European Federation of Pharmaceutical Industries and Associations (EFPIA) HCP/HCO Disclosure Transparency Requirements
Methodology Note for Shire

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1. Overview of the EFPIA Requirements

European Federation of Pharmaceutical Industries and Associations (EFPIA):

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

Transparency Rationale:

EFPIA believes that interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a healthcare professional to prescribe a medicine is one of the pillars of the healthcare system. EFPIA recognizes that interactions between the industry and healthcare professionals can create the potential for conflicts of interest. Consequently, professional and industry associations, including EFPIA and its member associations, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

In order to continue to be successful, self-regulation needs to respond to the evolving demands of society. In particular, there is a growing expectation that interactions between corporations and society are not only conducted with integrity but are also transparent. Following the EU Commission initiative on Ethics & Transparency in the pharmaceutical sector, a multi-stakeholders' platform – including, among others, EFPIA – has adopted a "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector".

In line with these Guiding Principles, EFPIA believes that it is critical to the future success of the pharmaceutical industry to respond to society's heightened expectations. EFPIA has therefore decided that its existing Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the "HCP Code") should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals and organisations. EFPIA hopes that, by taking this step, it can enable public scrutiny and understanding of these relationships and thus contribute to the confidence of stakeholders in the pharmaceutical industry.

Countries in Scope:

Countries with an EFPIA Member Association currently include the following 33 countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

Please note that certain countries have an exception to the Code.

2. Decisions

The purpose of this methodology note document is to provide guidance on Shire specific decisions that explain the disclosure data. This document highlights the decisions that drive our collection, aggregation and reporting process.

Topic Area	Decision Made By Shire
Tax & VAT	Shire determined that: • For services and Consultancy, VAT is excluded unless local Code or Law explicitly requires otherwise. • For costs related to Events (such as registration fees, travel and accommodation), VAT is included unless local Code or Law explicitly requires otherwise (Examples include: Turkey and Spain) • For countries where there is a withholding tax, Shire will report the full invoice amount.
Currency	All payments and transfers of value will be disclosed in local currency. If a payment is captured in another currency, it will be converted into local country currency based on the date at which the transfer of value occurred and corresponding daily exchange rate.
Transfer of Value Dates	Shire used the payment date for Fee For Service and related payments for activities within the reporting period and used event date for all other Transfers of Value.
Reconciliation of the Data	On an annual basis, Shire will complete a full year reconciliation to identify any transactions that were submitted post data validation or post publication and update the reports accordingly to support the principles of full transparency.
Events that are cancelled or HCP does not participate	Shire will attribute the transfers of value that are incurred and can be reasonably associated to the HCP. In the circumstances when a flight or accommodation is booked but the event is cancelled or HCP does not attend, no transfer of value will be attributed to that HCP.
Disclosure of Cross-Border Transfers of Value	Transfers of Value to a HCP / HCO whose practice, professional address or place of incorporation is in Europe, are required to be disclosed in the country where the recipient has its principal practice. Shire will rely on a trusted third party data provider to determine the principal practice address of the HCP and HCO to ensure disclosure is only made once.
Language	Disclosure shall be made in language prescribed in the national code

	and will be made available in English.
Local Identifiers	Shire will disclose the "Country Unique Identifier" for HCPs and/or HCOs where the local code had mandated the population of this data point. In the case of Spain the "Country Unique Identifier" will be encrypted.
Disclosure of Recipient for Indirect Payments (per consent requirements)	Shire will disclose the entity or the legal person to whom we transferred the value. However, in circumstances where Shire can identify the HCP through the contract, as the ultimate recipient or beneficiary of a payment to a HCO, we will disclose the name of the HCP, and not the HCO if consent to disclose at an individual level is obtained.
Charitable Contributions	Shire decided: • A donation or grant to a HCO will be disclosed as a Transfer of Value under the Donation/Grant section of the applicable Disclosure report. • Sponsorships of a HCO or HCP will be disclosed as a Transfer of Value, under the Costs related to Events section of the applicable Disclosure report. • If a payment was made to a HCO for the benefit of HCPs, o And the identity of the HCP was known, Shire will disclose only once, and on an individual basis against the relevant HCPs. o And the identity of the HCP was unknown, Shire will disclose the Transfer of Value against the HCO under Costs related to Events. • Shire will report the payment to the HCP, regardless if the HCP then donates that money to charity.
Payment made to Institution (as an unrestricted grant) and HCO uses it to send HCPs to an event	Shire decided: •If a payment was made to a HCO for the benefit of HCPs o And the identity of the HCP was known, Shire disclosed only once, and on an individual basis against the relevant HCPs. o And the identity of the HCP was unknown; Shire disclosed the Transfer of Value against the HCO under Costs related to Events.
Country in which to report Research Payments	Shire determined that the transfers of value would be disclosed wherever the recipient resides. So in the case of a CRO with multiple sites, the transfer of value will be disclosed in the country where the site is located.

3. Consent Management

Consent Management	Shire is collecting consent for each* engagement with all HCPs and HCOs based on local requirements: • If consent is given for all engagements, Shire will disclose transfers of value to the HCP under the individual section of the applicable Disclosure report • If Shire does not receive consent for all engagements, we will default all transfers of values to the aggregate section of the applicable Disclosure report. • If the consent form is not returned to Shire, we will default all transfers of value to the aggregate section of the applicable Disclosure report. *Please note that Belgium and Turkey are collecting consent at the profile level on an annual basis. Spain is collecting consent at the profile level on a permanent basis, unless expressly revoked. Revoking of individual consent: • If a HCP or HCO revokes consent prior to publication of the data, Shire will update the data and include the transfers of value in the aggregate section of the applicable Disclosure report. • If a HCP or HCO revokes consent after publication of the data, Shire will update the information at the first reasonable time. In the case of Spain and according to the provisions regarding consent revocation in Article 17 of Royal Decree 1720/2007, of December 13, by which approves the Regulations implementing the Organic Law 15/1999, of December 13, of personal data protection, the consent revocation has no retroactive effectiveness. So the information (both aggregate and individual) will be publicly available for a minimum period of 3 years since its publication, unless legally a shorter period is established or the consent revocation is legally binding on Shire.

4. Submission Requirements

Disclosure Method	Shire will publish the disclosure file on our Shire.com website for the following countries: Bulgaria, Croatia, Cyprus, Estonia, Finland, , Hungary, Italy, Latvia, Lithuania, Malta, Norway, Poland, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey,

	and Ukraine Shire will publish on the local Shire website or Association website/central registry for the following countries: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Germany, Greece, Ireland, Latvia, Lithuania, Netherlands, Norway, , Romania, Russia, Serbia, Sweden, Turkey, Ukraine, and the United Kingdom
Disclosure Period	Each reporting period shall cover a full calendar year unless local Association law sets a different period.
Timing of Disclosure	Between June 20th and 30th unless local Association law sets a specific date like the UK, Belgium and Estonia.
Public Disclosure Retention Period	Per the guidance from EFPIA, Shire will ensure that the information disclosed shall be required to remain in the public domain for a minimum of 3 years or longer after such information is disclosed in accordance with the disclosure method unless, in each case: • A shorter or longer period is required under applicable national data privacy or other laws or regulations; or • The recipient's consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked. *(Section 2.02)*
Documentation & Records Retention	Per the guidance from EFPIA, Shire will ensure that all the transfers of value required to be disclosed must be documented and retained for a minimum of 5 years or longer after the end of the relevant reporting period, unless a shorter or longer period is required under applicable national data privacy or other laws or regulations. (Section 2.07)

5. Categories for Disclosure:

Description	Types of Transfer of Value Included
Donations and Grants to HCO's	Donations and Grants to HCO's that support healthcare including donations, grants and benefits in kind to institutions, organizations or associations that are comprised of HCP's and/or that provide healthcare.
Research & Development	Research and Development transfer of values to HCPs/HCOs associated with: • Non-clinical (Good Laboratory Practice (GLP)

	• Clinical trials in Phase I to Phase IV • Investigator sponsored studies • Non-interventional studies
Contribution to costs of Events (as per HCP Code): 1. Sponsorship agreements	Events include all scientific professional meetings, congresses, conferences, symposia and other similar events. Sponsorships with HCOs/third party appointed by an HCO to manage an Event. <u>Examples:</u> • Rent of booths at an event • Advertisement space • Satellite symposia at a Congress • Sponsoring of speakers/faculty • Courses provided by an HCO (where the Member Company does not select the individual HCPs participating)
Contribution to cost of Events: 1. Registration Fees	Registrations fees related to attending a Congress or Symposia.
Contribution to costs of Events: 2. Travel & Accommodation	• Travel in relation to attending a Congress or Symposia. • Accommodation in relation to attending a Congress or Symposia. <u>Includes:</u> • Fees for airfare, train, boat or ferry (incl. booking fees) • Car rental, car services, taxi transfers • Parking fees • Petrol • Tolls
Fee for service and consultancy: 1. Fees	Transfers of value resulting from or related to contracts between Member Companies and institutions, organisations, associations or HCPs under which such institutions, organisation, association or HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. <u>Examples:</u> • Speaker fees • Speaker training • Data analysis • Development of education materials • General Consulting/Advising
Fee for service and consultancy:	Related expenses agreed in the fee for service or consultancy contract:

2. Related expenses agreed in the fee for service or consultancy contract	Includes: • Fees for airfare, train, boat or ferry • Car rental, car services, taxi transfers • Parking fees • Petrol • Tolls

6. Definitions

HCO

Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services. Per guidance from Associations in some countries, if the personal name of the HCP is contained in the name of the legal entity, then the HCO will be considered a HCP for consent and disclosure purposes.

HCP

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 Europe. 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 practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

Donations and Grants

Collectively, means those donations and grants (either cash or benefits in kind) within the scope of Article 11 of the HCP Code.

Events

All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "**Event**") organised or sponsored by or on behalf of a company. (*Article 9 of the HCP Code*).

HCP Code

EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, adopted by the EFPIA Board on 5 July 2007 and ratified by the EFPIA Statutory General Assembly on 19 June 2008, amended on 14 June 2011, and as further amended on 24 June 2013, and as may be amended, supplemented or modified from time to time.

Medicinal Products

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. (*Article 1 of Council Directive 2001/83/EC, as amended*)

Member Associations

Collectively, the national member associations or their constituent members, as the context may require, that are members of EFPIA and bound by the EFPIA codes of practice.

Member Companies

Collectively, "corporate members" (as defined in the HCP Code) of EFPIA, their respective parent companies, if different, subsidiary companies (irrespective of whether a subsidiary is a company or such other form of enterprise or organisation) and any companies affiliated with corporate members or their subsidiaries if such affiliated companies have agreed to be bound by this Code.

Recipient

Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

Research and Development Transfers of Value

Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in *OECD Principles on Good Laboratory Practice*); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) 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 (*Section 15.02 of the HCP Code*).

1. Non-clinical studies as defined in the OECD Principles on Good Laboratory Practice

   The OECD Principles on Good Laboratory Practice (as latest revised in 1997) define non-clinical studies as follows (Section I – 2. Definitions of Terms; section 2.3.1):

   > *Non-clinical health and environmental safety study, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.*

   For complete reference, see www.oecd.org

2. Clinical trials (as defined in Directive 2001/20/EC)

The EU Directive 2001/20/EC (Article 2(a)) defines clinical trials as:

> *any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmaco-dynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.*

For complete reference, see EUR-lex.europa.eu.

3. Non-interventional studies

The EU Directive 2001/20/EC (Article 2(c)) defines non-interventional trials as:

> *Stud(ies) where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.*

Transfers of Value

Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of generic or branded prescription-only Medicinal Products exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, where the identity of such Member Company is known to or can be identified by the Recipient.

Appendix:

Sources

Name	Document	Edition
EFPIA HCP/HCO Disclosure Code	EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organisations	June 24th, 2013
Template	Schedule 2 – Template	June 2nd, 2013
EFPIAHCP/HCO Disclosure Code Q&A	EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organisations: Questions and Answers	DRAFT July 7th, 2013
EFPIA HCP Code Amendments	Amendments to the HCP Code	June 2013; to go into effect January 2014
EFPIA HCP Code	EFPIA Code On The Promotion of Prescription-Only Medicines to, And Interactions With, Healthcare Professionals	June 14th, 2011
EFPIA HCP Code FAQ	EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (EFPIA HCP Code) Frequently Asked Questions-FAQ	February 2014