

Recommendation No. 1 concerning the Pharma Cooperation Code (PCC)¹**Failure of healthcare professionals and healthcare organisations to consent to disclosure****Background**

On 24 June 2013, the General Assembly of the European Federation of Pharmaceutical Industries and Associations (EFPIA) adopted the new EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (EFPIA HCP/HCO Disclosure Code).² As the corresponding member association of EFPIA, scienceindustries was responsible for implementation in Switzerland. Accordingly, the Code of Conduct for the pharmaceutical industry in Switzerland was drawn up in cooperation with expert groups and patient organisations (Pharma Cooperation Code, PCC) on 6 September 2013 and approved by the scienceindustries Board.

Section 231 PCC requires the signatory companies to disclose pecuniary benefits granted by them to professionals (HCP) or healthcare organisations (HCO) on their corporate websites which are accessible to the public.

Section 232 recommends the pharmaceutical companies make reference in contracts with HCPs or HCOs to the fact that the pecuniary benefits linked to the contractually agreed service are to be disclosed pursuant to this code. For this purpose, these agreements stipulate that the recipients of the pecuniary benefits agree to disclosure.

Only a few pecuniary benefits are exempt from the disclosure obligation (sections 233 and 234 PCC).

In connection with the implementation of the PCC, the question is regularly asked as to how a signatory company should proceed if an HCP or an HCO declines to give its written consent to disclosure.

Recommendation

The main reason why HCPs/HCOs must give their written consent to disclosure lies in the stipulations of data protection law. Consent to data processing and data disclosure is essential before a company may proceed. The situation in the European context is not fundamentally different. Pursuant to the EFPIA HCP/HCO Disclosure Code the individual obligation of disclosure is the basic principle (Section 3.01) and, in this connection, the following recommendation is made to the pharmaceutical companies in a footnote to Art. 4, Section 4.01: [the pharmaceutical companies] should make provision with a view to the granting of pecuniary benefits to HCPs or HCOs in their written agreements with such recipients to ensure that the latter consent to the disclosure of the pecuniary benefits granted to them in compliance with the EFPIA HCP/HCO Disclosure Code. In addition, the companies must renegotiate existing agreements as soon as possible in order to include consent to disclosure.

In Art. 3 Section 3.02, the EFPIA Code makes provision for the possibility that pecuniary benefits may be disclosed in an aggregated (summary) form in cases where for legal reasons (precisely because of the absence of consent under data protection law) individual disclosure is not possible. This second provision is not explicitly set down in the PCC; on the contrary, the code maintains a qualified silence on this point.

Pursuant to Section 232 PCC the pharmaceutical companies make arrangements for consultancy, service or other benefits with HCPs or HCOs by means of a written agreement. In this context they call the attention of the contracting partner to the fact that the pecuniary benefits linked to the contractually agreed service

¹ <http://www.en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code>

² <http://transparency.efpia.eu/uploads/Modules/Documents/efpia-disclosure-code---august-2013-edited-final.pdf>

* PC: Pharmacode; PCC: Pharma Cooperation Code

are disclosed on their website. By appending his signature, the contracting partner confirms that he has been informed of and agrees to the disclosure.

If an HCP or an HCO declines to consent to disclosure, without a justified reservation, any pharmaceutical company concerned is advised not to sign an agreement because individual disclosure is no longer a possibility in this case for reasons of data protection law. However, the aim of the PCC, namely that of creating extensive transparency, is best achieved through individual disclosure and should therefore be the objective whenever possible.

This is **purely a recommendation** by the Code Commission. The PCC does not explicitly stipulate what is to be done if consent to disclosure is not given by a healthcare professional or by a healthcare organisation. **In such cases, this qualified silence leaves open the possibility for the companies either to continue cooperation without any payment of pecuniary benefits or to make provision for a summarised disclosure and, in that case, nevertheless to continue cooperation with an HCP or an HCO.** Various legal considerations prevent the Code Secretariat from intervening in such cases and from making the companies terminate its cooperation with the HCPs/HPOs because of their refusal to consent to disclosure. **This decision is left to the discretion of each signatory company.**

Withdrawal of consent

According to current general legal practice in relation to the data protection act, in Switzerland consent to data processing and data disclosure can in principle be withdrawn at any time. **However, such a withdrawal has no retroactive effect but in principle applies only for the future.**

Should a signatory company be confronted with a withdrawal of consent after providing the service and payment of the pecuniary benefits, it is recommended that this be noted and confirmed in writing to the HCP or HCO withdrawing consent, pointing out in the same letter that in accordance with the contractual agreement disclosure will take place for the service and payment already rendered.

Once again, the decision on continuation of further cooperation for the future after consent has been withdrawn is left entirely to the discretion of the signatory company. With a view to the desired objective of transparency, the signatory company is also recommended in that case not continuing the cooperation or to do so only with the exclusion of any pecuniary benefits in favour of the HCP/HCO withdrawing consent. However, if the cooperation is nevertheless continued, pecuniary benefits would have to be disclosed in a summarised/aggregated form.

Extract from the PCC rules which apply in this context

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23 Disclosure of pecuniary benefits

231 The pharmaceutical companies which are required to comply with this Code shall disclose pecuniary benefits which they grant to healthcare professionals or healthcare organisations in compliance with the following rules.

232 The pharmaceutical companies shall call the attention of the healthcare professionals or healthcare organisations in the contracts with them to the fact that they are required to disclose the pecuniary benefits connected with the contractually agreed service pursuant to this Code. They shall also stipulate in this contract that the recipients of the pecuniary benefits agree to disclosure.

EFPIA HCP/HCO Disclosure Code

Section 3.01. Individual Disclosure. Except as expressly provided by this Code, Transfers of Value shall be disclosed on an individual basis. Each Member Company shall disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to Transfers of Value to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

1. For Transfers of Value to an HCO, an amount related to any of the categories set forth below:

- a. Donations and Grants. Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 11 of the HCP Code).
 - b. Contribution to costs related to Events. Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, such as:
 - i. Registration fees;
 - ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and
 - iii. Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code).
 - c. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.
2. For Transfers of Value to an HCP:
- a. Contribution to costs related to Events. Contribution to costs related to Events, such as:
 - i. Registration fees; and
 - ii. Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code).
 - b. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and HCPs under which such HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

Section 3.02. Aggregate Disclosure. For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 3.01, cannot be disclosed on an individual basis for legal reasons, a Member Company shall disclose the amounts attributable to such Transfers of Value in each Reporting Period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

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Section 4.01. Enforcement through Member Associations. Each Member Association shall adopt Implementation and Procedure Rules (as set forth in more detail in Schedule 3), which will be binding upon its members, and set forth the framework for the implementation of this Code, the processing of complaints and the enforcement of sanctions in a manner consistent with applicable data protection, competition and other applicable laws and regulations.³

Note When making a Transfer of Value to a HCP/HCO, and in their written contracts with HCPs/HCOs, companies are encouraged to include provisions relating to the Recipients’ consent to disclose Transfers of Value in accordance with the provisions of the EFPIA HCP/HCO Disclosure Code. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure.