

1. Introduction and Approach for Presenting 2018 Data Reports:

The European pharmaceutical industry, and consequently that of Spain, introduced a Code of Good Practices in 2002 that regulates its relations with healthcare professionals and organizations to make them more rigorous, objective and independent, which, in turn, prevents unfair competition among companies.

This commitment to good practices, perfected over the years, has been reinforced with the transparency initiative.

Shire, as a company associated with Farmaindustria [the association of the pharmaceutical industry in Spain], and as a member of EFPIA [European Federation of Pharmaceutical Industries and Associations] is determined to pursue transparency and is committed to ensuring that the **Transfers of Value (ToV)** made to **Healthcare Professionals (HP)** and **Healthcare Organizations (HO)** are clear and transparent to the public. Therefore, Shire has made public the ToVs made directly or indirectly to healthcare professionals and healthcare organizations during 2018.

On June 3, 2016, Shire acquired Baxalta. According to the definition of member companies in the EFPIA HCP Code, Shire decided to announce its status as an entity as of the 2017 disclosure period, unless local law requires otherwise.

Due to the complexity of integrating the two companies, Shire wishes to highlight the key differences that still remain in the methodology of these two companies.

As of September 1, 2018, Shire ceded its oncology business to Servier. Any transfer of value as of September 1, 2018 will be reported by Servier. Any transfer of value that occurred prior to September 1, 2018, even if it involved activities subsequent to September 1, 2018, will be reported by Shire.

Shire will disclose the data using consistent methodology whenever possible for the data collected in 2018 and published in 2019.

This Methodological Note explains how Shire, in its commitment to transparency, records and publishes this information in accordance with the current edition of the Code of Good Practices for the Pharmaceutical Industry.

2. Scope of the Disclosure

The following countries, members of EFPIA, are within the scope of the disclosure:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine and United Kingdom.

In accordance with EFPIA, there is a complete or partial exception to the Transparency Code for the following countries:

- Denmark
- France
- Netherlands
- Portugal
- Slovakia
- Turkey

Shire will disclose data based on the local country's Code template. If the local country does not provide a template, Shire will use EFPIA's Transparency Code template by default.

3. Definitions:

1. Beneficiaries:

1.1. Definition of Healthcare Professional (HP):

Any member of the medical, dental, pharmaceutical profession, or from nursing, or podiatry, or any other person legally considered as such, or any other person who, in the exercise of their profession, may perform or influence the activities of prescribing, buying, supplying, dispensing or administering medicines for human use.

1.2. Healthcare Organization (HO):

Any legal entity or artificial person that is a medical or scientific association, health institution (irrespective of its legal form or organization), such as hospitals, clinics, foundations, universities and other academic institutions, scientific societies (excluding Patient Organizations), or through which one or more Healthcare Professionals provide services.

2. Types of Transfers of Value Included According to the EFPIA

2.1. Donations:

Financial contributions that are exceptional in nature that Shire provides to non-profit entities and those stated to be in the public interest, and which will always be earmarked for a specific and duly justified purpose. These are not considered a marketing tool but come under Corporate Social Responsibility; they have a specific budget outside of Marketing and are approved in Europe.

2.2. Sponsorships:

Direct or indirect financial contributions (which include, but are not limited to, travel or hospitality expenses) intended to sponsor activities, initiatives or projects that meet the following conditions:

- The mention of Shire's collaboration appears associated with an activity, for example, participation by showing a logo
- They offer Shire the opportunity to strengthen its reputation

The ToVs are made to the HO directly or to the event organizer or third party designated by the HO to manage the event. In these cases, the ToVs are documented, indicating the HO that receives the benefit.

When the contribution made to the HO is meant to cover travel, accommodation, or registration expenses of the HPs who attend scientific conferences and when the identity of the HPs who are the beneficiaries of the ToVs is unknown, this payment is assigned to the "Sponsorships" category.

2.3. Research and Development (to be published in the consolidation section of the transparency template):

Transfers of value in Research and Development to healthcare professionals/healthcare organizations associated with:

- Good Laboratory Practices (GLP) for non-clinical laboratories
- Phase I to Phase IV clinical trials
- Studies sponsored by the investigator
- Non-interventional studies

2.4. Registration Fees:

As part of its continuing support for the training of healthcare professionals, Shire covers the registration fees of the HPs who attend scientific conferences. The payments are given directly to the organizers of the event or to the service providers.

2.5. **Travel and Accommodation:**

As part of its continuing support for the training of healthcare professionals, Shire covers, the travel and accommodation expenses for HPs who attend scientific conferences. These expenses, which include plane and train tickets, taxis, buses and hotels, are paid directly to the event organizers or to the service providers.

2.6. **Service and consultancy fees, and related expenses agreed upon in the rate for the service provided or in the consultancy agreement:**

Shire authorizes hiring HPs and HOs for the provision of services provided there is a legitimate business need documented in writing (needs assessment form). These fees are based on a methodology that compensates the work done by the professional for Shire.

For example:

- Speaker fees
- Development of educational materials
- General Advice/Consulting

In addition to the corresponding fees, the presentation of services agreement may stipulate the payment of additional expenses that are related to and necessary for the proper provision of said services such as plane and train tickets, tolls, parking expenses, taxis, buses, hotels or fees for the issue of visas. The expenses are paid by Shire to the travel and/or accommodation service providers, to the meeting organizers (if applicable) or are reimbursed upon presentation of the corresponding receipts authorized by Shire.

3. **Transfers of Value Dates:** When the transfer of value is a payment, its amount is recorded on the date it is made, that is, on the date when the funds are transferred to the beneficiary's bank account.

Shire applied the date of the event to the remaining transfers of value such as transportation and accommodation, for example. For contracts with services that span multiple periods, Shire used the payment date as the date for the transfer of value.

4. **Transfers of Value**

4.1. **Direct Transfers of Value:**

The person or legal entity that holds the bank account to which the funds are transferred is considered the recipient of the Transfers of Value and will be the one appearing in the publication. Direct Transfers of Value are recorded in the DEZ system and are transferred to Shire's transparency reporting system. They are then assigned to one of the activity categories established by the EFPIA for creating reports.

4.2. Indirect Transfers of Value

- **Indirect Transfers of Value through third parties for R&D activities:**

When third parties manage R&D activities on behalf of Shire, making Transfers of Value to HPs and/or HOs, these Transfers of Value are regulated by the EFPIA Code and are published as aggregate data under the R&D category.

- **Indirect Transfers of Value through third parties:**

When an HO entrusts the management of an event to third parties and it is this HO that ultimately receives the Transfer of Value, the latter appears as the recipient of the benefit. When an event is organized on behalf of several HOs, without specifying which Transfers of Value correspond to each of them, the amount is divided up proportionally.

When Shire instructs third parties to organize travel and accommodation services for the HPs who provide services or attend events, these Transfers of Value are assigned to the HPs.

This does not include administration fees invoiced by the agencies, since neither the HPs or the HOs benefit from them.

- **Indirect Transfers of Value through HOs:**

When a Transfer of Value is made to an individual HP indirectly through a HO, Shire will indicate the identity of the HP receiving the benefit, in accordance with Farmaindustria guidelines.

- **Cancellation of events, contracts or cancellation of the participation of a healthcare professional:**

Shire will only allocate contracted transfers of value that can be reasonably associated with the healthcare professional based on supporting documentation. In those circumstances where a flight or accommodation is reserved but the event is canceled or the healthcare professional does not attend, no transfer of value will be made to that healthcare professional.

- **Disclosure of cross-border transfers of value:**

Shire undertakes to document and publish all Transfers of Value made to HPs and HOs whose main activity occurs in countries regulated by the EFPIA Code and/or [to comply with] other reporting obligations for cross-border Transfers of Value. Shire will disclose the main business address where the healthcare professional works and where the healthcare organization operates in order to guarantee consistency among all EFPIA countries. This address may not match the address included in the contract, in our financial payment system or in other supporting documentation.

- **Excluded Transfers of Value:**

All transfers of value to Patient Organizations are beyond the scope of this methodological note and the report is created separately.

5. Key Decisions and Differences in Methodology

The decisions that govern our collection and reporting process for 2018 data are listed below.

5.1. Taxes and VAT:

For the fees associated with services and consulting, Shire will report the full amount of the invoice, which will include withholding tax (personal income tax). VAT is excluded for all other payments.

5.2. Currency of the Disclosure:

All payments and transfers of value will be disclosed in the local currency pursuant to EFPIA guidelines. If a payment is collected in another currency, it will be converted to the local country's currency, taking into account the date on which the ToV took place and the corresponding daily exchange rate.

5.3. Reconciliation of Data:

Each year, Shire will create a reconciliation for the entire year to identify any transaction sent after validating the data, or after publishing and updating the reports, in order to uphold the principles of full transparency.

5.4. Language of the Disclosure:

All disclosures will be made in English on our public website (shire.com) but will be made mainly in the languages established by national codes. In the case of Spain, the publication language will be Spanish.

5.5. Disclosure of Local Identifiers:

In order to uphold privacy principles, Shire will disclose "the unique country identifier" for healthcare professionals and/or healthcare organizations whose local code requires this information. In the publication, Shire will include the tax identification number or the company tax number in an anonymous manner.

6. Focus of the 2018 Data Presentation:

- 6.1. Shire will publish the transparency file on our website, Shire.com.
- 6.2. Shire will publish a link and/or the report on the local Shire website:
<https://www.shire.es/who-we-are/how-we-operate/transparency-disclosures>

7. Schedule for Publishing 2018 Data:

- 7.1. Shire will publish the data for the period prior to June 27, 2019.