

Methodological Note regarding publication of transfers of value

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 & ARPIM (local EFPIA) Code of practice, SERVIER sees transparency reporting as an opportunity to demonstrate its commitment to implement, comply with and enforce the highest ethical standards.

This document is intended to provide all methodological information relevant for interpretation of the information disclosed by SERVIER in Romania in accordance with the provisions of art. 814 of Law no. 95/2006 on health reform, republished, with subsequent amendments and completions ("Law no. 95/2006") and of the Order of the Ministry of Health no. 194/2015 regarding the approval of the Norms for the evaluation and approval of advertising for medicinal products for human use ("Order no. 194/2015"), in particular art. 35 of the Norms for the evaluation and approval of advertising for medicinal products for human use approved by the Order of the Ministry of Health no. 194/2015 ("Advertising Norms"), as well as with the provisions of the ARPIM Code of transparency in the interaction with health professionals and organizations (ARPIM) and in accordance with articles 22, 23 and 24 of the EFPIA Code.

1. Definitions

1.1. Recipients of Transfers of Value

1.1.1. Healthcare Professionals

The following definition of Health Professionals is provided by Article 35 of the Norms for the evaluation and approval of advertising for medicinal products for human use approved by the Order of the Ministry of Health no. 194/2015 ("Advertising Norms"):

Healthcare professionals are understood as "doctors, dentists, pharmacists, and nurses or pharmacy assistants"

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,
- Pharmacists Assistants,
- Scientific Experts
- 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 health organizations is provided by Article 35 of the Norms for the evaluation and approval of advertising for medicinal products for human use approved by the Order of the Ministry of Health no. 194/2015 ("Advertising Norms"):

"Organization with activities in the field of health - any legal entity, with or without profit, that carries out activities related to human health, medical assistance or pharmaceuticals."

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.”

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

In accordance with the provisions of Law no. 95/2006, Order no. 194/2015 and the Advertising Rules, the obligation was established to declare to the National Agency for Medicines and Medical Devices (NAMMD) and publish certain data in relation to all sponsorship activities, as well as any other expenses incurred in the year prior to reporting, for health professionals, professional organizations, patient organizations and any other type of organizations carrying out activities related to human health, medical or pharmaceutical assistance incurred in the year prior to reporting.

Art. 814 of Law no. 95/2006 specifies that this obligation must be fulfilled under the conditions established by order of the Minister of Health. Annex no. 1 of Order no. 194/2015 provides in this regard that, among the information to be declared and published, are the following:

- (a) the name and surname of the healthcare professional/healthcare organization;
- (b) the specialty of the health professional;
- (c) the address where he/she carries out his/her main activity;
- (d) details related to sponsorships;
- (e) other types of expenses such as fees for services, namely: conference, consultancy: for example, but not limited to: advisory board, expert opinion, medical writing and training for company employees, assignment of copyrights;
- (f) expenses associated with the performance of the services provided for in the service contracts (transport and accommodation) when they are provided, paid or reimbursed to the Health Professionals or for their benefit, directly or indirectly.

Transfers of value disclosed by our Company consist in:

- Registration fees,
- Travel and accommodation expenses,
- Sponsorship contracts
- 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.

For the fees related to contracts concluded with health professionals registered for tax purposes as grouped practices, associates or medical civil societies, as well as in the case of LLC type companies and for which the suppliers have issued invoices, they are reported in the name of the respective company, and the name of the health professional who actually provided the service was included in the parenthesis.

1.2.2. Transfers of Value to Healthcare Organisations

In accordance with the provisions of Law no. 95/2006, Order no. 194/2015 and the Advertising Rules, the obligation was established to declare to the NAMMD and publish certain data in relation to all sponsorship activities, as well as any other expenses incurred in the year prior to reporting, for professional organisations and any other type of organisations carrying out activities relating to human health, healthcare or pharmaceuticals incurred in the year prior to reporting.

Art. 814 of Law no. 95/2006 specifies that this obligation must be fulfilled under the conditions established by order of the Minister of Health. Annex no. 1 of Order no. 194/2015 provides in this regard that, among the information to be declared and published, are the following:

- (a) the name of the health organisation;
- (b) the address where they carry out their main activity;
- (c) sponsorship details;
- (d) other types of expenses such as fees for services, namely: conference, consultancy: for example, but not limited to: advisory board, expert opinion, medical writing and training for the company's employees, assignment of copyrights;
- (e) expenses associated with the performance of the services provided for in the service contracts (transport and accommodation).

Transfers of value disclosed by our Company consist in:

- Donations and grants,

- 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:

- 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 and in compliance with the provisions of EU Regulation 2016/679 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" or "GDPR").

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.

All types of transfers of value - as identified in point 1.2.3 - offered to healthcare professionals or healthcare organizations in relation to research and development activities are published in aggregate. For transfers of value provided to patient organizations in relation to research and development activities, see section 1.2.4.

1.2.4. Transfers of Value related to Patient Organizations

In accordance with the provisions of Law no. 95/2006, Order no. 194/2015 and the Advertising Rules, the obligation to declare to the NAMMD and publish certain data in relation to all sponsorship activities, as well as any other expenses incurred in the year prior to reporting, for patient organizations incurred in the year prior to reporting, was established.

Art. 814 of Law no. 95/2006 specifies that this obligation must be fulfilled under the conditions established by order of the Minister of Health. Annex no. 1 of Order no. 194/2015 provides in this regard that, among the information to be declared and published, are the following:

- (a) the name of the health organization;
- (b) the address where they carry out their main activity;
- (c) sponsorship details;
- (d) other types of expenses such as fees for services, namely: conference, consultancy: for example, but not limited to: advisory board, expert opinion, medical writing and training for company employees, assignment of copyrights;
- (e) Expenses associated with the execution of the services provided in the service contracts (transport and accommodation).

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.

Transfers of value through professional conference organizers are reported on behalf of the recipient professional conference organizer (for the benefit of [...] - the name of the beneficiary healthcare organization is included).

2. Disclosure's scope

2.1. Products concerned

All Transfers of Value related to activities in connection with our Company's pharmaceutical products portfolio, are included in the disclosure.

2.2. Company concerned

The information disclosed by our Company in Romania 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:

- Items of medical utility,
- Meals and drinks, when they are not part of a sponsorship contract
- 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.

For 2024, transactions paid between 1.01.2024 and 31.12.2024 were considered, even if the contract was signed in 2023.

2.5. Direct and Indirect 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 to the recipient by our Company directly,
- 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*.

*Exclusively within the limits permitted by the applicable normative acts and in compliance with the provisions of EU Regulation 2016/679 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" or "GDPR")

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”.

2.6. Non-monetary Transfers of Value

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

2.7. Disclosure format of Transfer of Value through PCO

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”.

2.8. 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 Romania, the UCI is not applicable.

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.

4. Data protection legal basis

For transfer of value to healthcare professionals made by Servier Pharma SRL, you can find more information here: <http://servier.ro/content/protectia-datelor-cu-caracter-personal>

For transfer of value to healthcare professionals made by Les Laboratoires Servier, go to <https://servier.com/en/data-privacy/>

5. Form of Disclosure

5.1. Date of Publication

The date of publication is: 30/06/2025

This date has been defined in accordance with local legislation provisions and the ARPIM (local EFPIA) recommendation.

5.2. Reporting Year

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

Servier will document all transfers of value that must be published according to the normative acts in force, the codes mentioned in the preamble and will keep the relevant documents prepared according to the information note regarding the processing of personal data.

5.3. Disclosure Platform

The publication is provided through:

According to Art. 35 of Order no. 194/2015 issued by the Ministry of Health: (6) the information declared [...] shall be published in the second quarter of the year for the previous year on the website of the NAMMD and the entity.

Reports on transfers of value can be found in:

- on the www.servier.ro website
- website Servier Transparency <https://servier.com/en/transparency>
- on the website of the National Agency for Medicines
- Publication of value transfers related to research and development activity on the ARPIM (local EFPIA) website <https://arpim.ro/codul-de-etica/>
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5.4. Disclosure Language

The publication of the transfers of value to the HCP and HCO is made in Romanian.

The publication of the transfers of value related to the research and development activity is done in English.

6. Disclosure Financial Data

6.1. Publication Currency

The currency used for the current publication is: RON

6.2. VAT

For the fees related to the contracts concluded with health professionals registered for tax purposes as PFI/PFA, grouped practices, associates or medical civil societies, as well as in the case of LLC type companies and for which the suppliers have issued invoices, the net amounts paid based on the invoices received (excluding VAT) were declared.

The amounts related to the sponsorships granted and for the costs of participation in events are declared without VAT.

Regarding the publication of value transfers related to research and development activity: the amounts reported are net (excluding VAT) and paid in the calendar year 2024.

6.3. Calculation Rule

In the case of expenses that are generated by invoices in foreign currency and recorded in Servier's records, the NBR exchange rate applicable on the date of issuance of the invoice was taken into account.

Regarding the publication of value transfers related to research and development activity: in the case of expenses in foreign currency, the NBR exchange rate communicated on 30.12.2023 was taken into account.

6.4. Non-duplication of publication

Where a transfer of value to be disclosed under Section 2.5 or 2.7 is made in favour of a particular HCP indirectly, by means of an HCO, that transfer of value shall be published only once. As far as possible, this publication will be made with reference to the individual (HCP beneficiary), according to the ARPIM (Local EFPIA) code.

The amounts paid to the organizers as participation fees for health professionals at independent scientific events were declared in order to avoid double reporting as individual sponsorship contracts with each beneficiary.

Bucharest, June 30th 2025