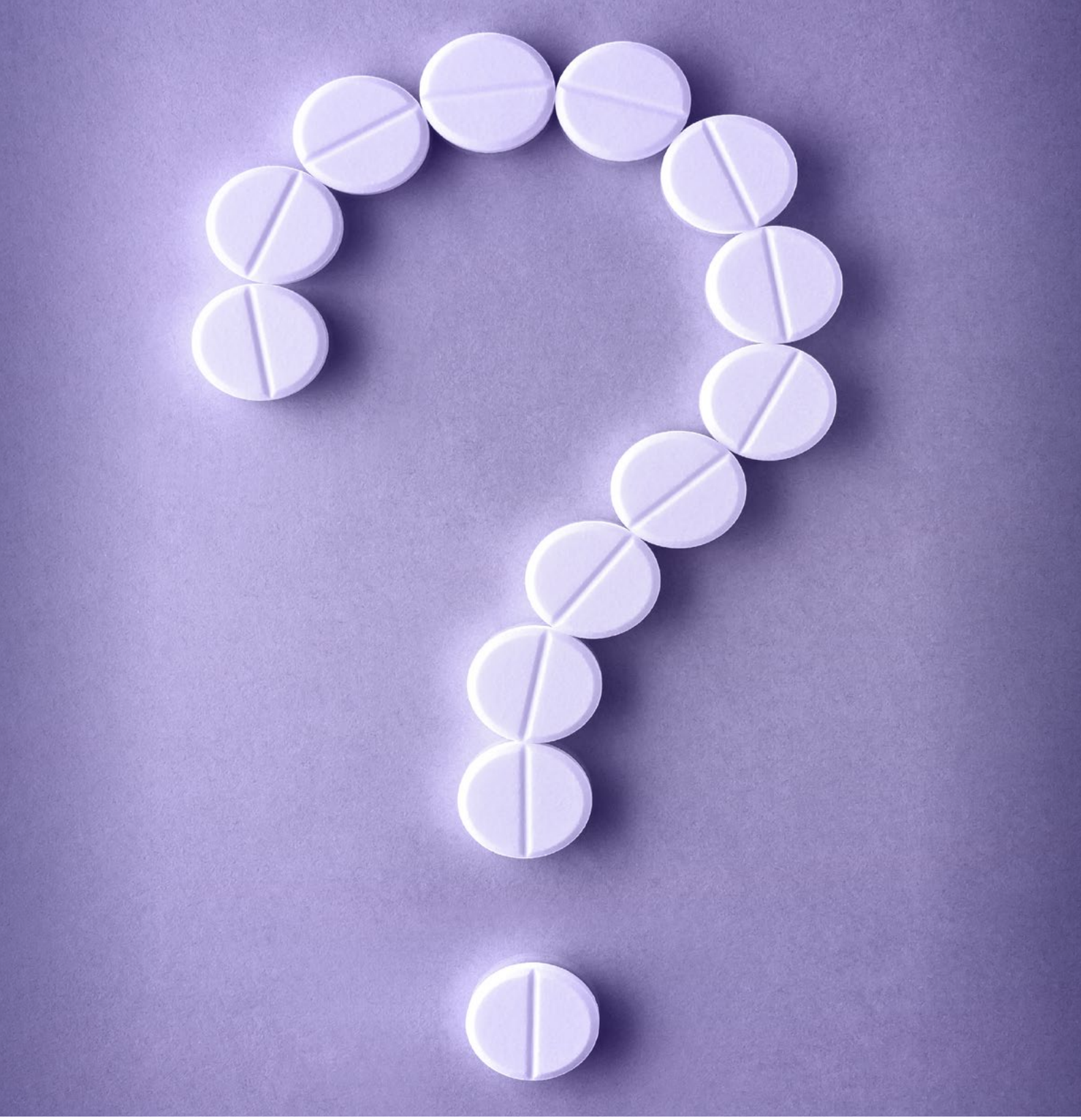

Pharma Industry Finland – Code of Ethics

QUESTIONS AND ANSWERS 2/2

– THE DISCLOSURE OF TRANSFERS OF VALUE (§ 124–130)

Pharma Industry Finland · 2014

Pharma Industry Finland – Code of Ethics: Questions and Answers 2/2 – The disclosure of transfers of value (§ 124-130)

This document is a tool to assist those who apply the Pharma Industry Finland's Code of Ethics (hereinafter: PIF Code of Ethics or PIF Code) in practice. The purpose of the interpretations contained here is to facilitate the work of the companies committed to the PIF Code on the one hand and, on the other hand, to support the supervisory system in its tasks.

I GENERAL INSTRUCTIONS

The principal aim of the code for the disclosure is the clear and transparent disclosure of the transfers of value between companies and healthcare professionals (HCP).The main rule is the disclosure at individual level, specifying the recipient.

The companies and HCPs can engage in several types and forms of cooperation in different situations. As a consequence, it possible that there is not always just one correct way to act, for example, as to what would be the most appropriate category for reporting a particular financial benefit ("transfer of value"). The companies must assume their own responsibility in interpreting individual cases, at the same time following the instructions and the Code as closely as possible. The interpretations and decisions made must be followed through and applied consistently to different cases. For this reason, the companies have the possibility – and the obligation – to clarify their own classifications in the note describing their disclosure methods (Article 129).

Moreover, the company must ensure that they aquire the consents related to disclosure, taking care of this obligation as they see most appropriate. However, Pharma Industry Finland (PIF) recommends that the companies follow the contents of the consent form template in this respect.

II DEFINITIONS

Transfers of value related to research and product development (R&D) are those pertinent to planning and implementation of

I. non-clinical studies;
II. clinical trials; or
III. non-interventional studies (see Art. 36).

If the transfer of value is related to research and development (R&D), the disclosure should be on an aggregate basis.

Healthcare professional (HCP) refers to persons who prescribe or dispense medicines in the contexts of their work. The professionals entitled to prescribe or dispense medicines include physicians, dentists, veterinarians, senior pharmacists and pharmacists. Moreover, nurses, opticians and dental hygienists who have a limited right to prescribe certain medicines are also among the HCPs referred to here.

Healthcare organisations (HCO) include:

- Healthcare, medical and scientific associations, societies and organisations;
- Companies and other corporations through which one or several HCPs provide their services.

Such HCOs may include hospitals, clinics, foundations, universities or other institutions of education and teaching. Patient organisations are not included in this category and this type of cooperation is regulated under different rules (Art. 41–47).

TEMPLATE FOR DISCLOSURE

All EFPIA members use the same template. The Finnish version of the template, to be used in Finland, will be provided by PIF. (please, see page 5.)

How to identify the recipients of transfers of value?

The companies must ensure that the recipients of transfers of value are identified with sufficient precision to be recognisable without difficulty. The limitations imposed by the data privacy legislation must be taken into consideration. In other words, any unnecessary disclosure of personal data must be avoided.

The recipients must be identified by filling in the fields in the disclosure template.

What is "Unique country identified" and where does it go to in the Finnish template?

The EFPIA template has this item for a more detailed identification of the recipients of the transfers of value. EFPIA has been informed by PIF that for data protection reasons we do not recommend that data such as the physicians' registration code (so-called SV code) be given here. Therefore, this item must be left empty in Finland.

III QUESTIONS AND ANSWERS

PLACE OF DISCLOSURE; DISCLOSURE MADE BY

Main rule:
In Europe, the disclosure takes place in the country in which the recipient has their/its principal place of business or practice, work address or place of registration.

Disclosing in a country in which the company is not a member of the national EFPIA affiliate

Although the company is not a direct member of the national affiliate in a country, it must follow the Code of Ethics issued by the national organisation in that country, also as concerns the disclosure procedure.

When a HCP or HCO is used as a consultant in another country, where should this be disclosed?

The disclosure relates to **transfers of value** to professionals or organisations with the *principal place of business or practice* in Europe. The transfers of value will be disclosed in that country following the national instructions and Code.

The physical address where the HCP/HCO is operative should be used as a reference when determining the principal place of business or practice. In situations that are open to interpretation, the companies must clarify in their note describing the disclosure methods how the cross-border transfers of value are being disclosed.

Examples:

- The US headquarters of a member company sponsoring a HCP whose practice is in Finland for a congress trip to Germany
  → disclosure must take place in Finland in line with the local legislation and national Code.

- An Italian member company sponsors an Italy-based HCO in a project providing expertise for a hospital in Tunisia
  → disclosure must take place in Italy in line with the local legislation and national Code.

- A Spanish member company sponsors a US expert for participation in an advisory board in Argentina.
  → there is no disclosure obligation under the *Code of Ethics*.

Which party is responsible for the practical disclosure? Can a parent company take care of all the disclosures for its subsidiaries? Can the different divisions of a company operating in one country each disclose part of the required data?

The company will decide how to organise the disclosure. However, it is not possible to divide the data so that it will BE disclosed in parts by the different divisions operating in a country. The practical disclosure can take place in the country chosen as long as the information is freely and readily accessible in the country that constitutes the object of disclosure.

In Finland, the information must be disclosed on the company's website and be available in Finnish.

If the company has no place of business or representation in the country where the recipient of the **transfer of value** has their principal place of business or practice, the company must still disclose the information in the country in question following the Code of the national EFPIA affiliate.

If the member company has several organisations operating in Finland, the company must choose one among them to take care of the disclosure. All **transfers of value** from one company to an individual recipient (transferred both from Finland and from abroad) must be disclosed in one place.

Which party will be responsible if no disclosure has been made?

If the company is found to be in breach with its disclosure obligation, the sanction will be a decision of the country's national EFPIA affiliate where the disclosure should have taken place, and the responsibility lies with the company offices in that country. The company's Finnish operative unit will be responsible for any failure to disclose information in Finland.

PRECISION AND MATERIAL IMPLEMENTATION OF THE DISCLO

What should be done if the company believes that – in an individual case – the information covered by the disclosure obligation contains such delicate business information or other data that cannot be disclosed?

When information is being disclosed, the company must ensure that the competition laws or other peremptory regulations are not violated. If the disclosure of the information at individual level would lead to the disclosure of sensitive business information, the data can be disclosed in the aggregate amount form whereby the information is protected as a premise. For example, any information related to research and development will be disclosed in aggregate amount.

In the note describing the disclosure methods (Art. 129), the company must discuss the methodology followed in the division of the disclosed data in different categories. Moreover, the note must refer to the principles followed by the company in assessing which data is sensitive from the business point of view and how such information has been disclosed.

The purpose of the note is to ensure that the disclosure takes place consistently, following the same methods and principles every time. The description of the disclosure methodology is each company's own responsibility.

How to quantify the value of the transferred benefit?

The value of the disclosed **transfer of value** will be determined on the basis of the respective expenses incurred by the company (i.e., not the value/benefit from the recipient's point of view).

What information should the companies disclose if they have non-medical, diagnostic or other healthcare divisions?

The disclosure obligation pertains to transfers of value covered by the scope of application of the PIF Code. The **transfers** related to medicinal products (including combination products with a medicinal and diagnostic product) must be reported in full in line with the Articles on disclosure of the Code. The devices not related to medicinal products or other devices are not covered by the disclosure obligation. Member companies can clarify the limits drawn in this respect in their note describing the disclosure methodology.

However, the following are excluded from the disclosure obligation:

- Drinks and meals (unless they are included in the overall sponsorship contract related to an event)
- Free medicine samples
- Informative and educational material and medicinal supplies (Art. 33)
- Ordinary purchase and sales operations.

Special cases:

Does the disclosure obligation also cover transfers of value to universities or other teaching institutions?

As a rule the disclosure obligation does not cover the interaction between companies and teaching institutions unless the institution in question is deemed to be *a healthcare organisation HCO*. If, however, such a transfer of value benefits *a healthcare professional HCP*, it must be disclosed and allocated to the teaching institution in question.

Transfers of value to faculties of medicine or university hospitals are covered by the disclosure obligation.

Will organisations engaged in research be classified as HCOs from the disclosure perspective?

As a rule, they will if they meet the definition. Depending on the purpose of the transfer of value, it should be disclosed in the appropriate category.

What disclosure category (HCP or HCO) should be used for a healthcare professional working as the sole employee of his/her own company?

If the company in question meets the criteria of a HCO, it will be treated, in principle, as a HCO. In this case, all the information must also disclosed under that category.

125 § DISCLOSURE

CONTRIBUTIONS TO THE COSTS OF EVENTS

What elements are included in the category "agreements with healthcare organisations or third parties named by them on sponsorship provided for the organisation of events?"

The companies must disclose the issues related to such agreements, dividing the items in applicable categories. If the agreement covers registration fees or travelling and accommodation expenses, such benefits must, as the main rule, be specified and disclosed in the relevant categories.

Examples of items included in the event sponsorship agreement:

- Rentals of exhibition stands or booths
- Purchase of advertising space
- Organisation of a satellite symposium
- Sponsoring of speakers/faculty
- If the agreement also covers meals or drinks, their value must also be included in the disclosed sum.

Member companies can clarify the limits drawn in this respect in their note describing the disclosure methodology.

SERVICE AND CONSULTATION FEES

What type of issues must be reported under "service and consultation fees"?

Generally, this type of cooperation is defined and described in respective agreements.

The category may include, for example:

- Speaker fees
- Medical writing
- Data analysis
- Development of education materials
- General consulting/advising.

The transfer of value is made to the contractual party (HCP or HCO).

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 in two separate amounts.

Member companies can clarify the limits drawn in this respect in their note describing the disclosure methodology.

CONSENT FORM AND RELATED ISSUES

What to do if the HCP does not give their consent on the disclosure of their data?

The companies must do their best to obtain the necessary consents for the disclosure of the information at individual level, and this should be the primary way of disclosing the information. However, if no consent can be obtained the information is disclosed in aggregate amount.

Is it obligatory to use PIF template consent form?

No. The company can decide how to obtain the consent for disclosure. However, it is important to note that the Finnish data protection regulation has stricter interpretations than the laws in the rest of Europe on average.

PIF recommends that the consent form is signed separately from any other agreements and is also signed separately for each entity.

TEMPLATE FOR DISCLOSURE

JULKISTAMISEN MALLIPOHJA

Julkistamisajankohta: .....

	(Sukunimi, etunimi) **Koko nimi** *(124 §)*	Pääasiallinen toimipaikka ja/tai rekisteröintipaikka: **Kaupunki** *(124 §)*	Pääasiallinen toimipaikka ja/tai rekisteröintipaikka: **Maa** *(124 §)*	Pääasiallinen toimipaikka ja/tai rekisteröintipaikka: **Osoite** *(124 §)*	Unique identifier: ***Ei käytössä Suomessa***	Lahjoitukset ja apurahat terveydenhuollon organisaatioille *(125 §/1.a)*	Tapahtumakustannuksiin osallistuminen *(125 §/1.b)*			Palvelu -ja konsulttipalkkiot *(125 §/1.c)*			**YHTEENSÄ** *VALINNAINEN*
							Terveydenhuolto- alan organisaatioiden tai kolmansien osapuolten kautta	Rekisteröintikulut	Matka- ja majoituskulut	Palkkiot	Palvelu- ja konsulttisopimuksiin liittyvät muut kulut, mukaan lukien matka- ja majoituskulut		
Terveydenhuollon ammattilaiset	***YKSILÖTASOINEN JULKISTAMINEN - yksi rivi/terveydenhuollon ammattilainen*** *(t.s. kaikki taloudelliset etuudet yhden vuoden aikana yhdelle vastaanottajataholle summataan; yksilöidyt euromääräiset summat voidaan pyynnöstä esittää vastaanottajalle ja/tai viranomaiselle)*												
	Nimi A				Ei käytössä	Ei käytössä	Ei käytössä	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*		
	Nimi B				Ei käytössä	Ei käytössä	Ei käytössä	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*		
	jne				Ei käytössä	Ei käytössä	Ei käytössä	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*		
	YHTEENVETOMUOTOINEN JULKISTAMINEN *- (kun tietoja ei juridisista syistä voida julkistaa yksilötasolla)*												
	Vastaanottajien taloudellisten etuuksien kokonaissumma(*) *- 126 §*					Ei käytössä	Ei käytössä	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*		*Valinnainen*
	Vastaanottajien lukumäärä *- 126 §*					Ei käytössä	Ei käytössä	*lukumäärä*	*lukumäärä*	*lukumäärä*	*lukumäärä*		*Valinnainen*
	Vastaanottajan saama %-osuus kaikkien vastaanottajien saamasta kokonaissummasta(*)					Ei käytössä	Ei käytössä	%	%	%	%		Ei käytössä
Terveydenhuollon organisaatiot	***YKSILÖTASOINEN JULKISTAMINEN - yksi rivi/terveydenhuollon organisaatio*** *(t.s. kaikki taloudelliset etuudet yhden vuoden aikana yhdelle vastaanottajataholle summataan; yksilöidyt euromääräiset summat voidaan pyynnöstä esittää vastaanottajalle ja/tai viranomaiselle)*												
	Organisaatio 1				Ei käytössä	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*		*Valinnainen*
	Organisaatio 2				Ei käytössä	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*		*Valinnainen*
	jne				Ei käytössä	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*		*Valinnainen*
	YHTEENVETOMUOTOINEN JULKISTAMINEN *- (kun tietoja ei juridisista syistä voida julkistaa yksilötasolla)*												
	Vastaanottajien taloudellisten etuuksien kokonaissumma (**) *- 126 §*					*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*	*Vuosittainen summa*		*Valinnainen*
	Vastaanottajien lukumäärä *- 126 §*					*lukumäärä*	*lukumäärä*	*lukumäärä*	*lukumäärä*	*lukumäärä*	*lukumäärä*		*Valinnainen*
	Vastaanottajan saama %-osuus kaikkien vastaanottajien saamasta kokonaissummasta (**)					%	%	%	%	%	%		Ei käytössä

T&K	***YHTEENVETOMUOTOINEN JULKISTAMINEN***		
	Tutkimukseen ja tuotekehitykseen liittyvät taloudelliset etuudet tulee julkistaa yhteenvetomuotoisesti kokonaissummina (128 §)	*YHTEENSÄ*	*VALINNAINEN*

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