

Methodological Note

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 Slovenia, as required by the Article 3 of the EFPIA 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

1.1.1. Healthcare Professionals

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

“Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe.

For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.”

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

- Physicians,
- Medical doctors,
- Pharmacists,
- Midwives,
- Nurses.

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:

“All single entrepreneurs and 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.”

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

- Hospitals,
- Healthcare institutions or clinics,
- Group medical practices,
- Single medical practice
- 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.
- ⇒ When provided, paid or reimbursed to Healthcare Professionals or for their benefit, either directly or indirectly.
- ⇒ Transfers of Value for fees for services and consultancy resulting from or related to contracts between Servier Pharma d.o.o. and HCPs under which such HCPs provide any type of services to Servier Pharma d.o.o. (or any other type of funding not covered in the previous categories, including agreed and/or contractually set costs related to remuneration for services) (Pursuant to Articles 7 and 8 of the HCP Code). 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 except when such expenses are not material (of limited value).

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,
 - Travel and accommodation expenses,
 - Fees for services,
 - Expenses agreed in the services or consultancy contracts.
- ⇒ When provided, paid or reimbursed to Healthcare Organisations or for their benefit, either directly or indirectly.
- ⇒ The disclosure of donations and grants shall be made in the name of the legal entity that is the recipient of the Transfer of value.
- ⇒ Contribution to costs related to events, including direct sponsorship to attend events such as: sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an event and costs of travel and accommodation (to the extent governed by Article 2.11. of the HCP Code). Transfers of Value for fees for services and consultancy resulting from or related to contracts between Servier Pharma d.o.o. and institutions, organisations or associations of HCPs under which such institutions, organisations or associations provide any type of services to Servier Pharma d.o.o. or any other type of funding not covered in the previous categories, if such services (or other financing) (x) are provided with the intent of supporting healthcare or research and (y) do not constitute an inducement to recommend, prescribe, purchase, supply or sell specific medicinal products (pursuant to Articles 7. and 8. of the HCP Code). 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.

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.

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 EFPIA 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.

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

In case of partial attendance 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.

3.2. Self-Incorporated Healthcare Professionals

Self-incorporated Healthcare Professionals are assimilated to Healthcare Organisations for the purpose of the Disclosure. Disclosure of Transfers of Values is made on the Healthcare Organisations profile.

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 each transfer of value through a dedicated consent form.

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

In case no consent is given, or if our Company was unable to obtain a consent form duly filled by the recipient, the publication is made under the aggregate category.

4.2. Management of Consent Withdrawal

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

In cases of withdrawal or termination of consent after performance of services, two distinct situations may occur:

1. Withdrawal occurs after the service is completed, but prior to publishing of information: if the individual withdraws their consent prior to publishing of the transaction, data on said transaction shall not be published individually (i.e. by publishing data on the individual and amount transferred to said individual), but shall in accordance with Article 3.2. of the Disclosure Code be disclosed in group form (in aggregated form) for each reporting period (i.e. in a way that does not allow identification of the individual that received the funds).

2. Withdrawal occurs after the service is completed, but after (individual) publishing of data: if the individual revoked their consent to publishing of transaction data after said data have been published, they shall, in accordance with the opinion of the Information Commissioner, remain as such (such data shall therefore not be revoked from the web page); however, any further publishing of new transactions related to said individual and further processing of data after revocation of consent shall not be allowed (e.g. in the form of a publication on some other platform).

Any termination or withdrawal of consent for a certain activity by a healthcare professional shall therefore influence only future disclosures of transfers of value and shall not apply to previously published data.

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.

5. Disclosure Financial Data

5.1. Publication Currency

The currency used for the current publication is EUR.

5.2. VAT and other taxes

Financial amounts indicated in the publication are expressed VAT and other taxes included.

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: 28.6.2016.

This date has been defined in accordance with the Forum of International research & development pharmaceutical companies, EIG 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:

- Servier's publication page on <http://www.servier.si>

6.4. Disclosure Language

The publication is provided in Slovene.

2016-01