



Methodological Note

Version adapted according to the requirements defined by the Association of Innovative Pharmaceutical Industry AIFP in the Czech Republic (affiliated to EFPIA)

Servier fully supports the objectives of the EFPIA Disclosure Code. We believe this Code will contribute to provide a better insight on the long established relationship between healthcare professionals and pharmaceutical companies for the improvement of patient care.

The present document is intended to provide all methodological information relevant for interpretation of the information disclosed by Servier in the Czech Republic, as required by the Article 3 of the AIFP Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations.

1. Definitions

1.1. Recipients of Transfers of Values

According to the Schedule 1 to the AIFP Disclosure Code, recipient is any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in the Czech Republic.

1.1.1. Healthcare Professionals

The following definition of Healthcare Professionals is provided by the AIFP Disclosure Code:

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.

This definition allows identifying the following professionals our Company is interacting with:

- Physicians,
- Medical doctors,
- Pharmacists,

nb: the term “*physician*” refers in this context to a professional qualified to practice medicine.

1.1.2. Healthcare Organisations

The following definition of Healthcare Organisations is provided by the EFPIA Disclosure Code:

“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 EFPIA PO Code) 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.

This definition allows identifying the following Organisations our Company is interacting with:

- Hospitals,
- Healthcare institutions or clinics,
- Group medical practices,
- Clinical research organisations or equivalent service providers,
- Service provider in preclinical research,
- Universities (Medical departments),
- Foundations and charities involved in the medical domain,
- Medical or learned societies,
- Medical education companies,
- Associations of healthcare professionals.

1.2. Types of Transfers of Values being Disclosed

1.2.1. Transfers of Values to Healthcare Professionals

Transfers of values disclosed by our Company consist in:

- Registration fees,
 - Travel and accommodation expenses,
 - Fee for services,
 - Expenses agreed in the services or consultancy contracts (“other expenses” related to the payment or agreed in the consultancy contract, in case when these payments are not separated from the payment (e.g. separation is not suitable or is not possible at all) – such as travel or accommodation costs, tax or insurance, related to the particular activity are included in the Transfer of Value).
- ⇒ When provided, paid or reimbursed to Healthcare Professionals or for their benefit, either directly or indirectly.

1.2.2. Transfers of Values to Healthcare Organisations

Transfers of values disclosed by our Company consist in:

- Donations and grants,
 - Registration fees,
 - Sponsorship agreements (such as lease costs, operational costs),
 - Travel and accommodation expenses (incl. parking, insurance, local tax),
 - Fees for services,
 - Expenses agreed in the services or consultancy contracts (incl. lease costs, insurance, tax).
- ⇒ When provided, paid or reimbursed to Healthcare Organisations or for their benefit, either directly or indirectly.
- ⇒ Transfers of Values which are in fact dedicated to the particular department of the hospital, or part of the university, etc. are disclosed as a benefit of the Healthcare Organisation identified by the unique identifier of that Healthcare Organisation.

- ⇒ Situations when there is more than one Healthcare Organisation sponsored by the Company within one activity the benefit is disclosed adequately according to the number of Healthcare Organizations.

1.2.3. Transfers of Values related to Research and Development Activities

According to the EFPIA Disclosure Code, Research and Development activities correspond to:

- Non-Clinical Studies (laboratory),
- Clinical Trials,
- Non-interventional Studies.

All kind of Transfers of Values – as identified in 1.2.1. and 1.2.2. – provided to Healthcare Professionals or Healthcare Organisations in relation with Research and Development activities are disclosed in aggregate.

Post marketing authorizations studies are also included in the figures provided for Research and Development activities.

- ⇒ Company ensures the documentation of all disclosed ToVs and archives relevant records of its disclosure at least for 5 years.

1.3. Origin of the Transfers of Values

The information disclosed by our Company in the present country is provided on behalf of the Servier Group.

Servier is a Group of companies with affiliates in other countries that can initiate interactions with Healthcare Professionals or Healthcare Organisations.

A Group process is implemented to ensure that the local disclosure includes all transfers of values provided by companies of the Servier Group, either established locally or in foreign countries, during the previous calendar year (from 1st January to 31st December).

2. Disclosure Scope

2.1. Products Concerned

The Transfers of Values related solely to activities in connection with Over-The-Counter products are out of the scope of the disclosure.

2.2. Excluded Transfers of Values

The Transfers of Values corresponding to the following categories or provided in relation with the following activities, are not included in the disclosed information:

- Activities solely related to Over-the-counter pharmaceutical products,
- Items of medical utility,
- Meals and drinks,
- Travel expenses in line with the threshold applicable to Meals and drinks,
- Medical samples,

- Commercial activities that are part of ordinary course purchases and sales of medicinal products,
- Or any Transfer of Value which is out of the reporting scope, as defined by the AIFP Disclosure Code.

2.3. Date of Transfers of Values

As a standard rule, the date considered to prepare the disclosure corresponds to the date of the financial payment made to or for the benefit of the recipient.

Exception: when a Transfers of Value is provided in relation with the participation to an event, the date retained for the disclosure purpose will correspond to the date of the event.

2.4. Direct and Indirect Transfers of Values

The disclosure includes both direct and indirect Transfers of Values provided to recipients or for their benefit.

In this context:

- Direct Transfers of Values are provided to the recipient by our Company directly,
- Indirect Transfers of Values are provided to the recipient through a third party. In this situation, our partners are required by contract to share with our Company all information relative to Transfers of Values in order to allow an appropriate preparation of the disclosure.

2.5. Transfers of Values in Case of Partial Attendance or Cancellation

In case of partial attendance or cancellation of the participation, Transfers of Values provided for the benefit of a recipient will remain within the disclosed information.

Exception applies when Transfers of Values can be refund.

2.6. Cross Border Activities

A Group reporting process is implemented to ensure that the local disclosure includes all Transfers of Values provided by the companies of the Servier Group, either established locally or in foreign countries.

All Transfers of Values initiated by foreign companies of the Group are thus captured for disclosure in the country where the recipient has its physical address or principal place of practice, if applicable.

3. Specific Considerations

3.1. Country Unique Identifier Code (UCI)

The allocation of a Unique Country Identifier Code is intended to facilitate the identification of recipients at country level and to prevent confusion when several recipients have the same name.

This code is optional according to the EFPIA Disclosure Code.

In the Czech Republic, the UCI corresponds to: a registration number assigned by the Czech Medical Chamber as for doctors and a registration number assigned by the Czech Chamber of Pharmacists as for pharmacists. The unique identifier of a Healthcare Organisation is IČ (IN).

3.2. Self-Incorporated Healthcare Professionals

Self-incorporated Healthcare Professionals are assimilated to Healthcare Organisations for the purpose of the Disclosure.

However if the Healthcare Professional can be identified by the registration number of the professional Chamber, he/she will be registered under this number as an HCP. Disclosure of Transfers of Values is made on the Healthcare Professional profile in order to comply with data privacy principles. IČ (IN) does not turn a physical entity into a legal entity.

3.3. Multi-year Agreements

Multi-year agreements refer to contracts with Healthcare Professionals or Healthcare Organisations that generate Transfers of Values beyond a period of twelve months.

This kind of agreement has no impact on the disclosure: only the date of each Transfer of Value, as isolated operation, is taken into consideration to prepare the reporting.

4. Consent Management

4.1. Consent Collection

Consent to individual publication is collected prior to the publication through a dedicated consent form.

The consent expressed by the recipient (positive or negative) is deemed valid for a one year period and covers all the interactions that occur within this period.

In case no consent is given, the publication is made under the aggregate category.

4.2. Management of Consent Withdrawal

A recipient may decide to modify or withdraw his or her consent to individual publication.

In that case, the publication will be adapted in short delay in accordance with the decision taken by the recipient. Disclosed information will be updated to move the amounts from the individual information category to the aggregated information category as defined by the reporting publication template.

4.3. Management of Recipient's Request

Recipients may initiate requests related to the information being published by our Company.

All demands will be processed according to our internal procedure.

4.4. Partial Consents

Partial consents are deemed equivalent to “negative consents” to the individual publication.

The information disclosed in the aggregated category of the publication includes as a result all the interactions in the scope of the Disclosure Code that occurred with a given recipient during the previous reporting period.

5. Disclosure Financial Data

5.1. Publication Currency

The currency used for the current publication is: CZK

5.2. VAT

Financial amounts indicated in the publication are expressed VAT excluded in case the Company is entitled to VAT deduction.

5.3. Calculation Rule

For Transfers of Values involving the use of foreign currencies, amounts are converted from the initial currency to the publication currency according to the Monthly Average Exchange Rate applicable at the date of the Transfers of Value.

6. Disclosure Form

6.1. Date of Publication

The date of publication is: [30.6.20XX]

This date has been defined in accordance with the Association of Innovative Pharmaceutical Industry recommendation.

6.2. Reporting Year

The publication relates to the previous calendar year (from 1st January to 31st December).

This information will remain available on Internet for a period of 3 years after the date of the publication.

6.3. Disclosure Platform

The publication is provided through:

<http://www.aifp.cz/cs/eticke-jednani/transparentni-spoluprace>

6.4. Disclosure Language

The publication is provided in Czech.