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 remunerate 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 2016 will be published according to the structure of Annex 2 of the 2014 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

In this section, we differentiate two subcategories in compliance with applicable legislation on the protection of personal data (Law 15/1999, of December 13, Protection of Personal Data which requires the express consent of HCPs to publish payments or VTs made on an individual basis.

3.1.1.- Individual publication: in cases where the HCP gives express consent for publication individually

In this first section, each HCP is 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.

3.1.2.- Aggregate publication: in cases where the HCP does not provide express consent for publication individually

In these cases, the HCP is not identified in the template with any of the above fields.

Servier will publish, for all HCPs who have not authorized the publication consent individually, the annual amount added by categories for the year; the number of HCPs whose data are published in aggregate form and the percentage they represent of the total HCPs who have received VT.

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 HEALTHCARE ORGANIZATIONS

Value transfers made by Servier to HCOs will be published individually in Spain since the legislation on protection of personal data applies only to individuals.

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 in order 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 in order 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, in the course of 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 2 of the 2016 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 stated will be 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

In order 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.- INFORMED CONSENT MANAGEMENT

Application procedure for express consent

At the time of the proposed transfer of value to the HCP, he or she is given an express consent document for completion, selection of reporting system and signature. Refusal to complete this document will result in the value transfer being withdrawn.

The HCP is informed that the maximum duration of the consent given in the express document is two years, with expiration in all cases being 31.12.2016.

HCO publication information

In the case of HCOs, all VTs will be published individually in Spain since the legislation on protection of personal data applies only to individuals.

However, 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 HCP has completed and signed the express consent document in the CRM software application, an identification event of the transfer of value is created, including the data reflected in that document (name of the HCP, main address of professional activity, type of consent (individual or aggregate) and date of consent).

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 for its entire effective period.

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, following the model proposed by that code, to obtain the consent it informs those affected of the various ends that affect the processing of data relating to transfers of value, allowing the affected parties to choose whether to allow individual or aggregate disclosure of their data, specifying that at any time the person can withdraw consent for individual publication of data.

It is likewise indicated that those affected may request, at any time, access to personal information that the Company has on then, and ask that this information be updated or corrected, if necessary. To ensure expeditious exercise of the rights recognized by the legislation a contact email is provided for those affected: mail.protecciondedatos@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, 2016 for transfer of values done in 2015 and by June 30, 2017 for those corresponding to 2016 for 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. This documentation includes but is not limited to: Express consent for the individual/aggregate publication of data, contracts, invoices, etc.

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 whose name is published on the Servier website

10.2.- The query comes from a HCO

10.1.- The query comes from a HCP whose name is published

The consultation could in turn originate for different reasons:

- Access: Query of published data
- Correction: Modification of contact details or incorrect data
- Cancellation: Change or withdrawal of consent
- Opposition: Disagreement with published data

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. For withdrawal of consent, the decision rests with the HCP in its entirety.

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 (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, in order to verify and confirm their identity.

(c) If the claim is a cancellation: "change of consent" or "withdrawal of consent"

Note: Each HCP is free to withdraw his or her consent and the Company cannot oppose this request.

- A letter will be sent to the HCP in order to inform him or her that the request has been received and is being processed.
- The change or withdrawal of consent will be reflected in the computer system
- The information will be updated on the website as follows:
  - Adding or removing the name of the HCP within the category of publication by name
  - Transferring the VT associated with that HCP to the aggregate category.

(a), (b) and (d) If the claim is "changing contact details", "Querying published data" or "disagreement with published data"

- The CP must determine the strength of the claim, carrying out the actions he/she deems necessary for the verification of information.
- 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:

Withdrawal of consent, data access and information correction are regulated by laws on Data Protection.

In the case of exercising the right of access, according to Article 29 of the Data Protection Regulations, the request for access shall be resolved within a maximum period of one month from receipt of the request.

In relation to other rights (correction, cancellation and opposition) in accordance with the Data Protection Regulations, the application must be resolved within a maximum period of ten working days from receipt of the request.

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 PC
- The CP must assess the validity of query and request additional details from the HCO issuing the claim, if deemed necessary, in order 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.