PC and PCC Practice*

scienceINDUSTRIES SWITZERLAND

Recommendations No. 3 to the Pharma Cooperation Code (PCC)[1]

Support by pharmaceutical companies for patient organisations: contractual provisions and disclosure of pecuniary benefits

Background

With the partial revision of 2008, a new Section 4 was added to the Pharma Code (PC) entitled: "Relations between the pharmaceutical industry and patient organisations". This new chapter replaced the "EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations" (of 5 October 2007, revised in June 2011[2]) for Switzerland.

With the creation of the Code of Conduct of the Pharmaceutical Industry in Switzerland covering cooperation with professional circles and patient organisations (Pharma Cooperation Code, PCC) of 6 September 2013[3] the previous Section 4 of the Pharma Code was deleted. Its content was accordingly added to the PCC as a new Section 3 entitled "Cooperation with patient organisations and disclosure of pecuniary benefits for such recipients".

That section 3 PCC requires the pharmaceutical companies which have signed the PCC to adopt contractual provisions governing financial or other support for patient organisations and to disclose the related pecuniary benefits.

Recommendations

A. Details of the contractual provisions (Section 32 PCC)

General: The pharmaceutical companies must regulate the support granted by them to patient organisations in a written contract with the organisation concerned. Such contracts must set out at the very least the criteria formulated in Section 32 PCC in full and in a way which is readily comprehensible, even to persons who are not directly involved. The companies are at liberty, if necessary, to regulate additional details in contracts with patient organisations.

A written contract pursuant to Section 32 PCC is not obligatory if the value of the financial support granted is small (recommended guide value: < 1000 Swiss francs). However, the companies are advised to provide written documentation for such support too (e.g. in an exchange of correspondence, a memorandum or in some other suitable way) and to disclose this as a matter of course (on this subject see Section B of this recommendation).

Remarks about the individual requirements placed on the contracts:

- The description of the nature and purpose of the support (section 322.2 PCC) should clearly show whether this is a *pecuniary benefit* or *a benefit in kind*.
- The examples quoted in Section 322.6 PCC explain what is meant by a *benefit in kind*. The term benefit in kind also includes work done free of charge by personnel of the pharmaceutical company in favour of the patient organisation. The contract must describe in specific terms the particular benefit(s) in kind provided by the pharmaceutical company for the patient organisation. The value of the benefits in kind does not have to be quantified in the contract.
- In the case of *pecuniary benefits* (financial support for the patient organisations) of every kind the contract must indicate the precise amount to be paid (Section 322.5 PCC).

[1] http://www.scienceindustries.ch/engagements/pharmakodex-und-pharma-kooperations-kodex
[2] http://transparency.efpia.eu/uploads/Modules/Documents/code_po2011.pdf
[3] http://www.scienceindustries.ch/_file/12857/pharma-kooperations-kodex-2013-d.pdf

* **PC**: Pharma Code; **PCC**: Pharma Cooperation Code

- The contract must clearly show *the purpose for which* this pecuniary benefit is provided: e.g. general (i.e. not dependent upon performance or on a particular project) financial support for the patient organisation; overall or partial payment for certain specific services or specific projects of the patient organisation; subsequent payment of the costs of services or projects which the patient organisation has already paid.
- The *period of validity* of the contract must be stipulated therein (Section 322.7 PCC). If the contract is signed for an indefinite duration, that fact must be stated in the contract. The contracting parties are at liberty to determine the method by which the contract may be terminated in compliance with the legal order.
- The *date* on which the contract was signed must be indicated therein (Section 322.7 PCC).
- *Legally valid signatures* must be appended to the contract by both contracting parties (pharmaceutical company and patient organisation) (see also Section 323 PCC).
- In the contractual provisions governing support for patient organisations, the pharmaceutical companies must likewise comply with the *further requirements of Section 3 PCC*.
- Before signing the contract they must inform the patient organisation of its obligations pursuant to Section 46 PCC to publish the relevant support. We recommend that this fact should be stated in every case in the contracts.

The provisions of the Swiss Code of Obligations likewise apply to contracts between pharmaceutical companies and patient organisations. On the basis of notifications, the Pharma Code Secretariat has sole authority to determine whether a particular contract satisfies the requirements of the PCC. Any more far-reaching disputes, if they are admissible, must be settled through civil law proceedings.

B. Publication (disclosure) of support (Section 35 PKK)

- The publication by the pharmaceutical company must contain a concise description of the nature of the support (Section 357.1 PCC), i.e. it must clearly show whether the support involves the payment for a particular service provided by the patient organisation or general support for the patient organisation or significant support of another kind (benefit in kind as defined above).
- In the interest of transparency and comparability with similar publications by other pharmaceutical companies, the Code Secretariat recommends use by the pharmaceutical companies of the following model for the publication of their support for patient organisations:

  1. Full name of the supported patient organisation with an indication of its domicile, postal address or Internet address.
  2. Concise description of the aim and purpose of the patient organisation which is supported, based on information provided by it or on provisions of its statutes.
  3. Description of the nature of the support in a language and presentation which satisfy the requirements of general comprehension and transparency:
     a. in the case of payment for particular services or consultancy or financial support for projects of the patient organisation: their specific designation (concise description of the service or project) and indication of the amount made available for this purpose in Swiss francs;
     b. in the case of general financial support for the patient organisation, i.e. support which is not granted for specific services or consultancy: an indication of this support and of the amount granted for this purpose in Swiss francs;
     c. in the case of significant non-financial support (benefits in kind as defined above): description of the service or consultancy(ies) provided. The term "significant" normally means a benefit in kind whose cost exceeds a total of 5000 Swiss francs for the supporting company (recommended guide value).

4. Indication of the date on which the general support or the supporting service or consultancy begins or date of the supported project (e.g. event) or of the period for which the pharmaceutical company grants this support to the patient organisation.
5. Reference to the entity at the pharmaceutical company which is responsible for answering enquiries in connection with support for patient organisations (contact form, email address or telephone number).

Extract of the PCC-regulations that are of relevance in the previous context:

32 Support for patient organisations

321 Where pharmaceutical companies grant financial or other support on a significant scale to a patient organisation, they must agree such support in writing with the patient organisation before it begins.

322 The following points in particular must be included in the agreement which is to be signed with due legal validity by both parties:

322.1 the name of the partner organisations: pharmaceutical companies, patient organisation, where appropriate the retained persons, companies or organisations;

322.2 description of the nature and purpose of the support;

322.3 aims and activities within the framework of the support (events, publications, other);

322.4 tasks, rights and obligations of the pharmaceutical company and patient organisation;

322.5 if financial support is provided: its amount;

322.6 in the case of other kinds of support: nature (payment of the costs of a public relations agency working for the patient organisations, training courses provided free of charge etc.);

322.7 date and duration of the agreement.

323 The pharmaceutical companies must make arrangements for the internal approval of such agreements.

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35 Disclosure of pecuniary benefits

351 The pharmaceutical companies shall disclose the pecuniary benefits which they have granted to particular patient organisations on an individual basis and annually for a full calendar year (reporting period).

352 The pecuniary benefits are to be disclosed in each case within six months of the end of a reporting period.

353 This information must remain accessible to the public for at least three years after its disclosure.

354 The pharmaceutical companies perform their obligation of disclosure on a website for which they are responsible and which is accessible to the public either in Switzerland or at international level.

355 If the international website of the pharmaceutical company is used for disclosure, its Swiss subsidiary of the pharmaceutical company must ensure that the requirements of this Code are respected.

356 In principle, disclosure must be made in the English and whenever possible in the German, French and Italian languages; for the indication of the healthcare organisations, their name in the relevant language or languages is to be used.

357 The pharmaceutical companies must publish:

357.1 The total amounts which they have paid in the course of a calendar year to one or more patient organisations;

357.2 The names of the particular patient organisations which they have supported financially or to a significant extent in some other way. This list must contain a short description of the nature of the support and be complete in the sense that the average reader can recognise the scale of the support. The description must include the pecuniary value of financial support and the invoiced costs. If significant non-financial support is provided, for which no meaningful pecuniary value can be determined, the non-pecuniary benefit must be clearly described showing the benefit received by the patient organisation;

357.3 The names of the patient organisations for which they have given a contractual assurance of the provision of substantial consultancy or services. The nature of the consultancy or services shall (without disclosing confidential details of the agreement) be specified in sufficient detail for the average reader to be able to recognise the scale of the support.