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

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) 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 the previous Section 4 of the PC 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".

It then became apparent that many PC signatory companies did not sign the PCC. This led to the unsatisfactory situation that the cooperation provisions with healthcare professionals (HCP), healthcare organisations (HCO) and patient organisations (PO) only applied to PCC signatories. In order to fill this gap, the PCC cooperation provisions were duplicated in the latest revision of the PC (Section 4 PC). However, the disclosure requirements still only have to be met by PCC signatory companies, as these remain exclusively regulated by the PCC.

These Sections 43 et seq. PC and Sections 31 to 35 PCC require the pharmaceutical companies to adopt contractual provisions governing financial or other support for patient organisations and Section 36 PCC (and only the latter) then requires the disclosure of the pecuniary benefits connected therewith.

Recommendations

A. Details of the contractual provisions (Section 44 et seq. PC and 3 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.

Remarks about the individual requirements placed on the contracts:

- The description of the nature and purpose of the support (Section 45.1 PC and 33.1 PCC) should clearly show whether this is a *pecuniary benefit* or *a benefit in kind*.
- The examples quoted in Section 45.2.6 PC and 33.2.6 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 itself. However, in the context of disclosure, a distinction is made

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

between significant and insignificant benefits in kind. This distinction can only be made by means of an estimate of expenditure, but the quantified result does not necessarily have to be recorded in the contract itself (see paragraph B.3.c. below).

- 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 (Sections 45.2.5 PC and 33.2.5 PCC).
- 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 (Sections 45.2.7 PC and 33.2.7 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 (Sections 45.2.7 PC and 33.2.7 PCC).
- *Legally valid signatures* must be appended to the contract by both contracting parties (pharmaceutical company and patient organisation) (see also Sections 45.4 PC and 33.4 PCC).
- In the contractual provisions governing support for patient organisations, the pharmaceutical companies must likewise comply with the *further requirements of Section 43 et seq. PC and Section 3 PCC*.
- Before signing the contract, PCC signatory companies must inform the patient organisation of its disclosure obligations pursuant to Section 36 PCC. 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 Code Secretariat has sole authority to determine whether a particular contract satisfies the requirements of the PC or the PCC. Any more far-reaching disputes, if they are admissible, must be settled through civil law proceedings.

B. Publication (disclosure) of support (Section 36 PCC)

- The publication by the pharmaceutical company must contain a concise description of the nature of the support (Section 36.3 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 300 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).

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