

## Methodological Note – SERVIER PHARMA d.o.o.

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 Croatia, 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.

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.”*

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. 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. 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 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.

#### 1.2.4. Transfers of Values related to Patient Organizations

Transfers of Values 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 Values provided to Patient Organizations are disclosed on nominative basis, even when related to Research and Development activities.

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

Transfers of values 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;

### **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 1<sup>st</sup> January to 31<sup>st</sup> December).

## **2. Disclosure Scope**

### **2.1. Products Concerned**

All Transfers of Values 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. 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.

## **2.5. Disclosure format of Transfer of Value to Patient Organizations**

For supports:

- The disclosure format includes a description of the nature of the support, the monetary value of financial support and of invoiced costs.
- For significant nonfinancial support that cannot be assigned a meaningful monetary value, the description describes the non-monetary benefit that the Patient Organization receives.

For contracted services: the total amount paid per Patient Organization over the Reporting Period is disclosed.

## **2.6. Disclosure format of Transfer of Values 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 Values) must be considered as indirect Transfer of Values and be reported on an individually named basis.

Transfer of Values through PCOs are reported in the name of benefitting HCO / HCP through the PCO.

The full value of the Transfer of Values 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. 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.

## **2.8. 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.

### **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**

### **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 until receipt of changed consent and covers all the interactions that occur until further notice.

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 requests 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 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: HRK (Croatian Kuna)

#### **5.2. VAT**

Financial amounts indicated in the publication are expressed VAT included.

#### **5.3. Tax and contributions**

Financial amounts indicated in the publication are without tax and contributions. The financial amounts are expressed in net amount.

#### **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 applicable at the date of the Transfers of Value.

## **6. Disclosure Form**

#### **6.1. Date of Publication**

The date of publication is: June 30<sup>th</sup>

This date has been defined in accordance with *Innovative Pharmaceutical Association* (IFI) recommendation.

## **6.2. Reporting Year**

The publication relates to the previous calendar year (from 1<sup>st</sup> January to 31<sup>st</sup> 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.hr/content/javna-objava-prijenosa-vrijednosti>

## **6.4. Disclosure Language**

The publication is provided in Croatian language.