

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

of December 4, 2003, partially revised on October 1, 2006 and June 12, 2008¹

Preamble

The Associations of the Pharmaceutical Industry in Switzerland:

- **SGCI Chemie Pharma Schweiz** (Swiss Society of Chemical Industries / Schweizerische Gesellschaft für Chemische Industrie / Société Suisse des Industries Chimiques)²,
- **ASSGP** (Swiss Association of Manufacturers of Non Prescription Medicines / Schweizerischer Fachverband der Hersteller rezeptfreier Heilmittel / Association Suisse des Fabricants de Médicaments non soumis à la Prescription)³,
- **Intergenerika** (Association of the Generic Medicines Manufacturers in Switzerland / Verband der Generikahersteller in der Schweiz / Union Suisse des Fabricants de Génériques)⁴,
- **Interpharma** (Swiss Pharmaceutical Research Companies / Verband der forschenden pharmazeutischen Firmen der Schweiz / Association des Maisons Suisses de Recherche Pharmaceutique)⁵ and
- **vips** (Vereinigung Pharmafirmen in der Schweiz / Association des entreprises pharmaceutiques en Suisse)⁶,

Knowing that:

- o Successful research and development, especially in the areas of medicine and pharmaceutical sciences, is dependent upon the support of the pharmaceutical industry. Nevertheless, in just such cases, conflicts of interest are possible. When these arise, they should be resolved in a transparent, fair manner that enables 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 incentives;
- o Postgraduate medical training and continuing medical education of those people (hereafter referred to as health care 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 In order that health care professionals can rationally decide about a medicinal product's administration and use, accuracy, balance, objectivity and fairness are of utmost concern when the pharmaceutical industry companies provide information about, or advertise medicinal products to health care professionals;
- o It is neither ethically justifiable nor conforms with the legal requirements, prescribed to protect from health risks, to influence, or to try to influence, the therapeutic decisions of health care professionals via financial incentives. The exception to this is that, to the extent that they are allowed, discounts in the

¹ *Partial Revision dated June 12, 2008:* The reference to the EFPIA Codes in the Preamble, the enlarged scope as well as Art. 121.1, 121.4, 134.5, 147.1, 147.2, 15, 163, 2, 212, 213, 223, 24, 27-29, 3, 37, 4, 521, 554, 554.1, 555.1, 555.4, 555.6, 6, 611-613, 62, 641, 642, 66, 661, 662, 83, 1023 and 104 are amendments or new.

Partial Revision dated October 1, 2006: The reference to the IFPMA Code (Revision 2006) in the Preamble as well as Art. 124, 134.6, 214-217, 243, 923 and 94 are amendments or new.

² www.sgci.ch

³ www.assgp.ch

⁴ www.intergenerika.ch

⁵ www.interpharma.ch

⁶ www.vips.ch

sale of medicinal products are permissible as long as they are aligned with an economically-justifiable purchasing behaviour. Nevertheless, the companies are, in this respect, obligated to obey the respective legislation and its federal enforcement⁷;

- The pharmaceutical industry shares interests with the organizations which represent or support the interests of patients and/or their carers and the relationships between the pharmaceutical industry and patient organizations must take place in an ethical and transparent environment;

and considering, in this connection, the relevant federal directives and international codes of the pharmaceutical industry:

- Federal Law on Therapeutic Products (LTP)⁸, Ordinance on Clinical Trials with Therapeutic Products⁹, Ordinance on Advertising of Medicinal Products¹⁰ and further ordinances to be observed in this context;
- IFPMA Code of Pharmaceutical Marketing Practices (Revision 2006), published by the International Federation of Pharmaceutical Manufacturers and Associations, IFPMA¹¹;
- EFPIA Code On The Promotion Of Prescription-Only Medicines To, And Interactions With, Healthcare Professionals, as adopted by EFPIA Board on 05/10/2007 (EFPIA Healthcare Professionals Code), issued by the European Federation of Pharmaceutical Industries and Associations, EFPIA¹²;
- EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations, as adopted by EFPIA Board on 05/10/2007 (EFPIA Patient Organizations Code), issued by the EFPIA¹³;
- "Collaboration between the medical profession and industry" – Guidelines issued by the Swiss Academy of Medical Sciences of 24 November 2005¹⁴;

have imposed the following, binding code of conduct for their members.

SGCI, ASSGP, Intergenerika, Interpharma and vips engage that affiliated manufacturers and distributors of the pharmaceutical industry pledge to follow the subsequent regulations and sign the corresponding declaration.

Additionally, companies that manufacture or distribute medicinal products in Switzerland, even though they do not belong to one of the aforementioned associations, may pledge to respect the Pharma Code regulations and its monitoring and enforcement.

These regulations are of particular relevance to the advertising of, and information about, medicinal products to/for health care professionals, the execution and the support of events providing information about medicinal products and the advertising to health care professionals for such; likewise, these regulations apply to events of postgraduate medical training and continuing medical education for health care professionals, non-interventional studies and the sponsoring of clinical trials with medicinal products by companies of the pharmaceutical industry as well as cooperation of such companies with patient organizations.

In cases where there has been an infringement of the Pharma Code, companies that have pledged to its observance will respect the appropriate enforceability rule and, as long as the corresponding proceedings are pending, as a matter of principle refrain from notifying Swissmedic, claiming a violation of the Swiss legislation on Therapeutic Products, or institute legal proceedings before a court, claiming unfair competition.

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To facilitate legibility of the Pharma Code document, the male gender is used throughout. Nevertheless, the corresponding text also applies to females among the groups mentioned.

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⁷ Art. 33 of the Law on Therapeutic Products (LTP): www.swissmedic.ch/files/pdf/HMG_English_New_version.pdf

⁸ http://www.swissmedic.ch/files/pdf/HMG_English_New_version.pdf

⁹ http://www.admin.ch/ch/d/sr/c812_214_2.html (text only available in German, French and Italian)

¹⁰ http://www.admin.ch/ch/d/sr/c812_212_5.html (text only available in German, French and Italian)

¹¹ www.ifpma.org/pdf/IFPMA-TheCode-FinalVersion-30May2006-EN.pdf,

<http://www.ifpma.org/pdf/IFPMA-TheCode-FinalVersion-30May2006-FR.pdf>

¹² <http://www.efpia.org/Objects/2/Files/code%20medicines%202007.pdf>

¹³ <http://212.3.246.100/Objects/2/Files/Code%20with%20Patients%20final%20Oct%202007.pdf>

¹⁴ http://www.samw.ch/docs/Richtlinien/e_Aerzte_Industrie.pdf

Regulations

1 Advertising and providing information about medicinal products to health care professionals

11 Principle

For advertising to, and providing information about, medicinal products to health care professionals, accuracy, balance, objectivity and fairness are to be considered generally valid principles.

12 Scope and Terms

121 Scope

121.1 In the area of advertising to health care professionals, the Pharma Code complements the Swiss legislation on Therapeutic Products, prescribed to protect from health risks, through its rules based on ethics and honesty. In this respect it embodies the codes of the international associations of the pharmaceutical industry for Switzerland called upon in the Preamble.

121.2 Subject to Art. 122, the Pharma Code applies to advertising for, and information about, medicinal products to health care professionals and their assistants issued by manufacturers and distributors of medicinal products operating in Switzerland (subsequently called companies).

121.3 The Pharma Code applies to advertising and providing information to health care professionals that a company itself makes available, as well as to the corresponding preparation and implementation that it outsources to other people or companies, e.g., such as external sales companies, market research companies, advertising or public relation agencies.

121.4 The Pharma Code also applies to other activities covered by it, where companies appoint third parties to undertake planning, design or implementation and such third parties act on their behalf but not in the name of the company.

122 Delimitation

The Pharma Code does not apply to:

122.1 The medicinal product's professional information as stipulated by the Swiss legislation on Therapeutic Products and that has been approved by the Swiss Agency of Therapeutic Products (Swissmedic);

122.2 The medicinal product's patient information (package insert) as stipulated by the Swiss legislation on Therapeutic Products and that has been approved by Swissmedic;

122.3 General information and text imparted on the container and packing material for medicinal products as stipulated by the Swiss legislation on Therapeutic Products and that has been approved by Swissmedic;

122.4 Information dealing with general health issues or about human disease, as long as this information does not refer to specific medicinal product, either directly or indirectly;

122.5 Information from companies regarding medicinal products that they manufacture or distribute provided in reports specifically for economic media as well as to shareholders, investors, or other people who are not health care professionals (Art. 123.2);

122.6 The advertising of medicinal products to a lay public (public advertising).

123 Terms

- 123.1 Considered as advertising to health care professionals is that advertising which is specifically targeted at, and addressed to, health care professionals or their assistants.
- 123.2 Considered as health care professionals are physicians, dentists and pharmacists working in a hospital or practice, as well as pharmacists and druggists active in retail businesses.
- 123.3 Additionally considered health care professionals are those who, according to Art. 24¹⁵ and 25¹⁶ of the Law on Therapeutic Products, are legitimately entitled to prescribe, dispense or administer drugs.
- 123.4 Considered as assistants are those people without the qualification of a health care professional as intended in Articles 123.2 and 123.3, who work with such professionals in a physician's or dentist's office, in a hospital or in a retail business (pharmacy, drug-store), and as such exercise activities regulated in the Pharma Code.
- 123.5 Considered as advertising to health care professionals is that information that encourages the prescribing, dispensing, administering or selling of certain medicinal products.
- 123.6 Considered as advertising to health care professionals are, in particular, advertisements in professional journals, advertising announcements on printed matter, on objects, at information stands or on posters presented at congresses and similar events, using audiovisual aids, pictures, sound and data transmitting media, internet or telephone, as well as mailings to health care professionals or their assistants.
- 123.7 Also considered as advertising to health care professionals are the activities of the companies' sales representatives (medical representatives) that are directed to health care professionals or their assistants, as well as those of other persons or companies that are appointed with this responsibility by the company.
- 123.8 Considered as information about a medicinal product are notices and corresponding reference material targeted at health care professionals, especially with respect to new indications, possible applications, dosages, pharmaceutical forms and packings, communications concerning product safety as well as sales catalogues and price lists, as long as these do not contain advertising messages for specific medicinal products.

124 Mailing lists

The companies will maintain their mailing lists up to date. If health care professionals or their assistants request that their addresses be deleted from such a mailing list then this request must be complied with.

13 Requirements for Advertising to Health Care Professionals**131 Principle**

- 131.1 Advertising to health care professionals for a specific medicinal product can only be commenced after it has received marketing authorization from Swissmedic.
- 131.2 The same applies to new indications, possible applications, dosages, pharmaceutical forms and packings of a medicinal product.
- 131.3 The statements made when advertising to health care 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.

¹⁵ Art. 24 of the Law on Therapeutic Products (LTP), www.swissmedic.ch/files/pdf/HMG_English_New_version.pdf

¹⁶ Art. 25 of the Law on Therapeutic Products (LTP), www.swissmedic.ch/files/pdf/HMG_English_New_version.pdf

- 131.4 As long as the professional information about the medicinal product is not available to health care professionals according to the ordinance on the marketing authorization from November 9, 2001¹⁷, then the version last approved by Swissmedic is to be appended.
- 132 **Layout**
- 132.1 Printed advertising (advertisements, pamphlets, brochures etc.) to health care professionals must be easily legible with respect to font size and layout.
- 132.2 Advertising to health care professionals may not veil or obscure the actual intention. In professional media, advertisements are to be clearly distinguishable from the contributions for which the editors of the professional medium are responsible. The same applies to information in the edited part (PR texts, reports for the public and similar) that is triggered either directly or indirectly (e.g., via advertisements in the same medium).
- 133 **Information about medicinal products that have not yet received marketing authorization by Swissmedic**
- 133.1 The companies may inform health care professionals and the media about medicinal products that have not yet received marketing authorization from Swissmedic, however, no advertisements for these medicinal products are 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/INN¹⁸).
- 133.2 With such information, it must always be clearly stated that this medicinal product, respectively, this new indication, possible application, dosage, pharmaceutical form or packing for the medicinal product has not yet received marketing authorization from Swissmedic.
- 134 **Advertisements in professional media**
- Advertisements must contain (subject to Articles 135 und 136):
- 134.1 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;
- 134.2 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;
- 134.3 The prescription category authorized by Swissmedic;
- 134.4 The name and the address of the company that is responsible for the medicinal product in Switzerland (holder of the Swissmedic marketing authorization); this information must be stated either in the advertisement itself or be clearly seen in the professional medium where the advertisement appears;
- 134.5 The indication that comprehensive information can be found in the professional information for the medicinal product and, if necessary, listing the medium in which the marketing authorization holder makes it available to professionals who are entitled to prescribe, dispense or administer the medicinal products in humans, in accordance with the respective specifications of the Swiss legislation on Therapeutic Products;
- 134.6 The date (month and year) on which the advertisement is produced or, if has been

¹⁷ http://www.admin.ch/ch/d/sr/812_212_22/index.html (text only available in German, French and Italian)

¹⁸ <http://www.who.int/medicines/services/inn/en/>

subsequently changed, the date (month and year) on which it was last changed.

135 **Informative advertisements**

135.1 Informative advertisements are considered advertisements with statements about the application of a medicinal product.

135.2 In addition to the statements according to Art. 134, such advertisements must at least include an indication or possible application that has been authorized by Swissmedic, dosage, category of application as well as a summary of limitations to use, adverse reactions and interactions (so-called "succinct statement").

136 **Reminder advertisements**

136.1 Reminder advertisements are considered those advertisements that should remind one of a well-established medicinal product. Such advertisements list solely the indications or the therapeutic category of the medicinal product; they contain no statements concerning the medicinal product's application.

136.2 Reminder advertisements must correspond to the requirements cited in Art. 134.

136.3 The information cited in Art. 135.2 is not required for reminder advertisements.

137 **Brand name advertising**

Should an advertisement be made exclusively for the brand name of a medicinal product then, in addition to the brand name (as writing, logo or both), only the official abbreviated designation (DCI/INN) of the active ingredient(s), the name of the company (holder of the Swissmedic marketing authorization) and its logo may be used.

14 **Qualitative Requirements**

141 **General**

141.1 Advertising to health care professionals for, and information about, medicinal products must be accurate, balanced, objective and fair.

141.2 The statements must be substantiated.

141.3 They may not be misleading due to misrepresentation, unsuitable emphasis, omission or other distortions.

142 **Inadmissible statements**

Inadmissible, because they are misleading, are specifically:

142.1 The use of the expression "safe", except when used in connection with an appropriate qualification;

142.2 Statements indicating that a medicinal product has no adverse reactions, does not evoke addiction, is harmless or risk-free, or other statements or expressions that minimize the possible risks.

143 **Reference to clinical trials or professional medical literature**

143.1 Should advertising to health care professionals refer to clinical trials, these trials must have been carried out in accordance with the Good Clinical Practice (GCP)¹⁹ guidelines that were valid at the time of the trials. The cited clinical trial reports must reflect the current state of scientific knowledge.

143.2 Should advertising to health care professionals refer to clinical trials, the corresponding clinical trial reports must have been published in an acknowledged scientific medium.

¹⁹ <http://www.ich.org/cache/compo/475-272-1.html#E6>

- 143.3 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.
- 143.4 Under the following conditions, advertising to health care professionals may refer to not-yet published clinical trial reports: They must have been submitted to, and accepted by, an acknowledged scientific medium for publication. These reports must be cited in the advertising to health care professionals with the full title, authors' names, and date as well as indicate the corresponding scientific medium. In the advertising to health care professionals, it must be mentioned that a copy of the full clinical trial report may be requested from the company.
- 143.5 Citations from professional medical literature or from lectures by experts at scientific events may not distort or in any other manner alter the results of the clinical trials or the intention or opinion of the authors.
- 144 **Reference to other data**
- Should professional advertising refer to investigations such as meta-analyses, pharmaco-economic studies or field reports from practice, these must have been published in an acknowledged scientific medium. The requirements for the citation should correspond to Art. 143.
- 145 **Comparisons**
- 145.1 Comparisons with other medicinal products must be scientifically correct and referenced. Possible references include the latest valid version of the medicinal product's professional information 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 Art. 143, respectively, 144, or citations from scientific statements marked and referenced as such, or guidelines issued by acknowledged scientific committees.
- 145.2 The same applies for qualifications such as "better", "more effective", "better tolerability" or similar expressions as well as for superlatives (e.g., "the best", "the most effective", "the most prescribed ") or similar expressions (e.g., "unique", "at the top of...", "the standard for...", "the number 1", "the drug of choice", "the gold standard").
- 145.3 Should advertising to health care professionals be based on trials whose results are founded on *in vitro* experiments or use animals, then this must be clearly evident from the citation.
- 146 **Novelty claim**
- Medicinal products, indications, possible applications, dosages, pharmaceutical forms and packings may be described as new only within one year from their marketing authorization in Switzerland. From the information, it must be obvious to what the term new refers.
- 147 **Samples**
- 147.1 A limited number of samples may be provided to health care professionals so that they may become familiar with a medicinal product and gain experience with its use in practice.
- 147.2 Samples must not be given as an inducement to recommend, prescribe, purchase, supply, sell or administer a certain medicinal product.
- 147.3 The dispensing of samples must otherwise follow the regulations of the legislation on Therapeutic Products and the Health Insurance.
- 148 **Important notices**
- 148.1 Should the companies need to urgently inform health care professionals of something

that could affect the safety of a particular medicinal product, and it is urgent and decisive for the health care professionals and the treatment behavior 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".

- 148.2 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.
- 148.3 This label may only be used for such information. Similarly sounding labels (e.g. "urgent information") are to be avoided so that attention is not detracted from the important notices.

15 Involvement of consultants

- 151 The companies may appoint health care professionals as consultants, in groups or individually, to undertake services such as providing reports and leading meetings, medical or scientific studies, clinical trials, training, consulting committees and market research, and reimburse them appropriately for the associated expenditure according to the usual standards.
- 152 The companies shall agree such contracts in writing before they begin; here the service to be rendered and its payment should be adequately specified.
- 153 In this context the companies adhere to the following principles:
- 153.1 There is a legitimate need for the service to be rendered.
- 153.2 The consultant(s) assigned to the project are suitably qualified.
- 153.3 The number of consultants appointed to perform a service should not be excessive and only necessary to deliver the desired results.
- 153.4 The contracting company shall document the services rendered by the consultant(s) and use the documents according to their purpose.
- 153.5 The fact that consultants are used for services does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer certain medicinal products.
- 153.6 Token consultancy arrangements to allow health care professionals to receive financial remuneration without having a duty to provide a service are not permitted.
- 154 The companies specify in the contracts that the consultants shall declare their consultant status if they write or talk publicly about matters which are the object of the contract or are otherwise connected with the companies making the contracts.
- 155 Companies which appoint practicing health care professionals on a part-time basis shall state in their employment contracts that these health care professionals will declare their employee status, if they write or speak publicly about matters which are the object of the employment contract or are otherwise connected to this company.
- 156 This is subject to Articles 29 and 37.

16 Advertising to health care professionals and information over the Internet

- 161 Articles 13 and 14 correspondingly apply for advertising and information to health care professionals about medicinal products as provided over the Internet by companies, their agents, or with their approval.
- 162 Furthermore, the following must be clearly evident from the internet presentation:
- 162.1 Which company operates or sponsors the website, either directly or indirectly,
- 162.2 Which information on the website is intended for health care professionals and which for the lay public.

163 Should a company provide information about a certain medicinal product on its website, then the health care professionals must also be guaranteed access to the last-approved version by Swissmedic of the corresponding professional information for this medicinal product.

164 Additionally, when advertising or providing information to health care professionals over the Internet, the companies observe the relevant legislation on Therapeutic Products and the recommendations by the IFPMA²⁰ and EFPIA²¹.

2 Events for the advertisement or provision of information about medicinal products as well as cooperation with organizations of health care professionals

21 Principles

211 Symposia, congresses and similar, even smaller events (hereafter referred to as: events), are recognized means for disseminating knowledge and experience about medicinal products and therapies, as well as for postgraduate medical training and continuing medical education for health care professionals.

212 The concept of events includes, for example, advisory board meetings, visits and viewings of research or manufacturing businesses in the pharmaceutical industry, meetings for planning of clinical trials or non-interventional studies or training of investigators for clinical trials.

213 The Pharma Code applies to events which are organized and implemented by the companies themselves or on their behalf (Art. 25) and those which are organized and implemented by third parties (e.g. specialist organizations of health care professionals) with financial or other support from companies in the pharmaceutical industry (Art. 26)

214 Events are to be organized and executed in a manner that conflicts of interests and financial dependencies are avoided.

215 Events which are organized or receive financial support from companies with subsidiaries in Switzerland and which are aimed purely at participants from Switzerland should fundamentally be staged in Switzerland. The incentive to attend such an event should be derived from the specialist topic and if necessary 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.

216 Events which are organized or receive financial support from 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.

217 Invitations to events which are staged abroad by the headquarters or regional centers of international companies can be issued by the subsidiary to participants from Switzerland and in this context must make an appropriate contribution towards the costs.

218 The same applies for events of an international nature which are staged abroad by international medical or pharmaceutical professional societies and sponsored by companies with registered offices or subsidiaries in Switzerland and within the framework of which events are also staged, if necessary, by companies (e.g. satellite symposia).

²⁰ IFPMA Code, Addendum 1: www.ifpma.org/site_docs/News/Code_English_2000.pdf ;
www.ifpma.org/News/news_market_cd8.aspx

²¹ EFPIA Code 2004, Annex B: www.efpia.org/6_publ/codecon/Promomedicines2004.pdf

22 General regulations

- 221 The events should impart to the participants knowledge, skills and abilities for patient care that are objective and balanced, useful and necessary.
- 222 Communication of scientific or professional information is the main purpose of these events. The time invested for this part of the program must clearly surpass that for non-professional activities (such as hospitality and entertainment).
- 223 The events should take place in appropriate venues conducive to the main purpose of the event (Art. 222). They should be chosen with regard to the desired achievement of the main objectives, mainly according to the suitability of the facility location and infrastructure. Locations which are renowned for their entertainment facilities or are considered extravagant should be avoided.
- 224 The financial expenditure for the event should approximately correspond to the amount which the average participant would be willing to spend should he have to pay for it himself.
- 225 An invitation, either as a participant or speaker, to health care professionals who do not work for the company organizing or financially supporting the event, may not be made dependent upon the recommendation, prescription or dispensation of certain medicinal product.
- 226 In an appropriate manner, the speakers are to make their interests known to the event organizer, the professional society and, before beginning their presentations, also to the participants.
- 227 The speakers' honoraria must be appropriate to the extent of work performed. The speakers may additionally be compensated for their expenses associated with participating in the event, including travel costs.
- 228 Travel or hotel expenses associated with the event may not be covered by the companies for those persons who accompany the health care professionals invited to the event.
- 229 Should companies disseminate lectures or discussion contributions that were held at an event, or reports about these, then the companies must ensure that the information sent out correctly and accurately relates what was communicated at the event. The same applies if the companies charge other people, media or companies to transmit the information.

23 Financial contribution by the participants

- 231 In the interest of the participants maintaining their independence, the companies require as a matter of principle that health care professionals attending 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 health care professionals.
- 232 A reduced contribution may be requested from health care professionals who are still in postgraduate medical training.
- 233 For events that are held in Switzerland and last less than one day, the financial contribution by the participant may be waived.
- 234 These regulations also apply for events that are financially supported by companies, and they must be considered when regulating the financial support in a contract (Art. 252).
- 235 Should companies invite health care professionals to an event that is offered or carried out by professional societies, universities, clinics, health care professionals or other in-

stitutions, then, along the same lines, the companies will also request an appropriate financial contribution from the health care professionals.

236 The 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.

24 Financial support for health care professionals attending events

241 The companies should not allow health care professionals to receive any financial compensation purely for the time they spend attending an event.

242 If a company does grant a health care professional financial support for taking part in an event with international participation, such financial support is subject to the rules of the jurisdiction where such health professional carries out their profession.

25 Events by companies

Should companies carry out events for advertising and providing information about a medicinal product to health care professionals, or for the purposes of postgraduate medical training or continuing medical education, or should they charge someone else to carry out these events, such as congress organizers, then, in addition to Articles 21 – 23, the following will be observed in particular:

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

252 The costs for additional hotel expenses, trips or other activities that have no connection with the event subject must be completely paid for by the participants and, if applicable, their accompanying persons.

253 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 such for health care professionals. This does not include events held exclusively for charitable purposes.

26 Company support of events

Should 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, health care professionals or other institutions, financially or otherwise, they shall observe, in particular, the following:

261 When an event is announced, at this event itself, and in publications concerning this event, the fact of the financial support must be clearly recognizable, likewise, which companies support the event.

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

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

264 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 companies and the professional societies.

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

266 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 there are several medicinal products, medical devices or processes available for the diagnosis under discussion, these should be mentioned.

27 Advertising and information materials used at events with international participation

271 Advertising 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 there subject to different conditions.

272 Such specialist advertising and information material must be accompanied by the following declarations:

272.1 Reference to 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 there;

272.2 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.

28 Supporting research and other work in the health sector

281 Companies may support institutions, organizations or associations of health care professionals performing research in the health sector or providing other services, either financially or in some other way, in so far as such support:

281.1 is restricted to research and other services in the health sector;

281.2 is confirmed in writing and the relevant documents are available in the company;

281.3 they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer certain medicinal products;

282 the financial or other sponsoring of individual health care professionals is not allowed. The conditions about health care professionals taking parts in events according to Art. 2 apply.

283 On request, the company will make it known to whom they have given support and on what basis.

29 Contracts for services

Subject to Art. 28, companies may make contracts with institutions, organizations or associations of health care professionals, according to which the latter perform certain services for the said companies provided that these services:

291 are limited to research and other work in the health sector

292 do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer certain medicinal products.

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

31 Principle

By following the rules and regulations cited below, companies that sponsor clinical trials with medicinal products contribute to ensuring 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.

32 Observing Good Clinical Practice

In Switzerland, clinical trials with medicinal products must be prepared, carried out and evaluated in accordance with the ordinance on clinical trials with therapeutic products²², or, on an international basis, in accordance with the respective requirements of Good Clinical Practice (GCP)²³.

33 Contractual regulation

331 The financial support for clinical trials by companies is to be specified in a written contract. These contracts must be signed, in a legally binding manner, by the companies or company that finance(s) the clinical trial as the sponsor, the health care 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.

332 The contract details the parameters that define the clinical trial, specifically:

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

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

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

332.4 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;

332.5 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 health care professionals with a reasonable amount of effort.

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

34 Independence of the investigator

The company that sponsors the clinical trial pays attention that the responsible investigator and his assistants carry out the trial independent of the interests of the sponsor company(-ies) and that they have no financial interest in the trial results.

35 Independence of research projects and product purchase

351 Companies that sponsor clinical trials with medicinal products may not make them dependent, either directly or indirectly, upon a sale, or purchasing conditions, of any medicinal product they either manufacture or distribute, or other products for the therapeutic needs of the institution where the trial takes place.

352 Likewise, companies may not acquiesce to the wishes of those institutions that seek to make the purchase or the purchasing conditions of the company's products dependent on the clinical trials, either directly or indirectly.

36 Publication

361 In principle, results of clinical trials should be published. 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. It should be stated in the publication that this was a company

²² www.admin.ch/ch/d/sr/c812_214_2.html (text only available in German, French and Italian)

²³ <http://www.ich.org/cache/compo/475-272-1.html#E6>

sponsored clinical trial and the sponsor is to be mentioned.

362 When publishing the results of a clinical trial, a statement or a footnote that clearly indicates the sponsor of the clinical trial must be made. 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 clearly indicated.

363 The interpretation of the results of a clinical trial must be independent from the interests of the sponsors.

37 Non-interventional studies using authorized medicinal products

371 Those studies which do not fall within the regulations of the Swiss legislation on Therapeutic Products for Clinical trials (e.g. reports on practical experience), and show the following characteristics, are considered non-interventional studies with authorized medicines:

371.1 An authorized medicinal product is prescribed, dispensed or applied by the health care professionals taking part in the investigations in the usual way, complying with the currently valid professional information.

371.2 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.

371.3 No additional diagnosis or control measures are provided for patients; epidemiological methods are used for analyzing the collected data.

372 The appropriate regulations of the Swiss legislation on Therapeutic Products shall apply to non-interventional studies that are prospective in nature including individuals or groups of health care professionals where patient data is collected specially for the study.

372.1 Non-interventional studies must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a certain medicinal product.

372.2 On request companies must provide health care representatives with the summaries of the study results in appropriate form.

373 The company's medical representatives may only collaborate in non-interventional studies under the supervision of the scientific service of the company and from an administrative point of view. Their collaboration may not be associated with a promotion for medicinal products.

374 The companies shall also basically observe for all other studies, including epidemiological and other retrospective studies Articles 372 and 373 and similarly Articles 15 and 29.

4 Relationships of the pharmaceutical industry with patient organizations

41 Principles

411 The companies shall respect the independence of the patient organizations with regard to their political position, their methodology and their activity.

412 All partnerships between patient organizations and companies should be based on mutual respect, where the views and decisions of both partners are of equal value.

413 The companies shall neither ask patient organizations to promote certain medicinal products nor respond to corresponding requests of patient organizations.

414 The aims, the scope and the agreement of support and partnerships should be transparent and documented in writing.

415 It is expected that patient organizations will strive for support from several companies. Companies may not ask patient organizations to be their sole company support overall or for individual projects, financially or in any other form.

42 Scope and concepts

421 Article 4 applies to relationships of companies which have undertaken to adhere to the Pharma Code, to their subsidiaries and persons, companies or organizations who appoint them in this connection, with regard to patient organizations active in Switzerland.

422 Patient organizations are non-profitable organizations (including organizations to which they are associated) which are mainly composed of patients or carers representing or supporting the needs of patients and their carers.

43 Support of patient organizations

431 If companies grant a patient organization financial or other support they shall agree this support in writing with the patient organization prior to commencement.

432 The following points shall be included in the agreement to be signed by both sides and made legally binding:

432.1 Names of partner organizations: companies, patient organizations, if necessary persons, companies or organizations appointed;

432.2 Description of the type and purpose of the support;

432.3 Aims and activities as part of the support (events, publications, other);

432.4 Tasks, rights and duties of the company and of the patient organization;

432.5 For financial support: the amount

432.6 For other support: its nature (assuming costs of a public relations agency working for the patient organizations, free training courses, other);

432.7 Date and duration of the agreement.

433 The companies control the internal approval of such agreements.

44 Use of logos and legally protected documents

If the company wants to use logos or legally protected documents of patient organizations for publications, it requires the permission of this organization in writing. The company must clearly state the specific purpose of use and publication with regard to such permission and how it wants to use the logo or the legally protected documents.

45 Documents of patient organizations

Companies may not try to influence in their own commercial interests the text of documents of patient organizations to which they are granting financial or other support; the right to correct factual errors is reserved.

46 Transparency

461 The companies must publish a list of the patient organizations which they support financially or otherwise to any significant extent. This list must include a short description of the type of support. It must be updated at least once per year.

462 The companies guarantee that such support is transparent from the outset.

47 Events and hospitality

471 The events should take place in 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 facility location and infrastructure. Locations which are renowned for their entertainment facilities or are considered extravagant should be avoided.

- 472 Any form of hospitality which patient organizations are allowed to accept from companies should be at a sensible level and subordinate to the main purpose of the event, irrespective of whether the event is organized by patient organizations or by companies.
- 473 Hospitality in connection with events must be limited to travel, subsistence, accommodation and participation fees.
- 474 The companies may not organize or sponsor any events which take place outside of Switzerland, except in the following cases:
- 474.1 Most invitees come from other countries which means that it makes more sense logistically to hold the event in another country: or
- 474.2 The critical resources or specialist knowledge which form the professional or personal reasons for holding an event are available in another country, therefore it makes more sense logistically to hold the event there.

5 Enforcement of the Pharma Code in the area of advertising and providing information to health care professionals

51 Company personnel

- 511 The companies ensure that their personnel responsible for the preparation, supervision, and release of advertising, as well as its presentation to health care professionals, are familiar with the Pharma Code and the corresponding clauses of the Swiss legislation on Therapeutic Products and observe the corresponding regulations.
- 512 In particular, the companies ensure that the medical representatives perform their tasks in a responsible and ethically correct manner. They must be appropriately trained and have sufficient knowledge of the Pharma Code to be able to correctly inform others about their company's medicinal products. The companies ensure that their medical representatives continue to satisfy these requirements and that their training is continuously updated.
- 513 The medical representative are obligated to inform their company, on a continuous basis, of any specialized information that they learn through their activities, especially about reports of adverse reactions of medicinal products.
- 514 The type of compensation may not entice the medical representatives to mislead health care professionals to incorrect prescribing or dispensation practices of medicinal products.

52 Release of professional advertising and information

- 521 Before advertising and information about medicinal products are transmitted to health care professionals or their assistants, the companies shall ensure that this information has been approved by an authorized and competent person who is either employed, or entrusted with the responsibility, by the company. This person makes their decisions independently of the marketing and sales interests of the company.
- 522 The companies shall provide the name of this person to the Pharma Code Secretariat.

53 Monitoring the observance of the Pharma Code

- 531 The SGCI authorizes an appropriate professional (as a rule, a physician), who is independent of the companies, with the directorship of the Pharma Code Secretariat. It also ensures that a deputy position has been organized.
- 532 The Pharma Code Secretariat is, administratively, affiliated with the SGCI Secretariat.

- 533 In particular, the Pharma Code Secretariat ensures:
- 533.1 The objective and unbiased supervision of the advertising and information about medicinal products that have been made or contracted out by the companies, to the extent that the Pharma Code applies,
- 533.2 That companies that have verifiably violated the Pharma Code shall discontinue, retract or correct the corresponding advertising to health care professionals,
- 533.3 The mediation with the goal of a mutual settlement of disagreements with the companies involved in on-going proceedings for an alleged violation,
- 533.4 That the administrative activities necessary for supervision are fulfilled, supported by the SGCI Secretariat,
- 533.5 That companies are periodically informed about rulings handed down by it (without naming the company or specific medicinal product) as well as about experiences in connection with the practical implementation of the Code that are of general interest, and
- 533.6 The annual report covering its activities and publications.
- 534 The SGCI provides the necessary administrative infrastructure for the appointed person.

54 Providing documentation of mailings to the Pharma Code Secretariat

- 541 The companies will make available to the Pharma Code Secretariat a complete sample copy of all mailings of professional advertising or information about their medicinal products that are directed to health care professionals or their assistants. To this end, they shall include the Pharma Code Secretariat on their mailing lists.
- 542 The companies shall mark these sample copies in such a manner that they can be registered by the Pharma Code Secretariat as expediently and rationally as possible. The Pharma Code Secretariat shall provide the companies with practical and specific information about this if and as required.

55 Procedures in connection with violations against the Pharma Code

551 Charges and notifications

- 551.1 The Pharma Code Secretariat investigates, either on its own or upon receiving notification, alleged Pharma Code violations in the areas of information and advertising to health care professionals.
- 551.2 Anyone may notify the Pharma Code Secretariat of specifics that are alleged violations.
- 551.3 The Pharma Code Secretariat acts upon notifications when they are in writing and the charge is founded. As necessary, it may request that the informant supplement or document his substantiation, and sets an appropriate deadline for these to be submitted.
- 551.4 The Pharma Code Secretariat will not respond to anonymous notifications of alleged violations.
- 551.5 When investigating a charge of an alleged violation, the Pharma Code Secretariat may request documents from the involved companies, and shall set an appropriate deadline for their submission; additionally, it may question the company's employees or appointed agents.

552 Exchange of documents and rulings by the Pharma Code Secretariat

- 552.1 Should the Pharma Code Secretariat itself open a case, it shall inform, in writing, the involved company stating the grounds for the asserted violation.

- 552.2 Should the Pharma Code Secretariat be notified of alleged violation(s), it shall provide to the involved company, as quickly as possible, a comprehensive copy of the notification of alleged violation(s).
- 552.3 The Pharma Code Secretariat shall provide the involved company with the opportunity to make a written rebuttal and sets an appropriate deadline for this.
- 552.4 Should no consensual resolution of the case be reached from written correspondence, the Pharma Code Secretariat may convene the adversaries for oral negotiations.
- 552.5 The Pharma Code Secretariat records, in writing, the results of the negotiations together with a written summary of the arguments, and provides these to the parties involved.
- 552.6 Should the involved company acknowledge the infringement, it ensures that the violation is rectified by discontinuing, retracting or correcting the information or professional advertising that violates the Pharma Code. The company confirms this in writing to the Pharma Code Secretariat.
- 552.7 The Pharma Code Secretariat sets deadlines for the remedial measures to be undertaken and for their written confirmation. These deadlines will be commensurate with the severity of the violation.
- 553 Patent, serious violations**
- 553.1 Should the Pharma Code Secretariat consider a violation to be patent and serious, it will make, as soon as possible, a written summons to the involved company to the effect that the corresponding professional advertising or information must be immediately discontinued, retracted or corrected; further, a short deadline will be set for these remedial measures to be undertaken and for a written confirmation of their enactment.
- 553.2 Should the involved company assert, with well-founded arguments, and within the stated deadline, that there has been no violation or serious infringement, then the Pharma Code Secretariat shall reassess the situation, as necessary.
- 554 Procedure with unresolved cases**
- 554.1 Should the involved company not comply with or refuse to follow, within the stated deadline, the ruling of the Pharma Code Secretariat, or should it not conform to its confirmation according to Art. 552.6 or 553.1, then the Pharma Code Secretariat will, if it considers the violation of the Pharma Code to be a possible health risk, immediately dispatch the affair to Swissmedic for evaluation and further procedures.
- 554.2 At the same time, the Pharma Code Secretariat informs (in writing) the company or person who reported the violation to the Pharma Code Secretariat.
- 554.3 In this case, the company that reported the violation to the Pharma Code Secretariat can appeal to the court due to unfair competition.
- 555 Duration of the proceedings**
- 555.1 According to the Pharma Code, the proceedings should be carried out within the shortest possible timeframe. Subject to Art. 555.4, the proceedings must not exceed 25 working days.
- 555.2 The proceedings commence on the date when the Pharma Code Secretariat receives notification of a charge, or with the date when a case is opened by the Pharma Code Secretariat.
- 555.3 The proceedings terminate on the date when the Pharma Code Secretariat receives the timely confirmation from the involved company that it is acting in accordance with the orders of the Pharma Code Secretariat or with the procedures to follow, as recorded by the Pharma Code Secretariat, for the mutually-acceptable settlement of the proceedings and the timely remedy of the violation.

- 555.4 When justified due to well-founded reasons, the Pharma Code Secretariat can extend this deadline once by, at most, ten working days.
- 555.5 The Pharma Code Secretariat and the companies involved in the proceedings do their utmost in contributing to these being resolved within the set deadlines.
- 555.6 If the proceedings cannot be completed even within a possibly extended deadline, the Pharma Code Secretariat will immediately dispatch the affair to Swissmedic for evaluation and further procedures, if it considers the violation of the Pharma Code to be a possible health risk.

6 Enforcing the Pharma Code in the areas of events and clinical trials and non-interventional studies as well as relationships with patient organizations

61 Company personnel

- 611 The companies ensure that their personnel responsible for the preparation, supervision and releases well as for the execution of events for the advertising and information about medicinal products to health care professionals and for the postgraduate medical training and continuing medical education (Art. 2), are familiar with the Pharma Code and the corresponding clauses of the Swiss legislation on Therapeutic Products and observe the corresponding regulations.
- 612 The same applies to the sponsoring of clinical trials with medicinal products, the implementation of clinical trials and non-interventional studies (Art. 3) and the relationships with patient organizations (Art 4).
- 613 The companies shall designate one person to be responsible for complying with the Pharma Code when the company participates in events with international attendees, and for upholding the appropriate foreign code. The same applies to events according to Art 47. The company shall make this person known to the Pharma Code Secretariat as its contact.

62 Scientific service of the companies

- 621 The companies set up a scientific service which is responsible for the information about their medicinal products and their advertising and also for the approval and control of clinical trials and non-interventional studies.
- 622 The companies are free to choose whether this service is responsible for both tasks or whether various services fulfil the named tasks separately.
- 623 The scientific service includes a doctor or, if suitable, a pharmacist or scientist who is responsible for the conformity of all promotional materials with the Pharma Code before they are deployed. This person must confirm to the person responsible according to Arts. 52 and 613 for the decision to release, that this final version of the promotional material has been checked, that it complies as far as they can tell with the Pharma Code and the Swiss legislation on Therapeutic Products.
- 624 The scientific service also includes a doctor or, if suitable, a pharmacist, who can control the clinical trials and non-interventional studies and monitor responsibility for such investigations and the collaboration of the medical representatives.
- 625 This person confirms that they have checked the protocol of the clinical trial or the non-interventional studies and that the latter complies with the valid regulations.
- 626 The companies inform the Pharma Code Secretariat of the persons defined according to Arts. 623 and 624 who are available as contacts.

63 Notifications

631 The Pharma Code Secretariat investigates, either by itself or upon receiving notification, alleged violations against the Pharma Code, in the areas of events (Art. 2) and clinical trials (Art. 3).

632 Art. 551 applies to the requirements placed on notifications of possible infringements and their processing by the Pharma Code Secretariat as well as for the behavior of the claimant making the notification.

64 Exchange of documents, patent serious violations and repeated infringements

641 Articles 552 – 554 apply to the exchange of documents, the processing of patent, serious violations and repeated infringements.

642 If the involved company acknowledges a violation as founded, it confirms this in writing to the Pharma Code Secretariat, in combination with a declaration that it shall, henceforth, avoid all such violations.

643 The Pharma Code Secretariat sets an appropriate deadline for this.

65 Duration of the proceedings

Art. 555 applies to the duration of the proceedings.

66 Procedure with unresolved cases

661 If the proceedings cannot be completed even within a possibly extended deadline, the Pharma Code Secretariat will, if it considers the violation of the Pharma Code to be a possible health risk, immediately dispatch the affair to Swissmedic for evaluation, in so far as Swissmedic is competent.

662 Should a company repeatedly and seriously violate the Pharma Code in the areas of events (Art. 2) or clinical trials (Art. 3), the Pharma Code Secretariat shall, if it considers the violations of the Pharma Code to be a possible health risk, submits a summary of the involved cases to Swissmedic.

7 Consulting activities of the Pharma Code Secretariat

71 In order to preserve its impartiality when evaluating notifications of alleged violations to the Pharma Code, the Pharma Code Secretariat judges no professional advertising, information, event programs or other documents regulated by the Pharma Code before these have been circulated by the companies.

72 Upon request, it provides information regarding the interpretation of the Pharma Code regulations, without establishing the concordance of certain statements in such documents.

8 Procedure at Swissmedic or before a court of law

81 Should companies appeal to Swissmedic or to a court of law due to a supposed violation against the federal regulation of advertising to health care professionals or other issues that fall under the responsibility of the Pharma Code, or are alleged acts of unfair competition, the Pharma Code Secretariat will continue with proceedings already initiated as long as none of the companies involved opposes this continuation.

82 The Pharma Code Secretariat refrains from participating in any proceedings that companies initiate at Swissmedic or in a court of law.

83 The SGCI und Swissmedic will come to a written agreement regarding the collaboration regarding supervision, especially to advertising to health care professionals, to the extent that this is regulated by the Pharma Code as well as by the Swiss legislation on

Therapeutic Products.

9 Pharma Code Committee

91 Appointment and composition

- 911 In agreement with the partner associations, ASSGP, Intergenerika, Interpharma and vips, the executive board of the SGCI appoints a committee that advises the Pharma Code Secretariat (Pharma Code Committee).
- 912 The Pharma Code Committee consists of seven to twelve professionals who are competent and experienced in the areas of various aspects of professional advertising (especially medicine, pharmacy, marketing, advertising and law).
- 913 At least three members of the Pharma Code Committee may not be employed or commissioned by companies of the pharmaceutical industry.
- 914 A member of the SGCI executive board shall be appointed the director of the Pharma Code Committee. The SGCI Secretariat handles the administrative matters of the Pharma Code Committee.
- 915 The term of office for the Pharma Code Committee members is four years, and respectively commences with the calendar year. Re-election is possible. New members taking over the responsibilities of predecessors shall finish the terms of office of the members they replace.

92 Activity and function

- 921 The director convenes a meeting of the Pharma Code Committee at least once annually.
- 922 Based on the Pharma Code Secretariat's annual report, and other reports from its enforcement activity, the Pharma Code Committee advises the Pharma Code Secretariat.

10 Final Provisions

101 Changes

- 1011 Should changes be made to the legislation on Therapeutic Products that directly affect the Pharma Code, or if IFPMA or the EFPIA change regulations in their codes that are mentioned as a basis in the Preamble of the Pharma Code in a way that is binding for the affiliated national associations, then SGCI, ASSGP, Intergenerika, Interpharma and vips will agree upon the corresponding modification of the Pharma Code.
- 1012 Prior to the enactment of such changes, the associations cited above will hold a consultation for the companies that have signed the declaration for observing the Pharma Code.
- 1013 In agreement with ASSGP, Intergenerika, Interpharma, and vips, the SGCI determines the date when such changes should become effective.

102 Coming into effect and the supersession of rights previously valid

- 1021 The Pharma Code becomes effective on January 1, 2004.
- 1022 It supersedes the Pharmaceutical Promotion Code of August 1, 1991, revised on June 8, 1995.
- 1023 The changes in the Pharma Code, resulting from the amendment to the EFPIA Codes of June 12, 2008, come into force on July 1, 2008.

103 List of pledged companies

The SGCI publishes a list of companies that, by signing this declaration, have committed themselves to adhering to the Pharma Code (Appendix).

104 Transitional Provision

The former regulations on advertising and information and events and clinical trials which were initiated or prepared before the amendment of the Pharma Code of June 12, 2008 to the EFPIA Codes mentioned in the preamble, shall continue to apply but only until December 31, 2008.

Appendix

Declaration

The company cited below hereby declares, independently of membership of one of the associations named in the Preamble, that it will follow the regulations of the Pharma Code from December 4, 2003 (partially revised October 1, 2006, and June 12, 2008), and will respect the rulings of the Pharma Code Secretariat.

Company name:

Address:

Date:

Stamp / legally binding signature(s):

Executive Director:

Responsible person(s) (Arts. 52, 613 and 623/624 of the Pharma Code):