

SERVIER RUSSIA

METHODOLOGICAL NOTE

Year 2019

Servier fully supports the objectives of the EFPIA Disclosure Code and AIPM¹ Code of Practice. We believe these Codes 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 Russia, 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 and by Article 7 of the AIPM Code of Practice Disclosure of Transfer of Value to Healthcare Professionals and Healthcare Organizations.

1. Definitions

1.1. Recipients of Transfers of Values

1.1.1. Healthcare Professionals

The following definition of Healthcare Professionals is provided by the AIPM Code of Practice:

Healthcare professionals - doctors and other medical professionals, heads of medical organizations, pharmaceutical professionals (including pharmacists), heads of pharmacy organizations, and other specialists the professional activity of which is concerned with pharmaceutical products and who in the process of their professional activity have the right to prescribe, recommend, purchase, supply, or administer pharmaceutical products.

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

- Medical doctors
- Heads of medical organizations
- Pharmacists
- Heads of pharmacy organizations

1.1.2. Healthcare Organisations

The following definition of Healthcare Organisations is provided by the AIPM Code of Practice:

any legal entity (i) that is a healthcare, medical, pharmaceutical or scientific association or *organisation* (irrespective of the legal or *organisational* form) such as a hospital, clinic, foundation, university or other teaching institution (except for patient organisations) whose business address, place of incorporation or primary place of operation is in Russia or (ii) which provides services through one or more healthcare professionals.

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

¹ AIPM – Association of International Pharmaceutical Manufacturers

- Hospitals,
- Healthcare institutions or clinics,
- Universities (Medical departments),
- Service providers in clinical and preclinical research (e.g. laboratories),
- Foundations and charities involved in the medical domain,
- Medical or scientific societies,
- 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.

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.

1.2.3. Transfers of Values related to Research and Development Activities

According to the AIPM Code of practice, Research and Development activities correspond to:

- Pre-Clinical Studies (laboratory),
- Clinical Trials,
- Post-registration observation (non-interventional) studies that are prospective in nature

All post-registration 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 non-interventional studies will be on an individual basis.

All kind of Transfers of Values – 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.

Post marketing authorizations studies are also included in the figures provided for Research and Development activities if such studies are prospective in nature and involve the collection of patient data from or on behalf of individual, or groups of, Healthcare professionals specifically for the study.

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 Rx (prescription) products are in 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 (when it is technically possible):

- 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 AIPM Code of Practice.

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, in case of individual disclosure, 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 and AIPM Code of Practice.

In SERVIER Russia, the UCI corresponds to:

- For Health care professionals - Insurance individual account number (SNILS) which is used for our internal records but is not published for personal data security reasons.
- For Health care organizations – Taxpayer personal identification number (INN) which is published together with other information about a Healthcare Organisation.

3.2. Self-Incorporated Healthcare Professionals

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

However if the name of Healthcare Professional appears in the Legal Name of the Healthcare Organisations, disclosure of Transfers of Values is made on the Healthcare Professional profile in order to comply with data privacy principles.

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 (Healthcare Professionals)

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 is deemed valid until it is revoked by the recipient 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 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 individual category of the publication includes as a result all the interactions in the scope of the AIPM Code of Practice 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: Russian rubles.

5.2. VAT

Financial amounts indicated in the publication are expressed VAT excluded, when it is technically possible.

5.3. Personal Income Tax & Insurance Social Contributions (Healthcare Professionals)

Financial amounts indicated in the publication are expressed Personal Income Tax & Insurance Social Contributions excluded, when it is technically possible.

5.4. 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 (i.e. monthly average of all daily exchange rates provided by the European Central Bank) applicable at the date of the Transfers of Value.

6. Disclosure Form

6.1. Date of Publication

The Data should be published no later than June 30, 2019.

6.2. Reporting Year

The publication relates to the previous calendar year (from 1st January to 31st December 2018).

This information will remain available on Internet for a period of 3 years after the date of the publication taking into account the transfer of the individual form of disclosure into aggregate, in case of a subsequent withdrawal of consent by the recipient.

6.3. Disclosure Platform

The publication is provided through:

- Servier's publication page «Disclosure of Information» on www.servier.ru

6.4. Disclosure Language

The publication is provided in Russian and English.