Recommendations No. 5 to the Pharma Code¹

Conduct of companies on the occasion of congresses, symposia and similar events which are held for health care professionals in Switzerland under the responsibility of professional organisations.

Background

National and international congresses, symposia and similar events of medical professional organisations are generally sponsored by industrial companies. The Pharma Code (PC) sets out rules on this matter:

• Definition of events:

Article 135 PC defines events as reunions 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

Article 211 PC defines symposia, congresses and similar, possibly smaller, events as recognized means of disseminating knowledge and experience about medicinal products and treatments and on the further training and advanced training of health care professionals.

$\circ~$ General obligations of companies on the occasion of events:

Article 36 PC determines the points which must be respected by companies in the pharmaceutical industry that provide financial or other support (sponsorship) for such events. This includes the contractual rules and the clear identifiability of the particular companies which sponsor an event.

$\circ~$ Obligations of the companies in connection with promotion and information at events:

Article 37 PC stipulates the points which must be respected by the companies if they use promotional and information materials for medicinal products at such events.

The PC sets out principles governing the conduct of companies and of their personnel on the occasion of congresses, symposia and similar events such as physicians' congresses. Such events are repeatedly exposed to critical observation. The critics may be participating health care professionals, third parties as well as the professional and lay media. The conduct of companies and of their representatives in this connection determines their image and their reputation, together with that of the pharmaceutical industry as a whole. The way in which the personnel taking part in the events conduct themselves is guided in each individual case by the rules of conduct of the particular company concerned. The PC does not set out generally valid specific rules of conduct for particular events and occasions within the framework of congresses, symposia and similar events such as satellite events, nor does it define the conduct of the company at information stands in the congress area.

Recommendations

The Code Secretariat recommends compliance by companies with the following rules of conduct on the occasion of congresses, symposia and similar events which are organised under the responsibility of professional organisations for health care professionals and are held in Switzerland.

¹ <u>http://www.en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code</u> <u>http://www.en.scienceindustries.ch/ file/12951/pharmakodex-version-2013-e.pdf</u>

^{*}PC: Pharma Code; PCC: Pharma Cooperation Code

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1. Information about new medicinal products which have not [yet] been authorised by Swissmedic or new indications for authorised medicinal products.

1.1 The companies may provide factual information at satellite events and similar meetings coinciding with congresses, symposia and similar events about new medicinal products which are not [yet] authorised in Switzerland, indications etc.

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- 1.2 The term information as used above means every form of fact-based information of a scientific nature. All forms of direct or indirect promotion for medicinal products, indications etc. which are not authorised in Switzerland are prohibited.
- 1.3 Anything which may be perceived by the addressees of information as a direct or indirect recommendation or incentive for off-label use in Switzerland is proscribed. The term recommendation should be interpreted strictly in this respect. <u>For example</u>, preparing document folders is considered to be an advertising measure.
- 1.4 The provision of information within the above definition is the prerogative of the speakers who are invited by the company but independent from it, together with the professional personnel of the medical service or research department of the company. The speakers should deal with the topic of the satellite event in a neutral manner, examining both sides of the case. The papers presented must satisfy scientific requirements.
- 1.5 Marketing and sales personnel may attend satellite events, but will not take part in the discussion.

2. General requirements for satellite events and similar meetings on the occasion of congresses, symposia and similar events

- 2.1 Satellite events and similar meetings must be part of the official programme of a congress or symposium or of a similar event.
- 2.2 Satellite events should be led by a health care professional who is independent of the company (e.g. a representative of the organising professional society). Companies must not arrange competing events held in parallel with the congress programme.
- 2.3 The title, programme and description of the satellite events must contain no promotion for medicinal products.
- 2.4 The companies will obtain approval from the appropriate entity (congress management or responsible scientific body) for the title, programme and description of satellite events.
- 2.5 Information activities at satellite events must be separated physically and also in other ways from promotional activities at congresses, symposia and similar events.
- 2.6 In order to highlight the informational nature of the event, no promotion for medicinal products is permitted on the satellite event premises.

3. Conduct of companies as sponsors of congresses, symposia and similar events.

- 3.1 Companies must not sponsor or otherwise support any congresses, symposia or similar events whose programme includes leisure, cultural, sport or other entertainment opportunities and events of a non-professional or non-scientific nature. Congress participants are at liberty to procure such services as they may need independently from the congress and for their own account from the appropriate local service providers.
- 3.2 Companies must not offer, implement or cause to be implemented any leisure, cultural, sport or other entertainment offerings and events of a non-professional nature in connection with congresses, symposia or similar events which are unrelated to the topic of the event and to its professional and scientific programme. The following in particular are prohibited because they are critical in this regard:

3.1.1 Excursions for congress participants or persons accompanying them to shopping centres, factory outlets and so forth for the duration of the event.

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- 3.1.2 Arranging or booking leisure, cultural, sport or other entertainment offerings via the congress organiser's secretariat.
- 3.1.3 Offers of organised leisure travel, weekend stays and so forth before or after the congress, the symposium or the similar events.
- 3.1.4 Offers by third parties (e.g. manufacturers of, or dealers, in vehicles, sports equipment and so forth) to effect promotion for their products which are unrelated to the congress (e.g. by providing a shuttle service, test drives and so forth).
- 3.3 The offers made by companies on their information stands or otherwise on the congress site which extend beyond professional information and promotion (catering, distribution of information- and training materials or of writing implements and pads) must be of modest value and compliant with the customary practice. The offer on the information stands and their design should be appropriate for the congress and its professional-scientific organization. Writing implements and pads may not bear any references to the pharmaceutical company or to particular medicinal products.
- 3.4 Competitions or prize awards may be offered, but they must relate to the theme of the information stand and be generally appropriate to the professional and scientific congress environment. The prizes that are awarded should be of modest value and have to meet the requirements of the prohibition of gifts (especially Section 143.3).
- 3.5 The company must not pay participants to attend their information stand.
- 3.6 Alcohol is not to be served on the information stands. The catering provided by the company either there or elsewhere on the congress site should be confined to small refreshments, such as non-alcoholic beverages, snacks and similar small culinary items.
- 3.7 If the congress organiser offers catering opportunities to participants as part of a restaurant operation on the congress site or in its environs, the sponsoring companies must not compete with this offering.
- 3.8 Personnel of the company must adopt appropriate conduct and dress on the information stand and in the further framework of the congress, consistent with its professional and scientific environment.
- 3.9 Personnel of the company should behave fairly and properly in relation to the other companies which are taking part in a congress or symposium or a similar event as sponsors.

The Code Secretariat considers the presence at a congress as a coherent promotion measure. In this context, roll-ups or advertising panels do not need to quote compendious expert information or references. This information should however be available at the stand – at least electronically.

More Pharma Code rules that are relevant in the case of events

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;

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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 Writing implements and pads of modest value, made available to participants at events by pharmaceutical companies; these writing implements and pads may not bear any references to the pharmaceutical company or to particular medicinal products;
- 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.
- 144 The laws and ordinances applicable in this connection are reserved as is their enforcement by the State authorities.

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.
- 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.
- 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/INN).
- 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.

27 Samples

- 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.

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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

- 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).

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.

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.

52 Responsible persons at the pharmaceutical company

- 521 The pharmaceutical companies shall ensure that the activities regulated by this Code are ap-proved 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.

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