

## Methodological Note

### Servier Hellas

#### A. Forward

This methodological note accompanies the Disclosure report clarifying matters pertaining to this document, through which Servier Hellas discloses all the transfers of values has made to the HCPs and HCOs for the year 2016.

According to the regulation [Law 4316 (FEK 270A/24.12.2014, art. 66, par.7(a)], the EFPIA Code and the SFEE Code, the companies /members of SFEE should disclose their interactions with HCPs and HCOs in order to reinforce the transparency and built up the trust between the pharmaceutical industry, the medical community and the society.

On this page all transfers of value concluded by Servier Hellas to Health Care Professionals (HCPs) are disclosed on an aggregate basis and all transfers of value to Health Care Organizations (HCOs) in detail for the period 01/01/2016 - 31/12/2016.

We explicitly note that this present disclosure was modified following the issuance of nr. 5/2016 and 2/2017 Opinions of the Greek Data Protection Authority.

In any event, this present disclosure aims to the enhancement of transparency of the relationship between pharmaceutical companies and HCPs and HCOs as well as to upholding the right of patients to be informed on the relationship between the pharmaceutical companies and the scientific community.

#### B. Definitions

**Recipients:** any HCP or HCO who have received transfer of values by Servier Hellas and their primary practice, principal professional address or registered office is in Greece.

##### **Healthcare Professionals**

*“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 Greece.*

*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.”*

## Healthcare Organisations

*“Any legal person:*

- (i) that is a healthcare, medical or scientific association (scientific society or an association of HCPs) or healthcare organisation (irrespective of the legal or organisational form), such as a hospital, clinic, foundation, university or other educational institution or learned society of any type (e.g. NGOs) sponsored by pharmaceutical companies (except for patient associations within the scope of the SFEE Code of Ethics on the Relationships between Pharmaceutical Companies and Patient Associations), which has registered office or is active in Greece; or*
- (ii) through which one or more HCPs provide healthcare services, including private Primary Healthcare Providers (Presidential Decree 84/2001, Gov. Gazette 70/A/10.4.2001).*

## Transfer of values

Any transfer of objects and rights, either in the form of fee for service or in the form of a grant for an educational/training activity. The definition includes all direct or indirect transfers of value, whether in cash, or otherwise, made for promotional or other purposes, in connection with the development and sale of generic or branded medicinal products, intended exclusively for human use.

## Events

All promotional, scientific or professional meetings, congresses, conferences, board meetings, symposia and other similar events that are not associated with Research & Development (including, but not limited to type A, B, C & D events in accordance with EOF Circulars, as applicable from time to time, on scientific events) organised or sponsored by or on behalf of a company (Articles 17, 18 and 19, Chapter A of this Code).

## C. Types of transfers

### 1. Transfers of Values made by Servier Hellas to Healthcare Professionals, pertaining to

**a) Events** (Registration fees, Travel and accommodation expenses)  
and

**b) Fees for consultancy and other services**

(Fees resulting from or related to contracts between Member Companies and HCPs, under which HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories, are disclosed on an **aggregate** basis.

**c) Transfers of Values made for Research and Development**

Transfers of value concerning Research and Development activities for each Reference Period are disclosed on an aggregated basis. These are:

- A. Transfers of value to HCPs or HCOs related to the planning or conduct of
  - (i) non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice);
  - (ii) clinical trials (phase I, II, III & IV, as defined in Directive 2001/20/EC); and
  - (iii) prospective 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
- B. Costs related to events that are auxiliary to activities falling within the scope of this section:



- Investigator meetings
- Advisory boards for clinical research
- Steering committee meetings, consultancy meetings for clinical research (e.g. biostatistics, epidemiological, etc)
- Technical training for clinical research (e.g. laboratory procedures, equipment and systems trainings etc)

## 2. Transfers of Values made by Servier Hellas to HCOs, pertaining to

### a) Donations and grants

Any kind of donation or grant (either cash or benefits in kind), made to foundations and charities, organisations, associations, hospitals, universities, learned societies, education companies, all associated with medical domain or practice.

### b) Sponsorship of events

Organised by HCOs or PCOs, as

- i. Group registration fees for HCPs (when participating HCPs are not selected by the sponsor, but by the organising entity);
- ii. Amount of sponsorship, as specified in agreements with HCOs or third parties appointed by an HCO to manage an event, provided that the sponsorship is not intended for a specific HCP.

### c) Fees for consultancies and other services

Fees resulting from or related to contracts between Member Companies and HCOs, under which HCOs provide any type of services to a Member Company or any other type of funding not covered in other categories (e.g. fee for service and consultancy which is payable directly to a HCP). 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.

## D. Disclosure amplitude

- **Related to products:** all transfers of values related to activities in connection with Servier pharmaceutical products.
- **Exclusion from the Disclosure Obligation.** Excluded from the scope of the disclosure obligation are transfers of value that:
  - 1) are solely related to over-the-counter medicines,
  - 2) meals and drinks, medical samples and medical utility items of insignificant value, and
  - 3) are part of ordinary course purchases and sales in the business of medicine trading (such as pharmacists, wholesalers) and/or HCOs, within the distribution chain of medicinal products.



- **Date of the transfer of values:** for the disclosure purposes it has been agreed to take into consideration the date of the legal voucher (i.e receipt or invoice date).  
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.
- **Direct transfers of value:** are those made directly by the company for the benefit of a recipient, e.g. registration fee, tickets, accommodation or payment for consultancy services.
- **Indirect transfers of value:** are those made on behalf of a Member-Company (e.g. Servier Hellas) through a third party (e.g event organiser /PCO) for the benefit of a recipient (HCP or HCO), where the Member-Company is known or can be identified by the recipient. In this situation, the third party is required to share with Servier Hellas all information relative to transfers of values.
- **Cross Border Activities:** each company is obliged to disclose the transfer of values to HCPs and HCOs who have their physical address of residence or principal place of practice in Greece. In general, disclosure is made according to the national Code in the country where the recipient has his principal place of practice/physical residence. The physical residence/place of practice, is the criterion for disclosing the transfer of values. For example, if an HCP resident and practicing his medical profession in Greece, receives a fee from LLS for the services he provided in a third country, the disclosure of this transfer of value will be made in Greece.
- Also, when Servier Hellas pays to a French HCP (resident in France), a fee for consultancy services in Greece, the disclosure will be made in France. In these cases, there is communication and exchange of the relevant data between Servier Hellas and LLS.

## E. Specific Considerations

### 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.

### Multi-year Agreements

Multi-year agreements refer to contracts between Servier Hellas and HCPs/HCOs that generate Transfers of Values beyond a period of twelve months. Only the date of each Transfer of Value, as isolated operation, is taken into consideration to prepare the reporting.



## F. Consent Management

In Greece because of the implementation of Law 4316 (FEK 270A/24.12.2014, art. 66, par.7(a), the disclosure of transfers of values (payments or reimbursements) to HCPs and HCOs either directly or indirectly, is mandatory.

### Personal Data Protection Authority

Servier Hellas, has made this notification to the Greek Personal Data Protection Authority, about the collection, processing and keeping data with the aim “Obligation for the disclosure of transfer of values made by the pharmaceutical companies to HCPs and HCOs”

HCPs may at any time have access in these data and ask for update or modification, if applicable.

## G. Disclosure Form

**Disclosure form:** in Servier Hellas, the template used is the one proposed by the EFPIA and was adopted by the SFEE and the companies –members.

**Date of Publication:** referred to the date on which the disclosure template is published and uploaded on the Servier Hellas website. On the same date a CD-rom is submitted to EOF through the protocol, in order to upload it at their special platform created in their website.

For the **reporting year 2016** (1.1.2016 to 31.12 2016), the date for publishing the Disclosure template is the **30 June 2017**.

**Disclosure Platform:** (for common access-view)

A special platform at EOF’s website: link [www.eof.gr](http://www.eof.gr)

Webpage on the website of Servier Hellas: link [www.servier.gr](http://www.servier.gr)

**Disclosure Language:** Greek

## H. Disclosure financial data

- The **currency** used for the current publication is: EUR
- **VAT:** For travelling and accommodation expenses, VAT is included.  
For other payments (registrations, consultancy fees, honoraria), VAT is excluded.
- **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. Does not apply for Servier Hellas, this year.



For the purpose of disclosure, all financial data used, are extracted from Servier Hellas archiving system.

The amounts have been checked and reconciled with the valid vouchers / invoices, that Servier Hellas has received from the relevant, proper corporations.

The amounts presented in the Servier Hellas disclosure template for the year 2016, concern:

**Transfer of values to HCPs**

These transfers of values are amounts paid to HCPs for registration fees, travelling and accommodation expenses, consultancy and other services fees. In the published template, the total amount paid by Servier Hellas for the HCPs is disclosed, as aggregate.

**Transfer of values to HCOs**

Servier Hellas has co-operated directly or indirectly (through a third party) with a number of HCOs. The transfer of values concern:

- grants and donations,
- sponsorship of events and
- consultancy fees.

**Transfer of values for Research and Development**

The transfers of values made by Servier Hellas for Research and Development at local level, are disclosed on an aggregate basis.