- 253.2 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.
- 254 Professional promotion must (subject to Sections 256 and 257) contain:
- 254.1 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;
- 254.2 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, summarized form;
- 254.3 The category of the medicinal product determined by Swissmedic;
- 254.4 The name and the address of the pharmaceutical company that is responsible for the medicinal product in Switzerland (holder of the Swissmedic marketing authorization); this information must be stated either in the promotion itself or be clearly seen in the professional medium in which the promotion appears;
- 254.5 The indication that comprehensive information can be found in the professional information for the medicinal product, with a reference to its official publication¹³;
- 254.6 The date (month and year) on which the promotion is produced or, if has been subsequently changed, the date (month and year) on which it was last changed.
- 255 The term *informative promotion* means promotion which is which contains statements about the application of a medicinal product. In addition to the statements according to Section 254, such promotion must at least include an indication or possible application that has been authorized by Swissmedic, the dosage, category of application as well as a summary of limitations to use, adverse reactions and interactions (so-called "succinct statement").
- 256 The term *reminder promotion* means promotion which is intended to remind the reader of a well-established medicinal product. Such promotion lists solely the indications or the therapeutic category of the medicinal product; they contain no statements concerning the application of the product. Reminder promotion must satisfy the requirements of Section 254. The “Succinct statement” (Section 255) is not required in reminder promotion.
- 257 The term *brand name promotion* means professional promotion in which the promotion is confined to the brand name of a pharmaceutical or the general brand of a range of medicinal products. In brand promotion, apart from the particular pharmaceutical brand 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.
- 26 References and comparisons**
- 261 Should promotion to healthcare professionals refer to clinical trials, these trials must have been carried out in accordance with the Good Clinical Practice (GCP)¹⁴ guidelines that were valid at the time of the trials. The cited clinical trial reports must reflect the current state of scientific knowledge.
- 262 Should promotion to healthcare professionals refer to clinical trials, the corresponding clinical trial reports must have been published in a recognized scientific medium.

¹³ Publication on the Swissmedic website: <http://www.swissmedic.ch>

¹⁴ http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1_Guideline.pdf

- 263 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.
- 264 Under the following conditions, promotion to healthcare professionals may refer to clinical trial reports which have not yet been published:
- 264.1 They must have been submitted to, and accepted by, a recognized scientific medium for publication;
- 264.2 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;
- 264.3 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 the healthcare professionals.
- 265 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.
- 266 Should promotion refer to investigations such as meta-analyses, pharmaco-economic studies or field reports from practice, these must have been published in a recognized scientific medium. The requirements for the citation should correspond to Sections 261 to 265.
- 267 Comparisons with other medicinal products must be scientifically correct and referenced. 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 authorization decree by Swissmedic, clinical trials or other studies that satisfy the requirements according to Sections 261 to 266, or citations from scientific statements marked and referenced as such, or guidelines issued by acknowledged scientific entities.
- 268 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").
- 269 Should promotion to healthcare professionals 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.

27 Samples

- 271 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.
- 272 Samples must not be given as an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.
- 273 The dispensing of samples must otherwise comply with the relevant stipulations of Swiss legislation on therapeutic products.

28 Important notices

- 281 Should the pharmaceutical companies need to urgently inform healthcare professionals of something that could affect the safety of a particular medicinal product and is urgent and decisive for the healthcare professionals and the treatment behaviour of the patients, in particular, 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, then this information must be marked as an "important notice". The same stipulation applies if the pharmaceutical companies have to inform healthcare professionals of the interruption or cessation of supply of a medicinal product for other reasons.
- 282 The label, "important notice", must be added in an easily visible and clearly legible manner both on the envelope of the mailing as well as on the information itself.

- 283 This label may only be used for such information. Similar sounding labels (e.g. "urgent information") are to be avoided so that attention is not detracted from the important notices.
- 3 Events for the professional promotion of medicinal products or for the provision of information about them as well as for postgraduate medical training and continuing medical education for health care professionals**
- 31 Principles**
- 311 Events within the meaning of Section 135 are recognised means of circulating knowledge and experience about medicinal products and treatments and for further training and advanced training of healthcare professionals.
- 312 Events are to be organized and executed in such a way that conflicts of interests and financial dependencies are avoided.
- 313 Events which are organized or receive financial support (sponsored) 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 are to talk on the subject and not from the location of the event or within any associated tourist or hospitality-related framework.
- 314 Events which are organized or receive financial support(sponsored) 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).
- 315 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.
- 316 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**
- 321 The events should impart to the participants knowledge, skills and abilities for patient care that are objective and balanced, useful and necessary.
- 322 Communication of scientific or professional information is the main purpose of these events. Refreshments or meals (including beverages) must accompany the main purpose of the event; they may be offered only to the participants in the event and must be modest and reasonable in compliance with the customary local standards pursuant to Section 143.5 of this Code. The pharmaceutical companies must not offer or pay for any entertainment or other leisure or hospitality activities.
- 323 The events should take place at appropriate venues conducive to the main purpose of the event (Section 322). 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.
- 324 The financial expenditure for the event should correspond approximately to the amount which the average participant would be willing to spend should he have to pay for it himself.
- 325 An invitation, either as a participant or speaker, to healthcare professionals who do not work for the pharmaceutical company organizing or financially supporting the event, may not be made dependent upon the recommendation, prescription or dispensation of a specific medicinal product.

326 The speakers are to make their interests known in an appropriate manner to the event organizer, the professional society and, before beginning their presentations, also to the participants.

327 The speakers' honoraria must be appropriate to the extent of the work performed. The speakers may additionally be compensated for their expenses associated with participating in the event, including travel costs.

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

329 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 contribution by the participants

331 For the purpose of maintaining the independence of healthcare professionals who participate in an event, the pharmaceutical companies require as a matter of principle that these persons should make an appropriate financial contribution. When determining this financial contribution, the following are to be considered in particular: the duration of the event, the location, the distance from the domicile of the participants and the professional level of the participating healthcare professionals.

332 A reduced contribution may be requested from healthcare professionals who are still in postgraduate medical training.

333 For events that are held in Switzerland and last less than one day, the financial contribution by the participant may be waived.

334 These regulations likewise apply to events that are financially supported by pharmaceutical companies. They must be respected when regulating the financial support in a contract (Section 362).

335 Should pharmaceutical companies invite healthcare professionals to an event that is offered or carried out by professional societies, universities, clinics, healthcare professionals or other institutions, then, along the same lines, the pharmaceutical companies will also request an appropriate financial contribution from the healthcare professionals.

336 The 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.

34 Financial support for healthcare professionals attending events

341 The pharmaceutical companies shall not allow healthcare professionals to receive any financial compensation purely for the time they spend attending an event.

342 If a pharmaceutical company does grant a healthcare professional financial support for taking part in an event with international participation, such financial support is subject to the rules of the jurisdiction under which such healthcare professionals carry out their profession.

35 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 organizers, then, in addition to Sections 31 – 33, the following provisions will be observed in particular:

351 The responsible professional society decides whether a particular event carried out by one or more pharmaceutical companies should be recognized as postgraduate medical training or continuing medical education.

352 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.

353 Pharmaceutical companies should 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. This does not include events held exclusively for charitable purposes.

36 Pharmaceutical company support of events

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, clinics, healthcare professionals or other institutions, financially or otherwise, they shall respect, in particular, the following provisions:

361 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 recognizable, likewise, which pharmaceutical companies support the event.

362 The financial support for the event is specified by the pharmaceutical company in a written contract with the organizer.

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

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

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

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

37 Promotion and information materials used at events with international participation

371 Promotion and information materials which are offered or given away at events with international participation may refer to medicinal products which are authorized in other countries but not in Switzerland or are authorized in Switzerland subject to different conditions.

372 Such promotional and information material must be accompanied by the following declarations:

372.1 Reference to the countries where the medicinal products concerned are authorized, and to the fact that the medicinal products concerned are not authorized in Switzerland or are subject to different conditions in Switzerland;

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

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

41 Principle

Through all of the clinical trials or scientific research sponsored or otherwise supported by them, the pharmaceutical companies intend to contribute to knowledge which is in the inter-

est of patients' well-being and advances the cause of science and medicine. The 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.

42 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).

43 Contractual regulation

431 The financial support for clinical trials by pharmaceutical companies is 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, clinic, foundation, research organization etc.) in which or with which the clinical trial is carried out.

432 The contract stipulates the parameters that define the clinical trial, specifically:

432.1 The clinical trial that is the object of the contract;

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

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

432.4 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;

432.5 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.

433 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.

44 Independence of the investigators

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

45 Independence of research projects and product purchase

451 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.

452 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.

46 Publication

461 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 is 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 sponsors is to be mentioned.

462 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, here, too, sponsorship must be mentioned; likewise, any possible financial interest of the authors must be disclosed.

463 The interpretation of the results of a clinical trial must be independent from the interests of the sponsor.

47 Non-interventional studies using authorized medicinal products

471 Those studies which are not covered by State law on research on human beings (e.g. reports on practical experience), and have the following characteristics, are regarded as non-interventional studies with authorized medicines:

471.1 an authorized medicinal product is prescribed, dispensed or applied by the healthcare professionals taking part in the investigations in the usual way, complying with the currently valid professional information;

471.2 the involvement of patients in such an investigation is not determined in advance by an investigation protocol and the prescription, dispensing or use of medicines is clearly separate from the decision to include a patient in the investigation;

471.3 no additional diagnosis or control measures are provided for patients; epidemiological methods are used to analyze the collected data.

472 The appropriate regulations of the Swiss legislation shall 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.

473 On request, pharmaceutical companies must provide healthcare representatives with a summary of the study results in appropriate form.

474 The pharmaceutical company's medical representatives may only collaborate in non-interventional studies under the supervision of the scientific service of the company and for administrative purposes.

475 The pharmaceutical companies shall also comply for all other studies, including epidemiological and other retrospective studies, with Sections 472 – 474.

5 Obligations of the pharmaceutical company when implementing this Code**51 Personnel of the pharmaceutical companies**

511 Pharmaceutical companies shall ensure that their personnel responsible for the preparation, verification and approval and also for the performance of the activities governed by this Code are familiar with this Code and with the applicable provisions of Swiss law in connection with this Code and that they comply with those rules.

512 In particular, the pharmaceutical companies must ensure that the medical sales representatives 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.

513 The pharmaceutical companies ensure that their medical sales representatives continue to satisfy these requirements and that their training is continuously updated.

514 The medical sales representatives are obligated to inform their pharmaceutical company, on a continuous basis, of any specialized information that they learn through their activities, especially about reports of adverse reactions of medicinal products.

515 The type of compensation may not entice the medical sales representatives to mislead healthcare professionals to incorrect prescribing or dispensation practices of medicinal products.

52 Responsible persons at the pharmaceutical company

521 The pharmaceutical companies shall ensure that the activities regulated by this Code are approved prior to their practical implementation by an expert person employed by the pharmaceutical company or instructed by it, who is designated for this purpose (responsible person).

522 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.

523 The pharmaceutical company may assign this responsibility, organized according to the subject matter pursuant to Sections 1 to 4, to different persons. The responsible person(s) shall take their decisions independently of the marketing and sales interests of the pharmaceutical company.

524 Pharmaceutical companies shall provide the names of this (these) person(s) to the Code Secretariat.

53 Scientific service of the pharmaceutical companies

531 The pharmaceutical companies 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.

532 The pharmaceutical companies are free to choose whether this service is responsible for both tasks or whether different services perform the named tasks separately.

533 The scientific service includes 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 52 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 the Swiss legislation on Therapeutic Products.

534 The scientific service also includes 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 representatives.

535 This person confirms that he has checked the protocol of a clinical trial or a non-interventional study that is prospective in nature (Section 472) and that the latter complies with the valid regulations.

536 The pharmaceutical companies inform the Code Secretariat of the persons defined according to Sections 533 and 534 who are available as contacts.

54 Specimen copies as documentation for the Code Secretariat

541 The pharmaceutical companies shall deliver as quickly as possible to the Code Secretariat a complete sample copy of all professional promotional material or information about their medicinal products that they issue to healthcare professionals. The same shall apply to mailings and information from specialists in connection with Sections 1 to 3. To this end, they shall include the Code Secretariat on their mailing lists.

542 The pharmaceutical companies shall normally communicate these sample copies to the Code Secretariat in electronic form, or if that is not possible, by post.

55 Dispatch lists

The pharmaceutical companies 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.

6 Supervision of compliance with this Code**61 Code Secretariat**

611 scienceindustries entrusts an appropriate healthcare professional (as a rule a physician) who is independent from the pharmaceutical companies to direct the Code Secretariat¹⁵. It also appoints a person with comparable qualifications as his substitute.

612 The Code Secretariat is attached to the scienceindustries secretariat for administrative purposes.

613 The Code Secretariat shall ensure the objective and impartial supervision of the work and activities governed by this Code performed or arranged by the pharmaceutical companies and of their duties prescribed in Section 5.

614 In particular, the Code Secretariat shall ensure that:

614.1 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;

614.2 Differences of opinion between the participants involved in a procedure are settled by joint agreement through mediation.

615 The Code Secretariat shall perform the administrative activities necessary for supervision, supported by the scienceindustries secretariat.

616 It shall 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.

617 It shall publish an annual report covering its activities¹⁶.

618 scienceindustries provides the necessary secretariat infrastructure for the appointed person.

62 Notifications

621 The Code Secretariat investigates, either on its own initiative or upon receiving notification, alleged breaches of the Code.

622 Anyone may notify the Code Secretariat of circumstances which are suspected to be in breach of the Code.

623 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 to supplement or document his substantiation and set an appropriate deadline for doing so.

624 The Code Secretariat will not respond to anonymous or manifestly unfounded notifications.

625 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.

63 Procedure adopted by the Code Secretariat

631 If the Code Secretariat itself opens a case, it shall inform in writing the pharmaceutical compa-

¹⁵ The 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 organizations (Pharma Cooperation Code).

¹⁶ <http://www.en.scienceindustries.ch/involvement/pharma-code/pharma-code-annual-reports>

ny concerned of the conduct found to be in breach of the Code, stating its reasons.

632 If a suspected breach of the Code is notified to the Code Secretariat, it shall forward a complete copy of the notification to the pharmaceutical company concerned at the earliest opportunity.

633 The Code Secretariat shall give the pharmaceutical company concerned the opportunity to state a written opinion and shall set a reasonable deadline for it to do so.

634 If the procedure cannot be settled by consensus, the Code Secretariat may invite the parties to verbal negotiations.

635 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.

636 If the pharmaceutical company concerned acknowledges the conduct in breach of the Code, it shall desist from that conduct and confirm that fact in writing to the Code Secretariat.

637 The Code Secretariat shall set deadlines for the remedial measures to be taken and for their written confirmation. These deadlines shall be commensurate with the severity of the breach of the Code.

64 Serious breaches of the code

641 Should the Code Secretariat consider a breach to be patent and serious, it shall, 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.

642 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 shall review the matter as appropriate.

65 Procedure for unresolved cases

651 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 Section 636 or 641, the Code Secretariat may refer the matter to the appropriate State authority for a judgment after a warning to comply has not been respected.

652 At the same time, the Code Secretariat shall inform in writing the pharmaceutical company or the person who reported the breach of the Code to the Code Secretariat.

66 Duration of the proceedings

661 The proceedings according to this Code shall be completed within the shortest possible deadline. They shall not last for more than one month.

662 In justified cases, the Code Secretariat may extend the duration of the proceedings by a reasonable length of time.

663 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.

664 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.

665 If cessation of the breach of the Code is not possible in the light of the concrete circumstances, the pharmaceutical company shall guarantee in writing to the Code Secretariat that it will desist from such conduct in future.

666 The Code Secretariat and the parties to the proceedings shall use their best endeavours to ensure that the proceedings can be brought to a speedy conclusion.

667 If the proceedings cannot be concluded by the specified time limit, the case shall be deemed to be unresolved (Section 65).

67 Proceedings before the State authorities or courts

671 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 shall 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.

672 The Code Secretariat shall refrain from any participation in proceedings which pharmaceutical companies bring before a State authority or a court.

673 scienceindustries and Swissmedic shall reach an understanding in a written agreement on cooperation in the supervision, in particular of professional promotion, insofar as the latter is governed both by this Code and by Swiss law on therapeutic products.

7 Consultative activity of the Code Secretariat

71 To safeguard its independence in the assessment of notifications of suspected breach of the Code, the Code Secretariat shall not assess any forms of conduct, documents or publications governed by this Code before they have been implemented or circulated by the pharmaceutical companies.

72 On request, it shall 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.

8 Code Committee

81 Formation and membership

811 In consultation with the associations designated in the preamble, the scienceindustries secretariat shall appoint a committee to advise the Code Secretariat (Code Committee).

812 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).

813 At least three members of the Code Committee shall not be employees or representatives of pharmaceutical companies.

814 A member of the scienceindustries secretariat shall be appointed to chair the Code Committee. The scienceindustries secretariat handles the administrative matters of the Code Committee.

815 The term of office of the Code Committee members is four years. It begins in each case on the first day of a calendar year. Re-election is possible. New members taking over the responsibilities of predecessors shall serve out the term of office of the members whom they replace.

82 Activities

821 The Chairman convenes a meeting of the Code Committee at least once annually.

822 Based on the Code Secretariat's annual report, and other reports concerning its enforcement activity, the Code Committee advises the Code Secretariat.

9 Final Provisions

91 Amendments

911 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 shall reach agreement with the partner associations referred to in the preamble on a suitable amendment to this Code.

912 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.

913 scienceindustries determines in agreement with the partner associations referred to in the preamble the date on which such amendments are to enter into force.

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

921 The Pharma Code entered into force on 1 January 2004.

922 The version of this Code revised on 6 September 2013 enters into force on 1 January 2014.

923 Sections 142 and 143 of this Code in the edition of 6 September 2013 enter into force on 1 July 2014.

93 List of obligated pharmaceutical companies.

scienceindustries shall publish a list of the pharmaceutical companies¹⁷ which have undertaken to comply with this Code by signing the declaration (Annex).

¹⁷ <http://www.en.scienceindustries.ch/involvement/pharma-code/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 the Pharma Code and respect the instructions given by the Pharma Code Secretariat.

Name of the pharmaceutical company:

Address:

Date:

Stamp and legally binding signature(s):

– Chief Executive Officer:

– Responsible person(s) (Sections 52 and 536 of the Pharma Code):