

# Methodological note of the Transfers of Value to Healthcare Professionals and Healthcare Organizations reporting - Merck Spain –

An affiliate of Merck KGaA, Darmstadt, Germany

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## 1. Introduction

This document summarizes the methodologies used when preparing the company's transparency disclosure in accordance with the EFPIA Transparency Code and the Code of Good Practices of the Pharmaceutical Industry in Spain ([www.codigofarmaindustria.org](http://www.codigofarmaindustria.org)), identifying transfers of value, made directly or indirectly to or for the benefit of a recipient.

Collaboration between pharmaceutical laboratories and healthcare professionals is necessary, since drugs are products of great scientific and technical complexity in their manufacture and administration. Healthcare professionals are involved as researchers, contributing their experience and knowledge in the drug development process, and laboratories promote training activities for healthcare professionals who are continually updating in relation to these treatments. This collaboration is widely regulated for both parties, ensuring that each patient receives the best possible treatment according to their needs.

## 2. Definitions

### Recipient

Any Healthcare Professional or Healthcare Organisation as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Spain..

### Healthcare Organization (HCO)

Any legal person or entity (i) that is a medical or scientific association, health institution (whatever its legal form or organization) such as hospitals, clinics, foundations, universities and other academic entities, scientific societies (excluding patient organizations), or (ii) through which one or more healthcare professionals provide services.

### Professional healthcare (HCP)

Any member of the medical, dental, pharmaceutical, nursing, or pediatry profession, any other person legally considered as such, or any other person who, in the exercise of their profession, could carry out or condition the activities of prescribing, buying, supplying, dispense or administer drugs for human use.

For the purpose of this Code veterinarian professionals are excluded from this concept.

### Transfer of value

Any direct or indirect payment or consideration in cash, in kind, or in any other way, regardless of its purpose. It will be direct when it is the laboratory who directly conducts the performance for the benefit of a recipient. It will be indirect when it is a third party (suppliers, agents, partners or affiliates, including –nes foundations), acting on behalf of the company, who performs it for the benefit of a recipient and the company identifies or can identify the recipient.

Excluded from this concept are transfers of value that are part of commercial operations between and distributors, pharmacies and health organizations.

## **Investigation and development**

Activities associated with the design or execution of (i) preclinical studies (defined by the OCDE in “Principles of Good Laboratory Practice), (ii) clinical trials (defined in Regulation (EU) No. 536/2014 of the European Parliament and of the Council, in Royal Decree 1090/2015 and contemplated in article 14.1 of the Code) and (iii) post-authorization studies (contemplated in article 14.2 of the Code).

### **3. Scope of application of transparency**

#### **Products to which it applies**

Prescription drugs.

#### **Excluded value transfers**

- A. Exclusively related to medicines not subject to medical prescription;
- B. Delivery of materials and objects of an informative or educational nature;
- C. Meals;
- D. Samples;
- E. Commissions of the logistics agencies that assist in the organization of trips and meetings;
- F. Discounts, price reductions and other commercial operations normally used in the sale of medicines;
- G. Sanitary packages offered by private entities and purchased by signatories for their employees;
- H. Related to anonymous market research studies

#### **Date Transfer of Value**

- A. The date of the transfer of value is the date of the invoice paid.
- B. In the case of sponsorships to healthcare professionals to attend scientific-training meetings organized by Merck or a third party, the date of the transfer of value will be the starting date of the meeting or training activity.

#### **Direct Transfer of Value**

- A. Transfers of value are reflected according to the amount disbursed by Merck and not the benefit to the recipient.
- B. Non-monetary value transfers are transparent based on the monetary value of the good or service.

#### **Indirect Transfer of Value**

- A. Transfers of value to a healthcare organization through a third party, for example, through the technical secretary of a medical congress, are made transparent with the healthcare organization as the recipient.
- B. Transfers of value to individual healthcare professionals made through a third party are made transparent with the healthcare professional as the recipient.

### **Transfer of value in case of partial assistance or cancellation**

A. In the case of partial assistance or cancellation, or services not performed, but in which the value was also transferred, for example, in compliance with a clause of the contract, the transferred value is transparent.

B. If no value was transferred, the value transfer information is not part of the publication.

C. The transfers of value made “not recovered” are not imputed or published individually, on behalf of healthcare professionals or healthcare organizations, which, due to external circumstances not attributable to their recipients (for example: cancellation motivated by health crisis) , cannot be used.

### **Cross-border activities**

A. Cross-border value transfers to healthcare professionals or organizations, within the scope of the Transparency Code, are transparent according to the country of practice (healthcare professional) or country of registration (healthcare organization) of the recipient.

B. If a healthcare professional or healthcare organization has a practice / registry in several countries, the country in which the recipient mainly develops their practice will make the transfers of value transparent.

## **4. Publication of value transfers that occurred in 2017 and later**

### **Individualized publication of value transfers**

On May 27, 2016, amendments to the Code of Good Practices of the Pharmaceutical Industry of Farmaindustria entered into force, the purpose of which is to individually publish the transfers of value to healthcare professionals made as of January 1, 2017. The Spanish Data Protection Agency (AEPD) recognizes the legitimate interest of the laboratories for reasons of transparency and, therefore, it will not be necessary to obtain the consent of the interested parties to publish the individual data; according to its report dated April 22, 2016 (which is available on the AEPD website). For all the above, the publication of transfers of value arising in 2017 and later will be carried out individually provided that the measures required by the Code are ensured, which includes prior information to healthcare professionals that their data will be published in accordance with the provisions of the Code before carrying out any transfer of value that may be disclosed.

### **Aggregated publication of transfers of value**

Regarding the right of Opposition, as established by the Code and in accordance with the provisions of the Spanish data protection Agency (AEPD) in its Report of April 22 (Annex I of the Code), if a Healthcare Professional, through this right, justifies that there are well-founded reasons and related to their specific personal situation that determined that the weighting rule was reversed and the legitimate interest of transparency that protects said publication did not prevail, Merck could exclude the data of that Healthcare Professional, exceptionally publishing the same in aggregate.

In the event that Merck receives a communication from a healthcare professional exercising his right to object, the laboratory will assess the possibility of suspending the publication of the value transfers made in favor of this professional while the well-founded and legitimate reasons relating to it are analyzed. your specific personal situation alleged by the healthcare professional. After carrying out this analysis and giving a response to the professional, the data of the healthcare

professional would be republished, individually or in an aggregate form in case of concluding that there are well-founded and legitimate reasons.

### **Compliance with applicable regulations on the protection of personal data**

Merck undertakes to strictly comply with the applicable regulations regarding the protection of personal data. The interested parties who are natural persons, health professionals, may at any time exercise their rights of access, rectification, deletion, restriction and opposition to the treatment and the right to portability of their data, by means of a written request addressed to the data protection officer in [Comite.lpd@merckgroup.com](mailto:Comite.lpd@merckgroup.com).

Additionally, the healthcare professional may exercise their right to submit any query to the competent data protection authorities, as indicated in the contracts and agreements that Merck signs with each healthcare professional.

## **5. Specific considerations**

### **Unique local identification by country**

As required by the EFPIA and Farmaindustria Codes of Good Practice, the mandatory data for identifying a recipient are:

- Full name,
- City of professional practice for healthcare professionals and city of registered office for healthcare organizations,
- Unambiguous local identifier by country, this being the partially hidden ID for healthcare professionals and the partially hidden VAT number for healthcare organizations.

### **Multi-year contracts and value transfers in different calendar years**

In the case of multi-year contracts or other contracts according to which the value transfers have been made in different calendar years, the information included in the report corresponds to those that were made effective to the recipient in a given calendar year / reporting period.

### **Updating of the transfer of value report already published.**

Transfers of value detected after the publication of the transparency report but referring to the period of said report, will be consolidated and published in the fourth quarter of each year.

## **6. Categories of value transfers**

### **Donations**

A donation (monetary subsidy or advantage in kind) consists of an act of liberality by which a company (donor) disposes of a pecuniary amount or a good or service (donation in kind) in favor of a third party (donee), free of charge, who accepts it. In any case, the donor will not obtain or request to obtain any consideration from the donee.

Merck carries out two types transfers of value within this category: donations for the benefit of patients and grants to healthcare organizations for training activities and independent scientific-professional meetings.

### **Educational activities and scientific-professional meetings**



The scientific-professional training activities and meetings consist of any scientific-professional, medical or promotional meeting, consisting of a congress, conference, symposium, seminar, course or similar organized by a health organization or by the laboratory.

#### Collaborations / sponsorships with healthcare organizations / third parties designated by healthcare organizations for event management

Merck sponsorships consisting of the provision of financial or other support, in the form of money, services, goods or other objects of value for a health-related event or activity for commercial, medical or scientific purposes, whether in whole or in part. , related to the Merck business for which Merck expects to receive a material benefit in exchange for your support (for example, a medical or scientific conference, a health-related community activity, such as fundraising for a particular illness or a community health fair). There are sponsorships that are not directly related to training activities and scientific-professional meetings, such as the sponsorship of the website of a health organization or a mobile application for health purposes, which are also included in this category.

#### Registration fees

Merck pays registration fees for healthcare professionals and healthcare organizations that request support for their training by attending scientific-professional meetings. This support is based on objective criteria directly related to the purpose of the training activity, such as its reputation and recognition by the scientific community, knowledge and experience in the therapeutic area or subject of the scientific program, the potential to increase its knowledge or the possible positive impact on the quality of patient care.

In the case of free registrations offered by the Health Organization within the sponsorship offers of the official commercial dossier and common to all the sponsoring laboratories of a scientific-professional meeting, Merck makes transparent to the Health Organization the value of the sponsorship by subtracting the value of the registrations published to each Healthcare Professional who receives this support, according to the criteria described above, the registration fee is made transparent according to its market value.

If the amount of these inscriptions to be published to the Health Professionals is greater than the amount of the sponsorship to be published to the Health Organization, 10% will be published to the OS and 90% of the amount to be divided among the Health Professionals. Ex: sponsorship of €50,000 with 150 virtual connections for a market value of €500, €5,000 of sponsorship will be published to OS and €300 of registration to each healthcare professional.

#### Travel and accommodation

In relation to the activities of third parties in the previous section and meetings organized by the laboratory, accommodation and / or travel expenses may be covered. Merck only offers hospitality within the framework of a scientific-professional meeting in a reasonable, moderate and time-sensitive manner. Expenses for companions or other guests other than the health professional, or leisure or entertainment, are not financed, nor is compensation offered to health professionals for attending such training activities.

#### **Provision of services**

Merck hires qualified healthcare professionals and healthcare organizations to provide services to the company so that Merck can promote the improvement of clinical practice and patient care and care. Merck hires healthcare professionals and / or healthcare organizations as consultants, speakers, or other service providers only when a legitimate need has been identified in advance.



The cash prizes awarded to Healthcare Professionals by a committee of experts in accordance with public bases in recognition of the contribution of scientific-medical projects will be published under the heading of "fees".

### Fees

The fees are according to market value, according to the nature of the services, role / responsibility assumed, professional category and time required. The selection of the professional is based on objective criteria directly related to the purpose of the hiring.

### Related expenses contractually agreed for the provision of these services, including transfers and accommodation

Merck only offers hospitality and other expenses associated with the provision of services (such as the printing of materials necessary for the performance of the service) in a reasonable, moderate and adjusted to the duration of the activity. The same criteria apply as in the case of sponsorships to attend training activities and scientific-professional meetings.

### **Investigation and development**

The research and development amount includes activities related to the design or execution of preclinical studies, clinical trials and post-authorization studies. This amount includes both transfers of value for global studies - mostly carried out by Merck Germany, as well as those related to local studies covered by the Spanish entity. In the case of studies in which the nationality of the healthcare organizations receiving the amounts cannot be determined, the publication will be made in the R&D section of the publication of the group's parent company (Merck Germany). It also includes research grants awarded to health organizations to carry out research projects, the decision of which is made publicly. Finally, transfers of value to clinical research organizations (CROs) are excluded from the calculation.

## **7. Disclosure mode**

### **Disclosure date**

The publication will be made in the six months following the end of the reporting period, which in Spain corresponds to the calendar year. The exact date of publication varies between EFPIA countries and depends on legal stipulations.

### **Update of the transfer of value report already published.**

Any transfers of value detected after the publication of the transparency report, but referring to the period of said report, will be consolidated and published in the fourth quarter of each year.

### **Disclosure platform**

The transparency reports will be published on the website of Merck Spain ([www.merckgroup.com/es-es](http://www.merckgroup.com/es-es)) and of the group ([www.merckgroup.com/en/sustainability](http://www.merckgroup.com/en/sustainability)).

### **Disclosure language**

The reports will be published in English and Spanish, using a bilingual transparency template.



## **8. Transparency of financial data and calculation rules**

### **Currency**

- A. The total value of the value transfers is published in the local currency, Euro, after its conversion from foreign currencies according to the exchange rate applicable on the day on which the documentation of the actual payments is made in the electronic system.
- B. The reference point for the conversion is the Euro.
- C. The basis for calculating the exchange rate is the internal currency exchange table of the company, which is updated monthly.

### **VAT included or excluded**

Transfers of value are published with VAT included and, where appropriate, prior to the withholding of personal income tax.

### **Calculation rules**

- A. The transfers of value made in the reporting period are added according to the segmentation of the requirements of the Farmaindustria transparency template.
- B. Only the amounts of payments made within the particular calendar year (reporting period) are taken into consideration for the calculation (see also the note on the date of value transfers and value transfers in different calendar years).
- C. The calculation is carried out with amounts of currency (see also currency note) harmonized (the same).
- D. Transfers of value are published without decimals, rounding the amount to be transparent.

## **9. Legal note**

The document with the information related to Merck's transparency collects, except for errors or omissions, the data that Merck is aware of in relation to this object, having made its best efforts in its preparation in order to ensure the accuracy and completeness of the information. the information collected.

Likewise, the publication of the information does not give rise to a general authorization so that those who access the website can carry out an additional treatment of the data of health professionals, such as their crossing with the information published on the websites of others. associated with EFPIA and / or Farmaindustria.