

AIFP METHODOLOGY ON AIFP TRANSPARENCY PROJECTS

CONTENT

1.	INTRODUCTION	3
2.	DEFINITIONS	3
2.1	MEMBER COMPANY	3
2.2	RECIPIENTS	3
2.2.1	HCP	4
2.2.2	HCO	4
2.2.3	PCO	4
2.3	KIND OF TRANSFERS OF VALUES	4
3.	DISCLOSURE'S SCOPE	5
3.1	PRODUCTS CONCERNED	5
3.2	EXCLUDED TRANSFERS OF VALUE	5
3.3	TRANSFERS OF VALUE DATE	5
3.4	DIRECT TRANSFERS OF VALUE	5
3.5	INDIRECT TRANSFERS OF VALUE	5
3.6	TRANSFER OF VALUES TO PCO	5
3.7	TRANSFERS OF VALUE IN CASE OF PARTIAL ATTENDANCES OR CANCELLATION	6
3.8	CROSS-BORDER ACTIVITIES	6
4.	SPECIFIC CONSIDERATIONS	6
4.1	COUNTRY UNIQUE IDENTIFIER	6
4.2	SELF-INCORPORATED HCP	6
5.	CONSENT MANAGEMENT	7
5.1	CONSENT COLLECTION	7
5.2	MANAGEMENT OF RECIPIENT CONSENT WITHDRAWAL	7
5.3	MANAGEMENT OF RECIPIENT'S REQUEST	7
5.4	PARTIAL CONSENT	7
6.	DISCLOSURE FORM	8
6.1	DATE OF PUBLICATION	8
6.2	DISCLOSURE PLATFORM	8
6.3	DISCLOSURE LANGUAGE	8
6.4	ADDRESS OF RECIPIENTS	8
7.	DISCLOSURE FINANCIAL DATA	8
7.1	CURRENCY	8
7.2	VAT	8
7.3	CALCULATION RULES	8

AIFP METHODOLOGY ON AIFP TRANSPARENCY PROJECTS

8.	BEST PRACTICES ON COOPERATION WITH HCO	9
8.1	REGULATION IN AIFP CODE	9
8.2	CONVENER (POŘADATEL)	9
8.3	AIFP RECOMMENDED BEST PRACTICES REGARDING HCOS AND PCOS	9
	8.3.1 Principle of individual disclosure	9
	8.3.2 Principle of respecting HCOs/ PCOs rights	9
	8.3.3 Principle of proper agreement	9
	8.3.4 Principle of AIFP unified approach	10
8.4	LEGAL ARGUMENTS BY HCO/ PCO	10
	8.4.1 Personal data	10
	8.4.2 Trade secret	10
	8.4.3 HCO does not receive any money	10
8.5	INTERNAL RULES OF HCOS	11
8.6	ENFORCEMENT OF BEST PRACTICES	11
9.	QUERIES	11
9.1	DEFINITION	11
9.2	TECHNICAL MEASURES	11
9.3	PROTECTION OF PERSONAL DATA	12

AIFP METHODOLOGY ON AIFP TRANSPARENCY PROJECTS

1. Introduction

EFPIA Disclosure is a Europe-wide project dealing with the disclosure of payments or other transactions between the pharmaceutical industry and healthcare professionals/organisations. In the Czech Republic, this obligation is extended to include the obligation to disclose values in the context of CME (see below) based on Articles 13 and 23 of the AIFP Code of Practice ("AIFP Code").

EFPIA Disclosure was implemented in two separate projects until 2024: (i) EFPIA Disclosure - transfer of value from AIFP member companies to medical professionals or medical institutions and (ii) CME Disclosure - transfer of value to support continuing medical education (CME) organised by professional congress organisers.

Professional Congress Organisers ("PCOs") are not considered to be Health Care Organizations ("HCOs") under the AIFP Code. If, in the context of a specific professional event, an HCO cannot be identified as the recipient of a direct or indirect transfer of value ("ToV"), the support provided is disclosed as CME support.

In order to simplify and clarify the disclosure of the support provided towards HCPs, HCOs and PCOs, these transparency projects have been merged in 2025, as a result of which value transfers will be published uniformly on a common platform from 2025 onwards.

The purpose of this document is to provide AIFP member companies further information on the methodology used in disclosing payments or other transactions. As the data will be published on a common central platform, this common methodology has been developed to cover all areas that need to be clarified. Some parts of the methodology that are not strictly defined in this document may differ slightly between the Member Companies, so each company will also issue its own methodology to clarify these areas.

This amended version repeals and completely replaces the other documents issued in connection with the CME initiative.

The new wording was approved by the AIFP Ethics Committee on 5th March 2025.

2. Definitions

2.1 Member Company

Has the meaning set forth in the AIFP Statutes. Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – are deemed to constitute a single company, and are as such committed to comply with the AIFP Code. For the purposes of this document, this term also includes a pharmaceutical company that is not a member of the AIFP but has voluntarily agreed to adhere to the AIFP Code of Practice and is therefore subject to the obligations set out therein.

2.2 Recipients

According to the AIFP Code, recipient is any HCP, HCO or PCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in the Czech Republic.

AIFP METHODOLOGY ON AIFP TRANSPARENCY PROJECTS

2.2.1 HCP

Any person entitled to either prescribe or dispense a medicine. This definition follows the legal definition of HCP in the Czech Advertising Regulation Act. With regards to this legal definition, transfers of values to other healthcare professionals, e.g. nurses, do not fall within the scope of the disclosure obligation.

2.2.2 HCO

The EFPIA code defines that a HCO is: *“Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the AIFP Code of relationships between Pharmaceutical industry and Patient Organizations) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.”*

The healthcare organization is also the company or other legal entity established by another healthcare professional who might also be its employee.

2.2.3 PCO

EFPIA Code defines PCO as *“a company/individual specialised in the organisation and management of congresses, conferences, seminars and similar events (all “Events”).* While excluding from this definition commercial companies involved in the organisation of travel (travel agencies) or accommodation (hotels, banquets in hotels, etc.). This definition is further clarified by the AIFP Code to include an entity that organises professional events in the Czech Republic using contributions from member companies to cover the costs of continuing medical education events, while at the same time being entities that are not considered to be health care organisations (HCOs) under the AIFP Code rules.

2.3 Kind of Transfers of Values

Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of generic or branded prescription-only Medicinal Products exclusively for human use.

Transfers of Value provided to an HCO are necessary to divide into following categories:

- donations and grants
- contributions to costs related to events, such as registration fees, sponsorship agreements and travel and accommodation
- fees for service and consultancy

Transfers of Value provided to an HCP are necessary to divide into following categories:

- contribution to costs related to events, such as registrations fees and travel and accommodation
- fees for service and consultancy

Payments and other benefits provided by the PCO are not divided into special categories for disclosure purposes. Member companies disclose sponsorships and contributions to event-related costs that have been negotiated in sponsorship agreements with PCOs.

3. Disclosure's scope

3.1 Products concerned

Each Member Company shall document and disclose Transfers of Value that are related to prescription medicines and are made, directly or indirectly, to or for the benefit of a Recipient.

3.2 Excluded Transfers of Value

Without limitation, Transfers of Value that (i) are solely related to over-the-counter medicines; (ii) are listed in Articles 17 and 19 of the AIFP Code, such as items of medical utility, samples; or (iii) are part of ordinary course purchases and sales of medicinal products by and between a Member Company and an HCP (such as a pharmacist) or an HCO do not fall within the scope of the disclosure obligation.

3.3 Transfers of Value date

Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year (the "Reporting Period"). The first Reporting Period in this new format shall be the calendar year 2024. Disclosures shall be made within 6 months after the end of the relevant Reporting Period (30th June).

In doubt about what to choose as a reporting period and when the Disclosure shall be made (e.g. with respect to the turn of the calendar year), a Member Company should choose a date when the Transfer of Value was made according to their own principles specified in companies' methodological notes. Concerning this, the principle shall not be changed through a year.

3.4 Direct Transfers of Value

Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient.

3.5 Indirect Transfers of Value

Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

3.6 Transfer of Values to PCO

The values transferred to the PCO are benefits provided by member companies in connection with continuing medical education relating to the support of congresses and other scientific and educational events and meetings organised by third parties in the Czech Republic, provided in the form of a contribution to the costs incurred in connection with such events.

AIFP METHODOLOGY ON AIFP TRANSPARENCY PROJECTS

3.7 Transfers of Value in case of partial attendances or cancellation

Cancellation fees that a company pays for an HCP will not be disclosed as the Transfer of Value. Publication of cancellation fees for services that have not been consumed for e.g. illness of an HCP does not correspond to the purpose of the Disclosure Code.

In the case of earlier leaving from the sponsored event actually paid Transfers of Value shall be disclosure (e.g. full or partial payment of the registration fee, payment of fixed amounts – travel, accommodation etc.).

3.8 Cross-border activities

The objective of the AIFP (and EFPIA) Code is to require transparency of Transfers of Value to ensure that this information can easily be found by the searching patient or other interested stakeholder. The address where the HCP practices, HCO or PCO is located should be used as the reference when determining in which country the data should be disclosed.

Disclosure of Transfers of Value to HCP, HCO or PCO whose practice, principal professional address or place of incorporation is in Europe must be made in the country where the recipient has its principal practice or registered office whether the Transfer of Value takes place in the country or outside it.

Examples:

- An American head office of a Member Company sponsors a Healthcare Professional who has his practice in Sweden and carries out his activities in Germany. He must disclose the Transfer of Value in the recipient's (Healthcare Professional's) name in Sweden (under the applicable laws, regulations and national code of Sweden).
- An Italian Member Company sponsoring a Healthcare Organisation, with registered office in Italy, providing consulting to a hospital in Tunisia, must disclose the Transfer of Value in the name of the receiving Healthcare Organisation in Italy (under the applicable laws, regulations and national code in force in Italy).
- A Spanish Member Company sponsors a Healthcare Professional from the USA during his work on an advisory board in Argentina does not need to disclose the Transfer of Value according to the EFPIA Code. Disclosure may be however required in other jurisdictions, for example in the United States under the one of the Freedom of Information Acts ("Sunshine Act").

4. Specific considerations

4.1 Country unique identifier

In the Czech Republic, a doctor's unique identifier is a registration number assigned by the Czech Medical Chamber; for pharmacists it is a registration number assigned by the Czech Chamber of Pharmacists. The unique identifier of a Healthcare Organisation or Professional Congress Organisers is IČ (IN).

4.2 Self-incorporated HCP

HCP – physical entity – who can be identified based on the registration number of the Czech Medical Chamber or Czech Chamber of Pharmacists will be registered under this number as an HCP. IČ (IN) does not turn a physical entity into a legal entity.

5. Consent management

5.1 Consent collection

The condition which is necessary for processing of personal data of the healthcare professionals in the EFPIA Disclosure includes obtaining the consent from the healthcare professional with processing of personal data or securing another title for the lawful processing of personal data.

For completeness, it should be added that personal data protection concerns solely physical entities, i.e. healthcare professionals. The legal entities i.e. healthcare organizations and professional congress organisers are not subjects to personal data protection under Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (hereinafter as "GDPR Regulation") and the Act No. 110/2019 Coll., on processing of personal data, as amended and therefore the consent collection is not required.

5.2 Management of recipient consent withdrawal

If the consent of HCP was revoked, the data controller (Member Company) and data processor (AIFP as a Database provider) shall terminate the processing operations pertaining to the respective personal data and withdraw corresponding personal data from its website and/or destroy any such personal data unless legislation imposed upon the data controller/processor prevents it from destroying all or part of the personal data processed.

In that case, these transfers of value will be disclosed on an aggregated basis.

If a HCP revokes consent with any single disclosure or category of payment all payments provided to this HCP will be included in the aggregate disclosure. This principle always applies to all benefits provided within a single reporting period.

5.3 Management of recipient's request

Recipients have the opportunity to dispute the disclosed data. Generally, it is recommended to give the Recipient the opportunity to verify the data before its publication. In a case that the Recipient agrees with the data before its publication but disputes it afterwards, despite of the previous verification the company is obliged change (keeping disclosure principles) or delete the data on request. This data subject's rights are based on Section 49 of the Act no. 110/2019 Coll.

5.4 Partial consent

If a HCP revokes consent with any single disclosure or category of payment, all payments provided to this HCP will be included in the aggregate disclosure. This principle should be applied to all payments provided within one reporting period.

6. Disclosure form

6.1 Date of publication

Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period (30th June).

6.2 Disclosure platform

Disclosures shall be made on the central platform provided by AIFP on www.transparentnispoluprace.cz.

6.3 Disclosure language

Disclosures shall be made in Czech and English.

6.4 Address of recipients

Member companies report the address of a recipient actual on a date when the transfer is made. However, the publicly visible address on www.transparentnispoluprace.cz is the last one reported by any member company in a reported year. For research purposes, it is enough to enter any relevant address of a Recipient.

7. Disclosure financial data

7.1 Currency

The payments are disclosed in CZK.

7.2 VAT

The payments are disclosed including VAT.

7.3 Calculation rules

This information shall be specified in companies' methodological notes.

8. Best practices on cooperation with HCO

8.1 Regulation in AIFP Code

According to the AIFP Code, each Member Company shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient.

8.2 Convener (pořadatel)

The term “Convener” refers to the event convener (the one on whose initiative the event is held and who has a decisive influence on the event programme, speakers, etc.) who is a potential recipient of value and therefore if a ToV has been made towards such an entity, it should be reported in accordance with this document.

8.3 AIFP Recommended best practices regarding HCOs and PCOs

Based on the AIFP Code and the principles described in this document, AIFP recommends that the Member Companies consider and apply the following methods when transfer of value is made to HCO/ PCO.

8.3.1 Principle of individual disclosure

According to the AIFP 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 in the AIFP Code.

8.3.2 Principle of respecting HCOs/ PCOs rights

When discussing the terms of disclosure under the AIFP Code with regard to particular events, Member Companies shall use their best efforts to explain the AIFP Code’s principles to the Recipients and obtain Recipients’ consent to or acknowledgement of the disclosure (“Consent”). This also applies in case transfer of value is carried out through a Third Party.

8.3.3 Principle of proper agreement

The provision of payments or other benefits must always be contractually agreed in writing.

AIFP METHODOLOGY ON AIFP TRANSPARENCY PROJECTS

8.3.4 Principle of AIFP unified approach

In all their dealings with Recipients or third parties, each Member Company shall apply transparent and unified approach agreed on the platform of and/or recommended by AIFP to protect and enhance its professional reputation. Under no circumstances shall Member Companies participate in, approve or promote structures or schemes contravening the principles stipulated in the AIFP Code or this document or resulting in contradicting signals vis-à-vis HCOs/PCOs or general public.

8.4 Legal arguments by HCO/ PCO

8.4.1 Personal data

European regulation (GDPR Regulation) and the Czech Act processing of personal data does not apply to data relating to legal entities (i.e. only individuals are protected under this law).

8.4.2 Trade secret

A Member Company may face an argument raised by a particular Recipient (HCO, PCO) that disclosure of Transfer of Value cannot be done due to the fact that the subject of the agreement concluded between the Member Company and the Recipient is part of Recipient's trade secret. In this context, please note that trade secret is defined in the Civil Code as follows:

"Trade secret represents competitively significant, identifiable, appraisable matters not commonly accessible in relevant business circles that are relating the enterprise and confidentiality of which is secured in an adequate fashion by their owner in its own interest".

In light of the above, if a particular Recipient is for example a public hospital, than in line with transparency requirements stipulated, e.g. in the Minister's Order (Příkaz ministra) or by law on free access to information (No. 106/1999 Coll.), such Recipient should not successfully use the trade secret argument (information available on the hospital's or Ministry's website cannot be at the same considered a trade secret).

8.4.3 HCO does not receive any money

Member Companies often hear this argument when discussing their support to a particular event. HCOs argue that no transfer of value took place to their benefit since there was no money wired to their bank account and PCO used all sponsorships to cover the costs of the event.

According to the AIFP Code, transfer of value can be made in cash or in-kind; thus, the fact that due to the Member Company's support a particular event could take a place, i.e. accommodation, congress venue, catering etc. could be paid for, represents a transfer of value within the meaning of the Code.

AIFP METHODOLOGY ON AIFP TRANSPARENCY PROJECTS

8.5 Internal rules of HCOs

With regard to the compliance of the AIFP Code with applicable laws, Member Companies are encouraged to acknowledge and respect internal rules and policies of HCOs relating provision of support that represent Transfer of Value under the AIFP Code.

8.6 Enforcement of Best Practices

According to AIFP Code, the AIFP Ethics Committee is entitled to supervise the compliance with the provisions of AIFP Code and the implementing rules established by AIFP.

9. Queries

9.1 Definition

For the purposes of this Regulation **a specific question** means a public inquiry seeking to clarify a single published information regarding a healthcare professional (HCP), healthcare organization (HCO), professional congress organiser (PCO) or member company and/or provided transfers of value.

For the purposes of this Regulation **a general question** means a public inquiry on the AIFP's transparency projects generally such as the rules of disclosure, orientation in the database of the Disclosure project, implemented rules for protection of personal data, classification of disclosure, etc.

9.2 Technical measures

AIFP as the founder and administrator of the database where the data of the Disclosure project will be disclosed (hereinafter as the "Database") is obliged to take such technical and personal measures which help timely answer general and specific questions from the public.

The following measures are especially concerned:

- a) Creating a signpost for the purpose of classification of inquiries to general, regarding the project as such and its rules which will be answered directly by AIFP, and the specific questions relating to single published information which will be automatically sent to involved member companies;
- b) Creating an electronic form for public inquiries that can be accessed directly in the Database and that will contain the following mandatory items which must be completed: name and surname of the enquirer (phone, email), field to indicate the inquiry addressee, i.e. a member company whose data the question concerns (by selecting from the list of pre-defined subjects) for the case of specific questions, or designation of AIFP for the case of general questions, and the place to fill in the question;
- c) Ensuring the system of sending inquiries to the appropriate recipients in real time;

The technical measures implemented to ensure answering the questions described above are the one of possible ways how the specific questions will be answered. In addition, general enquiries addressed directly to the AIFP may be received in other ways, e.g. by email.

AIFP METHODOLOGY ON AIFP TRANSPARENCY PROJECTS

9.3 Protection of personal data

The public inquiries regarding specific disclosed information can be answered only by the person who was given consent with processing of personal data from the respective subject (= a healthcare professional whose data is disclosed) i.e. the administrator of personal data (= a relevant member company). AIFP in the position of a processor of personal data is not entitled to answer this type of questions concerning a particular member company or single published payments.

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