

Methodological Note

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

As a pharmaceutical company, SERVIER works in collaboration with various stakeholders including healthcare professionals, healthcare organizations and patient organizations to improve health and quality of life. Healthcare professionals and organizations provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and scientific experience. They should be fairly remunerated for the legitimate expertise and services they provide to the industry.

Fully aligned with the objectives of the EFPIA Code of practice, SERVIER see transparency reporting as an opportunity to demonstrate its commitment to implement, comply with and enforce the highest ethical standards.

The present document is intended to provide all methodological information relevant for interpretation of the information disclosed by SERVIER in the Czech Republic.

1. Definitions

1.1. Recipients of Transfers of Value

1.1.1. Healthcare Professionals

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

“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,
- Pharmacists

nb: the term “*physician*” refers in this context to a professional qualified to practice medicine. With regards to the legal definition of HCP as it is stated in the Act. 40/1995 Coll. and in the AIFP Code of Practice, transfers of values to other healthcare professionals, e.g. nurses, do not fall within the scope of the disclosure obligation.

1.1.2. Healthcare Organisations

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

“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 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.

1.1.3. Patient Organizations

The following definition of Patient Organisations is provided by the EFPIA Code of practice:

“not-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers”

1.1.4. Professional Conference Organizers (PCO)

The following definition of PCO is provided by the EFPIA Code of practice:

“a company/individual specialized in the organization and management of congresses, conferences, seminars and similar events (all considered as events). Commercial companies involved in organization of travel (travel agencies) or accommodation (hotels, banqueting functions in hotels, etc.) are not considered as PCOs”

1.2. Kind of Transfers of Value being Disclosed

1.2.1. Transfers of Value to Healthcare Professionals

Transfers of value disclosed by our Company consist in:

- Registration fees,
 - Travel and accommodation expenses,
 - Fees 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.

1.2.2. Transfers of Value to Healthcare Organisations

Transfers of value 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.

1.2.3. Transfers of Value related to Research and Development Activities

According to the EFPIA Code of practice, Research and Development activities correspond to activities related to the planning or conduct of

- Non-Clinical Studies (laboratory),
- Clinical Trials
- Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study

All non-interventional studies that do not fall within the scope of “prospective studies”, publication is made on a nominative basis. As such, retrospective studies will be disclosed under the “consultancy / fee for services” category of the disclosure template. In case it is not possible to distinguish between prospective and retrospective non-interventional studies, the disclosure of all NIS will be on an individual basis.

1.2.4. Transfers of Value related to Patient Organizations

Transfers of Value disclosed by our Company consist in:

- Financial support
- Significant non-financial support
- Contracted services

⇒ When provided, paid or reimbursed to Patient Organizations or for their benefit, either directly or indirectly. Transfers of Value provided to Patient Organizations are disclosed on nominative basis, even when related to Research and Development activities.

1.2.5. Transfers of Value related to Professional congress organizers (PCO)

Transfers of value disclosed by our Company consist in contribution to costs related to events organized through PCO, such as:

- Registration fees;
- Travel and accommodation
- Speaker fees
- Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event.

2. Disclosure's scope

2.1. Products concerned

All Transfers of Value related to activities in connection with our Company's pharmaceutical products portfolio, whatever their status (Over-The-Counter pharmaceuticals or not) are included in the disclosure.

2.2. Company concerned

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, Healthcare Organisations, Professional Congress Organizers or Patient Organizations

A Group process is implemented to ensure that the local disclosure includes all transfers of value 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).

2.3. Excluded Transfers of Value

The Transfers of Value 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 Code of practice.

2.4. ToVs Date

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 Transfer 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.

2.5. Direct Transfers of Value

The disclosure includes both direct and indirect Transfers of Value provided to recipients or for their benefit. In this context:

Direct Transfers of Value are provided directly to the recipient by our Company.

2.6. Direct Transfers of Value

Indirect Transfers of Value 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 Value in order to allow an appropriate preparation of the disclosure.

Contributions provided to Events through PCOs (organized whether through their own initiatives or at a request of a HCO – that would therefore be the direct Recipient of the Transfer of Value) must be considered as indirect Transfer of Value and be reported on an individually named basis. Transfer of Value through PCOs are reported in the name of benefitting HCO / HCP through the PCO. The full value of the Transfer of Value provided through the PCO shall not be deemed as a benefit (in cash or in kind) to the HCO as the PCO may retain a part of this amount as “service fee”.

2.7. Non-monetary Transfers of Value

- Donations to HCOs or POs can be both monetary and donations in kind.
- For significant non-financial support to POs that cannot be assigned a meaningful monetary value, the description describes the non-monetary benefit that the Patient Organization receives.

2.8. Transfers of Value in Case of Partial Attendance or Cancellation and refund

In case of cancellation of the participation or no show, the HCP/ HCO does not receive the benefit and Transfers of Value will not be disclosed.

In case of partial attendance, only the benefits actually received are disclosed.

2.9. Cross Border Activities

The Servier Group makes their best efforts to capture and report all Transfers of Value to HCPs, HCOs, and POs provided by the companies of the Group, either established locally or in foreign countries.

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

2.10. Research & Development

All kind of Transfers of Value – as identified in 1.2.1. and 1.2.2. – provided to Healthcare Professionals, or Healthcare Organizations in relation with Research and Development activities are disclosed in aggregate. For Transfers of Value provided to Patient Organizations in relation with Research and Development activities, please see section 1.2. 4.

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 Code of practice.

In the present country, the UCI corresponds to: a registration number of HCP 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 HCO and of PCO is "IČ" (IN).

3.2. Self-Incorporated Healthcare Professionals

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

3.3. Multi-year Agreements

Multi-year agreements refer to contracts with Healthcare Professionals or Healthcare Organisations that generate Transfers of Value 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.

3.4. Country specificities

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.

3.5. Quality checks

Before reporting, our processes endeavor to ensure that Transfers of Value made to HCPs, HCOs and POs are collected and reconciled to the best of our ability. Additional data and process monitoring may take place for quality assurance prior to reporting.

4. Data protection legal basis

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, or if our Company was unable to obtain a consent form duly filled by the recipient, the publication is made under the aggregate category.

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.

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.

Partial Consents

Partial consents are deemed equivalent to "negative consents" to the individual publication. In case of partial consent, the publication of all the transfers of value that benefit to the HCPs is made in aggregate.

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

4.2. Legitimate Interests

HCO consent is not required for disclosure and ToVs to HCOs are disclosed in accordance with legitimate interests. We truly believe there is a legitimate public interest in better understanding the financial relationships that covered individuals may have with the pharmaceutical industry in the interests of transparency and trust in the pharmaceutical industry.

The HCO has the right to object to processing based on legitimate interests. In case of an objection request, Servier shall seek to ensure a balance is struck between the Contractor's rights and freedoms and our legitimate interests

5. Form of Disclosure

5.1. Date of Publication

The date of publication is: 30/06

Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period.

This date has been defined in accordance with the AIFP recommendation.

5.2. 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.

5.3. Disclosure Platform

The publication is provided through:

- The local association's website www.transparentnispoluprace.cz.

5.4. Disclosure Language

The publication is provided in Czech and English.

6. Disclosure Financial Data

2.1. Publication Currency

The currency used for the current publication is: CZK

2.2. VAT

Financial amounts indicated in the publication are expressed VAT included.

2.3. Calculation Rule

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

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