METHODOLOGICAL NOTE

Transparency of the interrelationships of the Pharmaceutical Industry with Healthcare Organizations and Healthcare Professionals

CONTENTS

1.- INTRODUCTION

Our society requires that the pharmaceutical industry be able to make available the best possible medications. To achieve this objective, it is necessary to invest in research and development, which inevitably requires close collaboration with healthcare professionals and healthcare organizations.

These collaborations must be transparent. In addition, society must be able to trust that such efforts respond to the need to develop new drugs and are accompanied by a constant updating of healthcare professionals according to scientific evidence and its application to clinical practice, all with the common goal of serving patients in the broadest sense.

Toward this end, since 2014 the pharmaceutical industry has voluntarily assumed new commitments regarding transparency. Beginning January 1, 2016, all laboratories adhering to the Code of Practice for the Pharmaceutical Industry will publish on their website transfers of value made to healthcare professionals and healthcare organizations in the form of donations, grants, training activities and sponsorship of professional scientific meetings as well as the provision of services and research and development for the previous year. This information will be updated annually.

More information about this initiative appears at www.codigofarmaindustria.es

Purpose of the initiative:

The purpose is to build credibility and confidence in the pharmaceutical industry as a whole and in the interactions between pharmaceutical companies and professionals and healthcare organizations.

To this end, this initiative:

- Promotes transparency in these interactions, especially when they produce value transfers.
- Provides information on the scope and nature of such interactions.
- Helps identify and understand how, among other aspects, such interactions are necessary for the development of new drugs and to ensure their rational use.

Recipients:

Patients and the general public: It informs them about the various ways that drug manufacturers and healthcare organizations and healthcare professionals collaborate, as well as the added value such collaborations represent and contribute to society.

Healthcare professionals and organizations: It quantifies the role of pharmaceutical companies in areas such as research and development and continuing medical education.

Researchers: It shows which part of the total investment made by R&D laboratories is dedicated to remunerating researchers and research centres.

Pharmaceutical companies: It documents their commitment to collaboration and continuous improvement, the legitimate need for such interaction, and provides evidence of their commitment to comply with the strictest ethical principles of professionalism and responsibility.

Laboratorios Servier fully supports the objectives defined in the EFPIA transparency initiative. We firmly believe that this project will help provide a better understanding of the relationship between healthcare professionals, healthcare organizations and pharmaceutical companies, resulting in improvements in patient care.

This document is intended to provide all relevant methodological information for the interpretation of the information published by Servier in Spain, as outlined in Article 3 of the EFPIA Code on Disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organizations.

2.- GLOSSARY OF TERMS

CRO: Contract research organization

EFPIA: European Federation of Pharmaceutical Industry Associations

FI: Farmaindustria

HCO: Healthcare organization

CP: Contact person

HCP: Healthcare professional

VT: Value transfer

3.- CATEGORIES OF VALUE TRANSFERS

All information for value transfers occurring in 2017 will be published according to the structure of Annex 2 of the 2016 Code of Good Practice in the pharmaceutical industry.

There are three categories:

3.1.- Value transfers made to HEALTHCARE PROFESSIONALS

3.2.- Value transfers made to HEALTHCARE ORGANIZATIONS

3.3.- Value transfers made in RESEARCH AND DEVELOPMENT

The following are the items included in each category:

3.1.- Value transfers made to HEALTHCARE PROFESSIONALS

VTs made by Servier to HCP will be published individually. Each HCP will be identified with the following fields:

- Full name

- City of professional practice

- Identity card number

- Country of professional practice and professional address

For each HCP, Servier will publish the corresponding VT for the year, grouped by categories (detailed below). The amount of the breakdown by category for each HCP will be available for consultation, as appropriate, upon request of the HCP, code enforcement bodies and/or competent authorities.

Categories of VT:

- Training activities and professional scientific meetings:
    - Registration fees
    - Travel and accommodation associated with training activity
- Providing services:
    - Honoraria: Presentations at meetings, national and international conferences, expert meetings, training activities, etc.
    - Expenses related to the service rendered

3.2.- Value transfers made to HEALTHCAREORGANIZATIONS

Value transfers made by Servier to HCOs will be published individually in Spain.

Each HCO will be identified with the following fields:

- Full name

- City of company headquarters

- VAT number

- Country of professional practice and professional address

For each HCO, Servier will publish the VT for the year grouped by categories (detailed below). The amount of breakdown by category for each HCO will be available for its consultation, as appropriate, upon request of authorized HCO supervisory personnel, code enforcement entities and/or the competent authorities.

Categories of VT:

- *Donations/grants* to HCOs that provide health care services, including grants and donations (cash or in kind) to institutions, organizations, associations or foundations composed of HCPs and/or that provide social or humanitarian health care, research, teaching or training.

- *Training activities and professional scientific meetings:*

    - Partnership agreements and/or sponsorships with HCO or third parties assigned by HCO for management to defray the costs associated with these events
    - Registration fees when the contribution is made through the HCO and the name of the HCP invited to attend training activities/professional scientific meetings is not known
    - Travel and accommodation associated with the training activity

- *Services:* Includes all VTs made by Servier to HCOs, institutions, organizations, associations or foundations composed of HCPs rendering a service or VT, distinguishing the following concepts:

    - Honoraria
    - Expenses related to the service rendered

3.3.- Value transfers in RESEARCH AND DEVELOPMENT

For each applicable period, Servier will publish in aggregate form all VTs related to research and development, including:

- Preclinical studies (defined by the OECD in “Principles of Good Laboratory Practice”) with universities or research centres.

- Clinical trials: Research conducted in humans to determine or verify the clinical, pharmacological and/or other pharmacodynamic effects, and/or detect adverse reactions, and/or to study absorption, distribution, metabolism and excretion of one or more drugs in research to determine its safety and/or effectiveness (defined in Directive 2001/20/CE).

This section does not include certain costs of clinical trials, such as additional tests, administrative costs or expenses for coordination and monitoring tasks carried out by staff or outside personnel (CRO).

- Post-authorisation studies: Clinical or epidemiological study conducted during the marketing of a drug under the conditions authorized in its summary of product characteristics, or under normal conditions of use, in which the drug or drugs of interest are the exposure factor investigated. Such studies may take the form of a clinical trial or an observational study.

In each of the three cases, both VTs funded directly from the Spanish subsidiary as well as those made from outside Spain by research and development departments to Spanish researchers or organizations will be included.

4.- SCOPE OF EFPIA DISCLOSURE

4.1.- Origin of VTs

Information published by Servier in Spain is provided on behalf of the Servier Group.

Servier is a group of companies with subsidiaries in different countries. The group has implemented a comprehensive procedure to ensure that the publication in a country includes all VTs carried out by Servier Group companies, both in the country of publication and in other countries, for one year (from January 1 to December 31).

4.2.- Area of application

Servier will publish VTs made to the HCPs and HCOs in donations, grants, training activities and meetings of scientific professionals, provision of services and research and development related to the previous year.

Excluded from this obligation are VTs (i) related to activities not detailed in Annex 2of the2016 Code of Good Practice of the pharmaceutical industry, such as: delivery of materials regulated in Article 10 Guarantees of Independence, delivery of samples regulated in Article 13, hospitality associated with meals or lunches regulated in Article 11 Scientific and Professional Meetings; (ii) that comprise part of the business operations between manufacturers and distributors, pharmacies and healthcare organizations and (iii) related to products or drugs that are non-prescription medications.

4.3.- Date of VTs

The date of value transfers will be stated based on the actual date of the event, regardless of the date of financial payment.

4.4.- Direct/Indirect VTs

Servier will publish both direct and indirect VTs to or for the benefit of recipients

- Direct: Whenever the company directly provides the benefit to a Recipient
- Indirect: When it is a third party (suppliers, agents, partners or affiliates -- including foundations -- acting on behalf of the company, who provides the service to the benefit of a recipient and the company identifies or can identify the recipient.

In any case, even if the payment is made through a third party, all VTs made by Servier will be published in the name of the end user.

4.5.- Cancellation of a planned VT

In case of cancellation of a refundable VT in full, the action is removed from the computer system, with no record of it remaining.

However, if the cancelled action has an associated cancellation fee it will be entered into the computer system and therefore the name of the healthcare professional or organization that is behind it will appear, depending on the nature of the VT.

4.6.- Cross border VTs

To ensure that the publication includes all VTs made by companies in the Servier group, established either locally (in the country of publication) and in other countries, the company has launched a global procedure.

Laboratorios Servier has created an international platform where payments are grouped for each country regardless of the country of the payer.

Servier Spain identifies these professionals with the internal code and prepares the joint statement for both local transfers and those paid from other countries to Spanish professionals.

Thus, all VTs made outside the country in which recipients conduct their professional activity or have their registered office are captured on the platform for dissemination in the country in which recipients have a physical address or, as the case may be, in the place of their clinical practice.

5.- VT COMMUNICATION MANAGEMENT

According to the Report issued by the Spanish Agency for Data Protection (AEPD), of April 22, 2016 (i), in which the Agency recognizes the legitimate interest in transparency; the express consent of the HCP for the publication of the payments or VTs made individually is not required, in accordance with article 6.1.f) of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016.

However, in order to comply with the general principles set forth in Articles 5 and 13 of Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 and the indications established in the previous Report, Servier, must meet in the treatment of data a series of requirements for information to the HCP, among which are: i) the duty to inform the HCP whose data will be published of the adequacy and pertinence thereof; ii) the purpose of collecting the data; iii) term of conservation of the data or the criterion to establish such term; iv) accuracy of the data and the possibility of exercising the rights of access, rectification, deletion, limitation of data treatment and oppositions to the portability of the data by the affected professionals.

So, prior to any action involving a VT to HCP, Servier delivers to these professionals an informative document they have to fill in and sign, which specifies that all those VTs derived from their relations with the company, will be published both individually and accumulated by category.
However, a detailed breakdown of them is available, upon request, for the Recipient and / or the competent authorities.

In case of refusal to complete the document, the offer of value transfer will be withdrawn.

The document does not have an expiration date.

HCO publication information

As in the case of VTs with HCPs, all VTs with HCOs will be published individually.

In all contracts signed with a HCO, a clause is included which reports that in order to comply with the transparency obligations imposed by pharmaceutical industry associations, Servier is collecting and processing information on the amounts related to VTs to a particular HCO or for its benefit resulting from their cooperation in scientific and professional meetings or provision of services (including fees and expenses related to lodging and transportation).

This disclosure shall consist of the publication of this information on an Internet website run by Servier.

6.- INCORPORATION OF DATA IN THE COMPUTER APPLICATION

Once the transfer of value is accepted by the HCP and the informational document has been completed and signed in the CRM software application, an identification event of the transfer of value is created, including the data reflected in that document.

The HCP is identified in the CRM application by a single individual code (not duplicable) throughout their stay in that application.

The scanned document is attached in the cited computer record and the original is forwarded to the relevant department for record-keeping purposes and custody under lock and key.

At the moment of creation of the event HCP allocation of the total amount of the agreed transfer is carried out, and if it is to be shared with other HCPs, the full amount of their participation is assigned individually.

For healthcare organizations the procedure is the same as for the HCPs. After signing a preliminary contract for the service, the allocation of transfer value is assigned to the organization in the CRM application according to the value of the service.

Unique identifier

For both domestic value transfers and cross border transfers to other countries Servier Spain will use a unique identifier code corresponding to the OneKey code of the HCP.

7.- PERSONAL DATA PROTECTION

The Company has signed the FARMAINDUSTRIA code of conduct under which it is required to document and publish payments and transfers of value made for the benefit of professionals or healthcare organizations, as well as to meet the strict regime for data protection established in the code of conduct.

Thus, Servier informs HCPs of the inclusion of their personal data in the corresponding records that are under the responsibility of the company, in order to meet the obligations for the control and publication of transfers of value that the company makes to healthcare professionals and organizations.

It also informs about the rest of the provisions of the applicable regulation, such as the fact that their data will not be transferred to other entities or other countries unless there is a legal obligation and/or requirement by the competent authorities, as well as about the rights of the interested parties, indicating, in order to ensure expeditious exercise of the rights recognized by the legislation, the possibility of exercising said rights through the following email address: mail.protecciondedatos@servier.com or by contacting directly the Data Protection Officer at dpd@servier.com.

8.- FINANCIAL ASPECTS

Currency

The currency used for publication of VTs is the Euro.

VAT

For VTs made to HCOs and the details of honoraria directed to HCPs, they will be published according to the taxable amount and excluding taxes (VAT and/or personal income tax).

By contrast, VTs that represent registration costs for a HCP will be published for the full amount (VAT included).

Exchange rate

Transactions in foreign currency are converted to Euros according to the average exchange rate applicable on the date on which the VT takes place.

9.- PUBLICATION and ARCHIVING

Data access location

Data will be available on the website of the Company by June 30, 2018 for transfer of values done in 2017for a minimum period of 3 years.

It can be accessed through the following website: www.servier.es

Language

The data will be published in Spanish.

The methodological note will be available in both Spanish and English.

Place and time of archiving documents

Servier will store all the documentation justifying and documenting the published VTs.

Archiving of the documentation will take place within the departments involved in the process depending on the nature of the document. They will be kept for a minimum period of five years following the completion of each applicable period.

10.- CONSULTATIONS AND ERROR CORRECTION

First the type of query received will be evaluated, assessing its origin:

10.1.- The query comes from a HCP

10.2.- The query comes from a HCO

10.1.- The query comes from a HCP

The consultation could in turn originate for different reasons:

- Access: Query of published data
- Correction: Modification of contact details or incorrect data
- Limitation of the treatment: due to inaccuracy of the data, if the interested party still needs his/her data to be available, if the interested party is opposed to the treatment
- Suppression: provided that the requirements are met

- Opposition: Disagreement with published data
- Portability of the data: receive the data the HCP has provided and concern him/her

According to the principles of data privacy, Servier must correct information (contact information or financial data) as requested by an HCP through a legitimate and specific request. In this sense, there is no time limit for the HCP to exercise their rights of correction, since it refers to inaccurate or incomplete data and must be modified so that they are correct.

Processing the query will follow the circuit described below:

- The HCP must send a formal written request to the following e-mail: mail.protecciondedatos@servier.com
- This request will be received and centralized by the contact person (CP) assigned by Servier: Director of Institutional Relations and in his/her absence the Project Manager.
- The CP must assess the validity of consultation and request additional details to HCP issuing the claim, if deemed necessary, to verify and confirm their identity.
- The CP will then proceed to carry out the necessary adaptations, both the computer system and internet website.
- A letter will be sent to HCP confirming acceptance of the inquiry/complaint or, if it is rejected, the reasons for that decision.

Time frames:

Data access and information correction are regulated by Regulation (EU) 2016/679 of the European Parliament and Council of 27 April 2016 and binding state regulations. In the case of exercising the right recognized by the regulation (access, rectification, suppression, limitation, portability and opposition) according to Article 12 of the General Data Protection Regulation (RGPD, its acronym in Spanish), the request shall be resolved within a maximum period of one month from receipt thereof. This period may be extended for another two months if necessary, considering the complexity and the number of applications. The responsible party will inform the interested party of any such extension within one month of receiving the request, indicating the reasons for the delay.

When the interested party submits the application by electronic means, the information will be provided by electronic means whenever possible, unless the interested party requests that it be provided otherwise.

10.2.- A claim from a HCO

The processing of the claim will follow the following circuit:

- The HCO must send the claim in writing, signed by the legal representative of the organization, to the following e-mail: mail.protecciondedatos@servier.com.
- The claim will be received and centralized by the CP
- The CP must assess the validity of query and request additional details from the HCO issuing the claim, if deemed necessary, to verify and confirm its identity.
- Subsequently, the CP shall perform the necessary adaptations, both in the computer system and on the internet website.

Time frames:

Modification or adaptation shall take place within one month.

How to update information published in pdf

Servier shall identify by a date and a version number the PDF document published on the Servier website.

In case of any issue where Servier is obliged to issue a new document, it shall identify it with a new number correlative with the previous version and with the date updated to the date of issue.

The frequency of updates shall be done according to the terms set forth in this section.