EFPIA Code of Practice Disclosure Methodology

1.4

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1. Document history

Geographic scope of this document: pan-EFPIA master methodology document **Latvia**

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29 February 2016	LV.1.2	Anita Locmele	Ieva Abele Gundega Auzina Rauls Velins	1St version
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2. Document overview

2.1 Introduction

This document outlines how Roche implements the disclosure requirements arising from the EFPIA Code of Practice. It details the requirements and processes related to Roche's disclosure of transfers of value (ToV) to Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) in Europe. The EFPIA Code of Practice also requires the disclosure of ToVs to Patient Organizations (POs), which are reported in the Roche Group sustainability reporting tool (GAIA) according to a separate process set out in the Sustainability Reporting Guidance (Economic Performance) [ref. 26] and are annually disclosed in a list of patient organizations.

Please note that many of the requirements detailed in this document are mandated by EFPIA (European Federation of Pharmaceutical Industries and Associations).

A disclosure, in this document, relates to the open publication of information about transfers of value to HCPs or HCOs whose principle practice is in a country that has opted to implement the EFPIA Code of Practice or has similar local requirements. In some countries, disclosure of transfers of value to local authorities is also required, but these are not within the scope nor are they covered in this document.

This methodology document has been prepared for all Roche affiliates that are required to disclose ToVs to HCPs/HCOs/POs in line with the EFPIA Code of Practice (EFPIA Reporting Affiliates). The requirements outlined in this document apply irrespective of whether the disclosure obligation stems from being an EFPIA Member Company as an affiliate of the EFPIA "corporate member" F. Hoffmann-La Roche Ltd or whether the local affiliate is member of a national association, which in turn is an EFPIA Member Association or has voluntarily adopted the EFPIA Code of Practice.

Since cross-border ToVs to HCPs/HCOs/POs in EFPIA Countries also need to be disclosed, information included in this document is also relevant for non-EFPIA affiliates and Global Functions teams (irrespective of their location). However, they will be provided with the relevant information separately and are not required to be aware of all details of this methodology document.

The most up-to-date version of this document can be accessed here [ref. 1; a full list of references can be found in section 9].

Localization:

No local differences.

2.2 Document purpose

The global EFPIA Code of Practice disclosure methodology document master is intended to serve two purposes:

1. To act as a baseline for use by all Roche affiliates required to disclose ToVs in line with the EFPIA Code of Practice or the relevant translation of the EFPIA Code of Practice by the local EFPIA Member Association, thus helping to ensure maximum consistency in Roche's activities across markets.
2. Support EFPIA Reporting Affiliates in their obligation to publish a local methodology by providing a template that can be adapted and supplemented as required locally.

Deviations from (as opposed to additions to) the standards outlined in this document must be kept to a minimum. Changes are only permitted where there are:

- local laws and regulations
- or differences of local IT systems and data available.

Throughout the document you will see some text which is marked as being 'globally applicable'. It must not be overwritten or altered. Local changes may only be made to the sections marked "localization". The localized

methodology document must accurately reflect the actual disclosure methodology applied in the affiliate. Please note if you are following the EFPIA Code of Practice then you will be required to justify any deviations from the global methodology. Affiliates should not maintain separate local methodology documents other than a localized version of this document.

Please contact TFSR Team regarding the use and adaptation of this document.

Localization:

No local differences.

2.3 Document structure

Due to its multiple purposes, this methodology document is structured as follows:

- Sections 1-6 & 8 (appendix) of this document are intended for Roche-internal use only to outline the *HOW?* of ToV disclosure by Roche Pharma in line with the EFPIA Code of Practice.
- Section 7 of this document is intended as methodological note for external use. It should be published alongside the disclosure report. It is designed to inform the general public, HCPs/HCOs/POs and media about the *WHAT?* of ToV disclosure by Roche Pharma in line with and as required by the EFPIA Code of Practice.

As mentioned previously, each section of the document contains both global and local text. Changes to the global text are not permitted, but affiliates that are implementing the EFPIA disclosures code can localize the text, as needed, in the boxes provided. Please keep in mind that you will be required to justify all deviations from the global methodology.

The language of the EFPIA Code of Practice disclosure Methodology document should be easily understandable by non-native English speakers (this applies to all sections of this document) and persons unfamiliar with this matter (this applies in particular to section 7) like the general public, HCPs/HCOs/POs and media representatives.

Localization:

No local differences.

3. Roles and Responsibilities

3.1 Methodology document maintenance

The Pharma HCO is responsible for maintaining the global master version of this document and for reflecting any changes to the EFPIA Code of Practice.

Each EFPIA Reporting Affiliate is responsible for maintaining its localized methodology documents (derived from the global master) and for ensuring that:

- The local document reflects the latest version of Roche's global EFPIA Code of Practice Disclosure Methodology master template
- It is in line with the applicable local transparency laws and regulations
- An up-to-date English version is maintained.

Affiliates that are responsible for ToV disclosure in two countries can maintain just one single localized methodology document if the definitions, processes, etc. are identical for both countries.

Non-EFPIA Affiliates and Global Functions do not need to create or maintain a localized version of the methodology document.

3.2 Key EFPIA disclosure roles

For disclosure in line with the EFPIA Code of Practice, several key roles need to be assigned. The following table outlines which EFPIA disclosure-specific roles are relevant for which team within Roche. Disclosure also requires support by Finance and IT as part of their regular business activities, which are not detailed in this document.

Role	Global	Regions	EFPIA Reporting Affiliates	Non-EFPIA Affiliates and Global Functions
(A) Engagement owner			X	X
(B) ToV data extractor			X	X
(C) ToV data validator	X		X	X
(D) UCI manager			X	
(E) Consent manager			X	
(F) Dispute manager			X	
(G) Report generator			X	
(H) Transparency manager			X	

In section 6 of this document, the above color-coding is used to indicate which subsections are relevant for **EFPIA Reporting Affiliates**, **Non-EFPIA Affiliates and Global Functions**, **Regions** or **Global**.

The key responsibilities of these roles are as follows:

(A) Engagement owner: Responsible for accurate entry of reportable ToV data in the appropriate IT systems/tool. The engagement owner can be part of either an Affiliate in an EFPIA country or a Non-EFPIA Affiliate. The engagement owner may belong to any function.

(B) ToV data extractor: Responsible for manually extracting any required data for disclosure from IT systems (typically SAP) and for entering it into other systems/tools which feed the EFPIA Disclosure data flow. Manual data extractions should only be required for a small subset of data, e.g., for cross-border interactions with HCOs located in EFPIA countries. This manual information must be entered into the "Low Volume" ToV spreadsheet). The ToV data extractor is only responsible for extracting data from its own Affiliate.

(C) ToV data validator: Responsible for validating the EFPIA Disclosure-relevant line items per ToV category and HCP/HCO. Upon validation, loads 3rd party and Low Volume ToV data into Transparency Spend Reporting Tool. Validates other data (e.g., those captured in iHCP) after they are loaded into Transparency Spend Reporting Tool. Validates local data. As general principle, validation is performed by the paying/engaging rather than the respective reporting affiliate.

Consolidates Affiliate data to create a detailed validation report. Liaises with source data owners to obtain required affiliate data (as needed). Requests data cleansing/completion activities from engagement owners and ToV data extractors. Conducts payment reconciliation as appropriate. Supports dispute manager to validate data correction requests and arranges required changes. Applies EFPIA methodology to ToV data as appropriate. Mainly for EFPIA Reporting Affiliates: Maintains cost element mapping table in TSR. Conducts periodic data quality checks: UCI and Industry Key in SAP vendor data. The Affiliate ToV data validator is responsible for validating data from its own Affiliate. Some of the tasks may be delegated to other functions within the Affiliate.

(D) UCI manager (EFPIA Reporting Affiliates only): Creates UCIs for local HCPs/HCOs (in response to Data Change Requests [DCR]). Is responsible to update (or to request updates of) the local CRM system to reflect the correct UCI. Liaises with data provider to request new customer record. Requests removal or consolidation of duplicate UCIs for the same beneficiary. Accountable for reporting affiliate's UCI management, including support (local and cross-border) to engagement owners to ensure that the correct UCI is assigned to all ToVs.

(E) Consent manager (EFPIA Reporting Affiliates only): Responsible for requesting consent for individual disclosure of HCPs/HCOs (as and where applicable), for maintaining the consent status in the local CRM system and for executing Roche's strategy to maximize consent of HCPs/HCOs. Raise awareness internally to e.g., local communication if concern for negative reactions from external stakeholders.

(F) Dispute manager (EFPIA Reporting Affiliates only): Serves as single point of contact (SPOC) for all requests for information or data correction of local HCPs/HCOs: Receives requests, seeks clarification and provides feedback. Sets dispute flag in the CRM system as appropriate (or arranges for consent manager to do so). Raise awareness internally to e.g., local communication if concern for negative reactions from external stakeholders.

(G) Report generator (EFPIA Reporting Affiliates only): Responsible for creating, publishing and maintaining an up-to-date EFPIA Disclosure report using the applicable transparency tools and in line with local rules and regulations and the EFPIA Code of Practice based on the applicable template.

(H) Transparency manager (EFPIA Reporting Affiliates only): Drives the overall local EFPIA Disclosure effort. Liaises with Region Europe and Global to advance Roche's regional and global transparency efforts. Raise awareness internally to e.g. local Communication if concern for negative reactions from external stakeholders. Collaborate with the local Communication function in executing the local disclosure communication strategy, both Roche-internally and -externally.

Affiliates and Global Functions teams should determine the allocation of the above roles to individuals locally. In most instances, one individual would assume more than one role to minimize the fragmentation of responsibilities. However, the appropriate segregation of duties must be ensured.

ToVs to POs are reported according to a different process set out in the Sustainability Reporting Guidance (Economic Performance) [ref. 26] in the Roche Group sustainability reporting tool (GAIA).

Localization:

(A) Engagement owner: Head of Sales and Marketing, Medical Value/Disease Area/Therapeutical Area strategy leads
(B) ToV data manager: Senior Accounting Business Partner/Accounting &Tax Lead
(C) ToV data validator: Senior Accounting Business Partner/Accounting &Tax Lead
(D) Master data manager: Senior Accounting Business Partner/Accounting &Tax Lead

(E) Consent manager: Accounting &Tax Lead
(F) Dispute manager: Finance & Business Analytics Head, HC affiliate contact
(G) Report generator: Senior Accounting Business Partner/Accounting &Tax Lead
(H) EFPIA transparency manager: Finance & Business Analytics Head, HC affiliate contact

3.3 Reporting obligations for Roche entities

Roche will not publish a consolidated pan-EFPIA HCP/HCO disclosure report. Disclosure is only made on a country-by-country level. This is mainly to avoid potential misinterpretation by externals due to the slightly different rules in several countries, which wouldn't allow for an "apple-to-apple" comparison of ToV data between countries.

The list of POs supported or engaged for services by Roche is published on a central platform: https://www.roche.com/sustainability/patientorganisations/patient-groups-list.htm

3.3.1 Countries in scope of the EFPIA Code of Practice disclosure reporting

An up-to-date list of the countries, for which the EFPIA Code of Practice is applicable ("EFPIA Countries") can be found here [ref. 2]. The table distinguishes between official EFPIA member countries and countries that have adopted EFPIA-like disclosure codes, although the respective industry association is not a formal member of EFPIA.

3.3.2 EFPIA Reporting Affiliates

The HCP/HCO reporting data are published only by one Affiliate for each country in scope. The reporting includes both local data from that Affiliate and cross-border data from other Roche Affiliates (EFPIA and non-EFPIA) related to ToVs to HCPs and HCOs based in the country.

EFPIA countries with one Roche entity

In EFPIA Countries with one Roche entity, the respective affiliate is in charge of disclosing Roche Pharma's ToVs in line with the EFPIA Code of Practice.

EFPIA countries with several Roche entities

In EFPIA Countries with more than one Roche entity, only one entity per country shall disclose Roche Pharma's ToVs in line with the EFPIA Code of Practice. This entity is referred to as "EFPIA Reporting Affiliate" in this document. A list of these Reporting Affiliates can be found here [ref. 3].

EFPIA countries with no Roche entity

Roche does not have affiliate teams in all EFPIA Countries. However, due to F. Hoffmann-La Roche Ltd being a corporate member of EFPIA, the company is required to disclose ToVs to HCPs/HCOs from these countries as well as those where it has an active affiliate. These disclosures will be made via the EFPIA Reporting Entities in other countries or via its distributor in the respective country.

ToVs to POs

ToVs to POs are reported according to a different process set out in the Sustainability Reporting Guidance (Economic Performance) [ref. 26] in the Roche Group sustainability reporting tool (GAIA).

3.3.3 Reportable Roche Entities

All Roche legal entities globally that provide ToVs to HCPs or HCOs based in EFPIA Countries in connection with the research, development and sale of prescription-only medicines (POMs) for human use are "Reportable Roche Entities". Hence, the EFPIA Code of Practice applies to Roche Pharma engagement owners worldwide, but not to

engagements made by Roche Diagnostics. In instances where Roche Pharma is hosted by Roche Diagnostics or the scope of a Roche entity is not entirely clear, it must still be ensured that the Pharma-related ToVs are reported.

ToVs to POs are reported according to a different process set out in the Sustainability Reporting Guidance (Economic Performance) [ref. 26] in the Roche Group sustainability reporting tool (GAIA).

4. EFPIA Code of Practice and national laws & regulations

4.1 Brief summary of the EFPIA Code of Practice disclosure requirements

The EFPIA Code of Practice [ref. 4] is a formal code of conduct that requires all EFPIA member companies and companies which are members of EFPIA member associations to disclose transfers of value to healthcare professionals (HCPs), healthcare organizations (HCOs) and patient organizations (POs). Under the Code, EFPIA member companies will have to disclose the names of HCPs, HCOs and POs that have received payments or other transfers of value from them. They will also have to disclose – by HCP, HCO or PO – the total amounts of value transferred, by type of transfer or value which could consist of, for instance, a grant to an HCO, a consultancy fee for speaking, payment for travel, or registration fees to attend a medical education congress. This information regarding HCPs/HCOs will be published on a public platform, which could be on the company's own website or a central platform combining data from different companies. The list of POs supported or engaged for services by Roche is published on a central platform:

https://www.roche.com/sustainability/patientorganisations/patient-groups-list.htm

The first EFPIA Disclosure Code was formally adopted in June 2013 and EFPIA member companies were required to implement it by 2016, making the first disclosure of transfers of value made to healthcare professionals and organizations from the previous year 2015. In 2019, EFPIA consolidated its three separate Codes (HCP Code, PO Code and Disclosure Code) into one simplified Code of Practice.

4.2 National transparency laws and regulations

Localization:

DISCLOSURE CODE, Approved by the Decision of the Meeting of Members of the Association of International Research-based Pharmaceutical Manufacturers of September 22, 2014 and by the Decision of the Meeting of Members of the Latvian Generic Medicines Association of September 30, 2014.
No differences to EFPIA Disclosure Code.

5. Key EFPIA disclosure parameters and definitions

For further details about the definitions, please also refer to the EFPIA Code of Practice FAQ document [ref. 5].

ToVs to POs are reported according to a different process set out in the Sustainability Reporting Guidance (Economic Performance) [ref. 26] in the Roche Group sustainability reporting tool (GAIA), and are therefore out of scope of this section 5. herein.

5.1 ToVs in connection with certain products only

Of interest for compliance with the EFPIA Code of Practice are only those ToVs (in cash or in kind) that are made by Roche Pharma to HCPs and HCOs in connection with the research, development and sale of prescription-only medicines (POMs) intended for human use. Thus, for example, ToVs related to sale of medical devices, diagnostics (applicable to Roche Diagnostics and Diabetes Care) and OTC medication are currently not subject to the EFPIA Code of Practice. However, the provision of such products as donation by Roche Pharma to an HCO, as permissible, constitutes a ToV that is reportable under the EFPIA Code of Practice.

Localization:

No differences.

5.2 Reportable recipients

In the context of the EFPIA Code of Practice, ToVs to those HCPs or HCOs are reportable, whose primary practice, principal professional address or place of incorporation is in an EFPIA country. The EFPIA definitions for the terms HCP and HCO are as follows:

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 organization (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 practicing HCP, but excludes all other employees of a Member Company and a wholesaler or distributor of medicinal products.

HCO: Any legal entity (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic or learned society whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services. ToVs to teaching institutions are reportable, where such ToVs ultimately benefits an HCP.

Local definitions for HCPs and HCOs in the different EFPIA Countries may include a broader range of individuals or entities. In case of doubt on whether a person/entity from an EFPIA country qualifies as HCP/HCO, the cross-border engagement owner shall contact the respective Reporting EFPIA Affiliate for guidance (e.g. regarding physicians who have an active license to practice but currently don't work as HCPs).

If a ToV is made to an HCO, and the HCO in turn passes the value on to HCPs, the reportable recipient of the ToV for EFPIA disclosure is only the HCO. Example: A grant provided to an HCO to fund congress attendance of HCPs employed by the HCO. The same holds true for self-incorporated HCPs (where he/she is the only employee of the corporation). Such legal persons qualify as HCOs and if ToVs are made to this "one man HCO", only the "one man HCO" would be reportable recipient.

Localization:

If a ToV is made to an HCO, and the HCO in turn passes the value on to HCPs, the reportable recipient of the ToV for EFPIA disclosure could be HCP, if HCP is clearly identifiable and ToV is allocable to individual HCP.

5.3 Country of disclosure

ToVs to an EFPIA HCP/HCO recipient is to be disclosed only in one country, the *principal country* corresponding to the primary practice, principal professional address or place of incorporation. All disclosures for recipients who have their principal practice in a certain country will be made by the affiliate responsible for disclosure in that country, the EFPIA Reporting Affiliate (see section 3.3.2). In case an HCP changes its principal address, the principal address at the time of the disclosure report's generation determines the country of disclosure.

In the rare event of an HCP with his/her primary practice in an EFPIA country also being licensed as a physician in the US, ToVs to the respective HCP might also be reportable according to the US Sunshine Act (only applicable to the few Roche Affiliates that are in scope of US Sunshine Act reporting), but this does not eliminate the need to disclose ToV to this HCP in line with the EFPIA Code of Practice.

Localization:

No differences.

5.4 Reportable ToV categories

Unlike US Sunshine Act and other local transparency regulations, the EFPIA Code of Practice does not include the general principle of reporting any kind of ToVs to HCPs and HCOs. Instead, the EFPIA Code defines and distinguishes only certain categories of ToVs that are reportable, six of them on an individual name basis and one in aggregate.

☑ Individual disclosure ☑ Aggregate disclosure ✘ ToV not allowed

	Recipient HCP	Recipient HCO
a.) Donations and Grants [1]	✘	☑
b.) Event Sponsorship	✘	☑
c.) Event Registration Fees	☑	☑
d.) Event Travel & Accommodation	☑	☑
e.) Fee for Service	☑	☑
f.) Expenses under a fee for service agreement	☑	☑
g.) R&D	☑	☑

Note:

(1) Donations, Grants, and Event Sponsorships: Sponsorship (as defined by the GSD Directive) is not allowed to individual HCPs, only to HCOs.

ToVs that cannot be validly assigned to one of the categories a.) – g.) do not require disclosure, e.g. event overhead costs (such as Roche's internal cost or fees of event management companies), meals and drinks, medicinal product samples, medical education and information materials, and ToVs related to ordinary sales of product (such as rebates).

The EFPIA Code of Practice does not require disclosure of ToVs related to:

- Market research (if the names of the HCPs are not known to Roche). In these instances, the ToV does not have to be disclosed in aggregate either.
- Independent medical education (IME), if the IME provider is not an HCO. If the IME provider is an HCO, the ToV would have to be disclosed against this HCO as "Event Sponsorship".

Schedule 2 - TEMPLATE

Article 2 - Section 2.03

		Full Name	HCPs: City of Principal Practice HCOs: city where registered	Country of Principal Practice	Principal Practice Address	Unique country local identifyer OPTIONAL	Donations and Grants to HCOs (Art. 3.01.1.a)	Contribution to costs of Events (Art. 3.01.1.b & 3.01.2.a)		Fee for service and consultancy (Art. 3.01.1.c & 3.01.2.c)		Transfers of Value re Research & Development as defined (Art. 3.04)	TOTAL OPTIONAL
		(Art. 1.01)	(Art. 3)	(Schedule 1)	(Art. 3)	(Art. 3)		Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accomodation	Fees	Related expenses agreed in the fee for service or consultancy contract	
INDIVIDUAL	HCPs	INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up. Itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)											
		Dr A					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	N/A	
		Dr B					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	N/A	
		etc.					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	N/A	
		OTHER, NOT INCLUDED ABOVE: - where information cannot be disclosed on an individual basis for legal reasons											
		Aggregate amount attributable to transfers of value to such Recipients - Art. 3.2					N/A	N/A	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	N/A	Optional
		Number of Recipients (named list, where appropriate) - Art. 3.2					N/A	N/A	number	number	number	number	N/A	Optional
		% of total transfers of value to individual HCPs - Art. 3.2					N/A	N/A	%	%	%	%	N/A	N/A
	HCOs	INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up. Itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)											
		HCO 1					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	N/A	Optional
		HCO 2					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	N/A	Optional
		etc.					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	N/A	Optional
		OTHER, NOT INCLUDED ABOVE: - where information cannot be disclosed on an individual basis for legal reasons											
		Aggregate amount attributable to transfers of value to such Recipients - Art. 3.2					Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	N/A	Optional
		Number of Recipients (named list, where appropriate) - Art. 3.2					number	number	number	number	number	number	N/A	Optional
		% of total transfers of value to individual HCOs - Art. 3.2					%	%	%	%	%	%	N/A	N/A
AGGREGATE		AGGREGATE DISCLOSURE												
		N/A	N/A	N/A	N/A	N/A	OPTIONAL	OPTIONAL	OPTIONAL	OPTIONAL	OPTIONAL	OPTIONAL	TOTAL AMOUNT	OPTIONAL

The reportable ToV categories a.) - g.) are defined as follows:

a.) Donations and Grants

Donations and Grants are ToVs (either cash or benefits in kind) to HCOs or to institutions, organizations or associations that are comprised of HCPs. For a more detailed definition of Roche's definition of donations and grants, please refer to the GSD Directive [ref. 6] Also non-event sponsorships shall be reported in this category even if they do not meet Roche's definition of a donation or grant. Labelled as "*Donations and Grants to HCOs*" in the EFPIA Disclosure template.

b.) Event Sponsorship

Event sponsorship covers any transfer of value to an HCO for the purpose of managing an event (or any part of an event). This includes rental of booths at an event, advertisement space (in paper, electronic or other format), satellite symposia at a congress, sponsoring of speakers/faculty, courses provided by a HCO (where Roche does not select the individual HCPs participating) and, only if part of a sponsorship package, drinks or meals provided by the organizers (included in the sponsorship agreement). Labelled as "*Sponsorship agreements with HCOs/with third parties appointed by HCOs to manage an event*" in the EFPIA Disclosure template.

c.) Event Registration Fees

Event registration fees only pertain to registration fees for events. This category does not include incidentals or any other expenses incurred as part of attending an event. Should event registration fees include catering or shuttle services, these amounts do not need to be separated, but can be reported under event registration fees as they likely represent only a small fraction of the total registration fee. Labelled as "*Registration fees*" in the EFPIA Disclosure template.

d.) Event Travel & Accommodation

Travel & accommodations expenses include accommodations in hotels or other commercial hospitality and travel including commercial air or rail services, public transportation, compensation for use of personal vehicles and bus/taxi/shuttle services. The expense does not include meals, except if included incidentally in hotel charges. If a compensation for time requirements of travel is paid, this would be reportable under "Fee for Service".

It is not required to disaggregate ToVs provided to a group of HCPs. For instance, where mass group transport (e.g. a bus/coach) is organized for an event, the cost can be disclosed on an aggregate basis and does not need to be apportioned /allocated to each individual HCP who benefitted. Labelled as "*Travel & accommodation*" in the EFPIA Disclosure template.

e.) Fee for Service

Fee for service includes payments for any activity that an HCP/HCO recipient might perform under contract with Roche, e.g., speakers' fees, speaker training, medical writing, data analysis, development of education materials and general consulting /advising.

All transfers of value categorized as fees for service need to be covered by a written contract; a written description of the work to be performed; and include only situations where a legitimate business need exists for the work. The recipient must be qualified for the work and the value of compensation must not exceed fair market value for the work. Labelled as "*Fees*" in the EFPIA Disclosure template.

f.) Expenses under a fee for service agreement

Such expenses include any legitimate business expense that was paid directly or reimbursed by Roche as part of a fee for service contract. Labelled as "*Related expenses agreed in a fee-for-service or consultancy contract*" in the EFPIA Disclosure template.

g.) R&D

EFPIA defines R&D as ToVs 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 15.01 of the HCP Code). Thus, clinical and preclinical studies and research, as well as meetings and activities such as investigator meetings or Data Safety Monitoring Board meetings shall be considered R&D. ToVs for the purpose of R&D are reportable only in aggregate. Only fees for service and travel & accommodation expenses for the purpose of R&D are reportable. Like for non-R&D spend, overhead cost (incl. CRO fees) and materials (such as study medication, injection kits, etc.) do not need to be disclosed. Please refer to the *"Decision Memo R&D"* [ref. 7] for further details. Labelled as "*Transfers of value re. research & development*" in the EFPIA Disclosure template.

Localization:

No differences.

5.5 Roche ToV definitions for EFPIA disclosure

5.5.1 Direct and indirect ToVs

The term transfer of value includes direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the research, development and sale of prescription-only Medicinal Products exclusively for human use.

- **Direct transfers of value** are those made directly by Roche for the benefit of a Recipient.
- **Indirect transfers of value** are those made on behalf of Roche by a third party for the benefit of an HCP/HCO, e.g. the provision of services for an HCO event through an event management company paid by Roche.

If the third party is an HCO that passes on the benefits of the ToV to HCPs, then the ToV is considered provided "directly to the HCO" rather than as "indirectly to HCPs" (see also section 5.2).

An exception from Roche's obligation to disclose indirect ToVs are instances where the contract requires the third party to keep the indirect recipient of ToVs secret from Roche (e.g. as often required in the area of market research). In this case there is no obligation to capture indirect ToVs to HCPs - not even for aggregate reporting. The reason for this is that in such cases (e.g. market research), the ToV recipients typically don't know the identity of Roche and no conflict of interest can arise from the ToV.

As soon as the purpose of a contract gives reason to expect an indirect ToV to a recipient such recipient is considered identifiable for Roche and the third party should be required within the contract with Roche to provide data about what ToVs were completed and to what recipient(s). Based on that information, Roche can then determine the actual recipients and actual value to capture as part of the reporting.

Localization:

If a ToV is made to an HCO, and the HCO in turn passes the value on to HCPs, the reportable recipient of the ToV for EFPIA disclosure could be HCP, if HCP is clearly identifiable and ToV is allocable to individual HCP.

5.5.2 Local vs. cross-border ToVs

ToVs may be *local* or *cross-border*. If the recipient's country of primary practice (HCPs) or primary business (HCOs) is identical to the country of the Roche event/engagement owner, the ToV is considered *local*. Any other ToV (as well as cases where the event /engagement owner is a Global Functions employee) is considered *cross-border* for the purpose of defining the reporting processes and systems.

Example: A ToV to a UK HCP originating from Welwyn would be considered *local*, if the local commercial organization is the engagement owner, but *cross-border* if the engagement owner is from PD (even if based in Welwyn as well).

5.5.3 Individual vs. aggregate disclosure of ToVs

R&D ToVs are disclosed only at an aggregate level (total spend of multiple HCPs/HCOs added together without specifying a beneficiary), as opposed to individual disclosure.

Non-R&D ToVs are disclosed wherever possible at the individual-level, naming the specific HCP and HCO as recipient, whereby the total amount per ToV category a.) - f.) per HCP/HCO is published per year. Unless disclosure is a legal requirement, usually consent has to be obtained prior to individual disclosure of ToV (see section 5.6 below).

Localization:

-No differences for general process for reporting of data collected until 2018.

-Disclosure in 2020 for data collected in 2019:
Due to the exceptional circumstances related to COVID-19 and taking in to consideration that it is inappropriate for companies to contact HCPs and HCOs to obtain consent and/or complete pre-disclosure activities, we cannot satisfy the requirements of the data protection regulations and therefore disclose the data for HCPs in aggregate level, HCOs - without pre-disclosure communication. It is not planned to revise data and publish at individual level later.

-For disclousures started from 2021 for data collected in 2020 and later:
Due to the local legal reporting requirement harmonization with the EFPIA repoting requirements data will be reported once in line with the local legal reporting requirements and therefore no consent is required to publish data on individual level anymore. No pre-disclosure communication will be done.

5.5.4 ToVs in foreign currencies

ToVs need to be disclosed in the local currency of the respective EFPIA country. However, as some ToVs are made in foreign currencies, they need to be converted in the respective local currency.

The need exists for:

- Cross-border ToVs made and available in Roche's systems in a foreign currency (iHCP, GSD and other low volumes transactions)
- CAMS data, irrespective of the currency of booking; data is available in paid currency and in CHF (calculated in CAMS with monthly exchange rate)
- CRO data, irrespective of the currency used for booking in Roche's systems (mainly USD, CHF, GBP, EUR, PLN)
- ToVs reported by a third party in a foreign currency.

For this conversion, the plan exchange rate for the respective reporting period is applied, i.e., 2015 ToVs are reported in early 2016 based on 2014 average (=2015 CER) exchange rates. The plan exchange rate at the time of ToV will be applied (as outlined in the "Decision Memo ToV Date" [ref. 8]; see also section 5.5.7). For an interaction in 2015 and payment in 2016, the plan exchange rate for either 2015 or 2016 applies depending on which date is considered the ToV date. The ToV date in turn determines whether the respective amount will be disclosed in the 2015 or 2016 report (published in 2016 or 2017, respectively).

The following scenario constitutes an exception to the above rule: A 2015 engagement recorded in iHCP, for which the actual spend is entered too late for reporting in June 2016, the actual cost will be published only in 2017 and converted based on 2016 CER. This is done to ensure that only one exchange rate is applied for all amounts included in the same disclosure report.

For ToVs made in a foreign currency but booked in the respective reporting currency, the exchange rate applied at the time of booking the amount in Roche's respective systems applies.

For further details, please refer to the "Decision Memo Exchange Rates" [ref. 09].

Localization:

No differences.

5.5.5 Handling of value-added tax (VAT) and withholding tax

In general, Roche defines ToV as "cost to Roche". Since (VAT) is recoverable in most cases, it does not constitute a cost to Roche and should be excluded from the reported ToVs.

Following the same principle, withholding taxes paid by Roche for a benefit provided to an HCP/HCO should be included in the reported ToVs.

Two exceptions from the above rule exist:

- For indirect payments related to events, VAT is typically not recoverable for Roche and the T&E systems don't capture VAT. In this instance, reported ToV will include VAT.
- The same applies to actual cross-border spend captured in iHCP, for which no VAT is readily available and gross amounts often include a blended VAT for expenses across different countries and VAT levels. In this instance, reported ToV will include VAT.

The following table summarizes the handling of VAT and withholding tax for EFPIA reporting:

Type	Data sources	Payment category	Proposed reference value	Comments
Local payments	SAP (ToV to HCPs)	Fee for service, direct out-of-pocket[1]	w/o VAT	If paid, VAT recoverable for Roche
	SAP (ToVs to HCOs)	Grants, sponsorships, donations	w/o VAT	If paid, VAT recoverable for Roche
	Indirect / Fees	Agency paying fees for ad board, CRO paying investigator fees	w/o VAT	Expenses passed on by agency would be net of VAT
	Payroll (direct spend)	Fee for service	Before deduction of tax & ind. charges	To be consistent with the ToV calculation for non-employed HCPs and to reflect the cost to Roche
	Indirect / Event	Agencies, hotels, CAMS..	with VAT	Amount paid by 3rd party VAT likely not recoverable for Roche VAT not available in T&E systems
Cross border payments	GSD tool	Grants, sponsorships, donations	w/o VAT	Typically no VAT paid
	iHCP	Fee for service	w/o VAT	Typically no VAT paid
	iHCP	Event costs, e.g. travel, accommodation, meals, incl. out-of-pocket expenses	with VAT	FMV limits typically include VAT and VAT amounts often not easy to split
	Other direct spend	Payments to HCOs if not in scope of GSD tool	w/o VAT	Typically no VAT paid
	Global CRO / other indirect spend	CRO, non anonymous market research, other 3rd parties	w/o VAT	Typically no VAT paid

For out-of-pocket expenses, recorded value would include VAT.

For more detailed information about handling VAT and withholding tax, please refer to the respective Decision Memo [ref. 10].

Localization:

Since VAT local legislation is very complicated and VAT could be recoverable, partially recoverable or non-recoverable within one type of payment category, recoverable part of VAT is excluded from ToV and non-recoverable part of VAT is included in to ToV.

5.5.6 Valuation of in-kind ToVs

ToVs can be provided in cash or in-kind. While the valuation of a cash payment is straight-forward (no "valuation step" required for ToVs in local reporting currency; application of exchange rates covered in section 7), a rule is required to determine the monetary equivalent of an in-kind ToV: As a general rule, the cost to Roche (to provide the benefit) shall be considered the ToV amount rather than the value to the HCP/HCO.

Example: Roche provides hotel accommodation to an HCP attending an advisory board meeting. Roche pays 125 EUR/night (excl. taxes) for the room due a favorable corporate rate, while the HCP himself would only be able to book the same room at 160 EUR/night (excl. taxes). Roche will disclose 125 EUR as ToV.

If Roche products are provided as in-kind ToV outside R&D, e.g., as donation, they should be valued at the applicable costs of goods paid by the affiliate providing the product ("transfer price"). The EFPIA Code of Practice does not require the cost for drugs or study materials used in clinical trials to be reported as ToV (see section 5.4 g).

Localization:

No differences.

5.5.7 Defining the date of ToV

In most cases, the date of payment should be considered as date of ToV for EFPIA disclosure purposes. However, the attendance start date will be used for data derived from iHCP, and the cross-charge date shall be considered as ToV date for data derived from CAMS.

Type	Data sources	Payment category	Proposed reference date	Comments
Local payments	**SAP** (direct spend)	Fee for service, direct investigator fees, out-of-pocket expenses, grants, sponsorships, donations	**Payment date – *to HCP***	SAP data are loaded after payment, no overwriting of interfaced data
	Indirect spend (incl. local CRO)	CRO, agencies, hotels, ...	**Payment date – *to Vendor*** Final invoice *(*)*	SAP data are loaded after payment, no overwriting of interfaced data (pre-payment not reported separately)
	Payroll	Fees	**Payment date – *to HCP***	
	CAMS data	Accommodation for events booked centrally in Basel	**Date of cross charge**	Final data communicated by GPS Finance to Affiliates every month
Cross border payments	**iHCP**	Consulting, meetings, events	**Attendance start date**	(split by year in case of multi year contract) Consistent with Sunshine Act
	Direct payments to HCOs	E.g., grants, sponsorships, donations	**Payment date – *to HCO***	Consistent with Sunshine Act
	Global CRO / other indirect spend	CRO, non anonymous market research, other 3rd parties	**Payment date – *to HCP***	Consistent with Sunshine Act Info included by vendor in template

(*) Event date available in systems for countries where event date is mandatory

SA: Sunshine Act reporting

Please refer the "Decision Memo ToV Date" [ref. 8] for more detailed information.

The same rules as above apply to engagements spanning two calendar years: The entire ToV will be reported only in one of the two years – either in the first year (if ToV date = attendance start date) or the second year (if ToV date = payment or cross charge date).

Multi-year cross-border engagements (recorded in iHCP), are typically split in iHCP forms that cover one quarter. In

such a case, the first day of each period is considered as ToV date to which the total engagement ToV is apportioned according to services performed in each period. This principle shall also apply to situations of pre-or late payments.

Localization:

No differences.

5.5.8 Cut-off dates

To ensure integrity of the data set to be disclosed, it is necessary to define cut-off dates (by which data are loaded into the respective systems) for each reporting period, i.e. data received/entered after a certain date cannot be considered for inclusion in the disclosure report for a given year. The cut-off dates depend on the deadline by which EFPIA Reporting Affiliates have to publish their respective disclosure report, and vary for local and cross-border ToV data:

Affiliate group	Local ToV data cut-off	Cross-border ToV data cut-off	Disclosure due by
January Disclosure	31 December	31 December	31 January
March Disclosure	31 January	31 January	31 March
June Disclosure	31 January	28/29 February	30 June

The disclosure due dates of EFPIA Reporting Affiliates can be found here. [ref. 11]

The cut-off date for updates of HCPs'/HCOs' consent statuses is determined by each EFPIA Reporting Affiliate individually in line with local rules and regulations and considering section 6.3.

Please refer to section 6.7 about the reporting of ToV data received/entered after the respective cut-off date.

Localization:

Local legal report to the Health Inspectorate via www.latvija.lv, information reported is publicly available, due by 30 June.

5.6 Consent management

While Roche is convinced that the individual disclosure of financial relationships with HCPs/HCOs is in the public interest, legitimate interests in disclosure must be outweighed by the data subjects' interest in keeping the control over the use of their personal data.

Hence, data protection considerations require consent from HCPs in most countries and in some countries also from HCOs prior to disclosing ToVs on an individual name basis. Consent is voluntary and can - in most countries - be withdrawn at any time, which might require Roche to update already published disclosure reports. In countries where such disclosure is mandated by law, consent is not required.

Please see section 6.3 for detailed instructions about the consent management process including information about the applicable local rules and regulations.

Two principles with regards to consent are of key importance:

- In those countries where consent is necessary, the absence or refusal of consent of an HCP or HCO will result in the ToV data being disclosed in aggregate
- EFPIA does not allow for "partial disclosure", i.e. an HCP (or HCO) can only consent to all (except R&D) his/her ToV to be disclosed individually. Otherwise, all ToVs to him/her will need to be disclosed in aggregate.

5.7 Disclosure and publication period

The EFPIA Code of Practice requires ToV reporting once per year. The reporting period is the calendar year. Only one amount per ToV category (see section 5.4) per HCP/HCO will be disclosed for the entire reporting period. The initial reporting period is 2015.

In most EFPIA countries, the disclosure report needs to be published latest by 30 June of the year following the reporting year, although timelines vary between countries based on national rules and regulations. The report is required to remain publicly available for a minimum of 3 years.

See also section 6.8 for further details.

Localization:

No differences.

5.8 Disclosure channel

According to the EFPIA Code, disclosures can be made on company websites, on national government body or industry association online platforms. The existence of national government body or industry association online platforms varies significantly between EFPIA countries as do rules and regulations about mandatory disclosure channels.

If several disclosure channels are permissible in an EFPIA country, the respective reporting affiliate is recommended to only disclose via one single channel. The recommended channel is the local Roche website.

Please see section 6.8 for detailed instructions about the disclosure process incl. information about the applicable local rules and regulations.

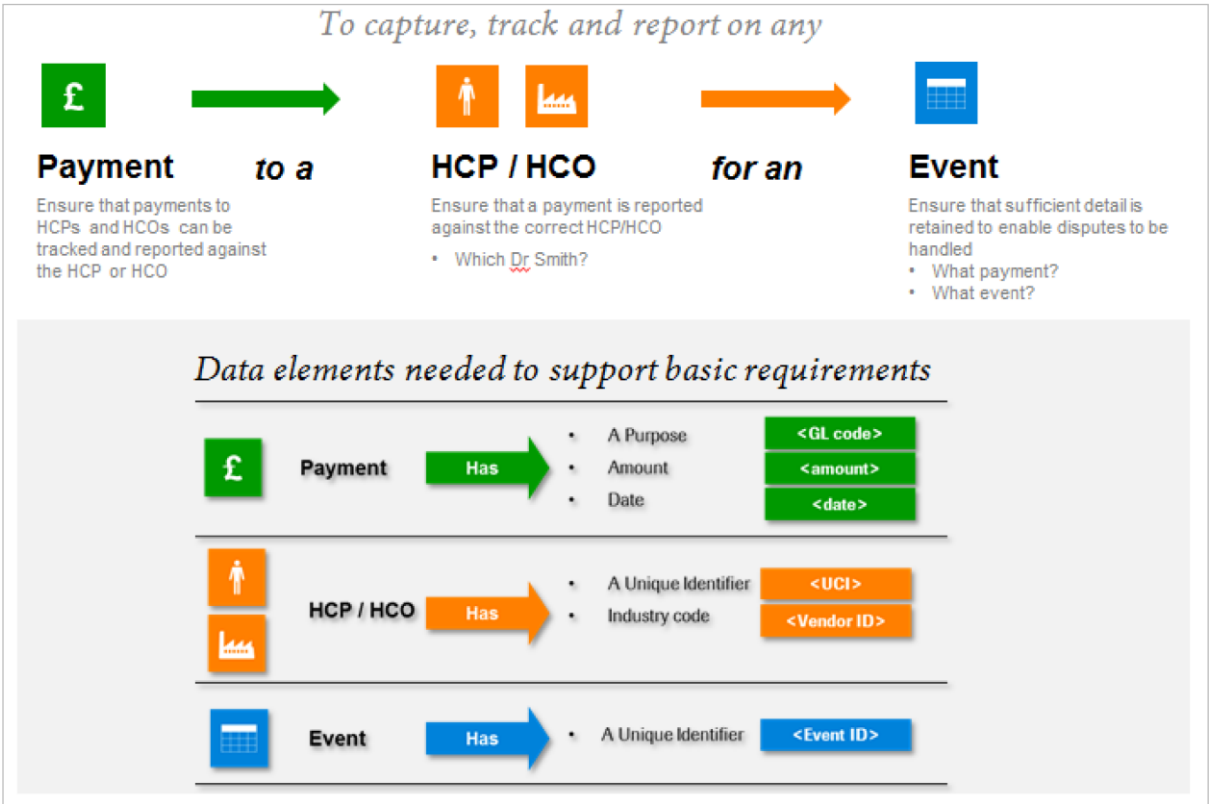
6. Key EFPIA disclosure processes

ToVs to POs are reported according to a different process set out in the Sustainability Reporting Guidance (Economic Performance) [ref. 26] in the Roche Group sustainability reporting tool (GAIA), and are therefore out of scope of this section 6. herein.

6.1 Data Cleansing

High quality, "clean" data are the prerequisite for accurate ToV disclosure.

As depicted below, full visibility is required regarding which value has been transferred to whom at what occasion/in which context:



Recipients of ToVs from Roche need to be uniquely identifiable (**step 01**) and identifiable as HCPs/HCOs (**step 02**) for inclusion in the disclosure report.

As **step 03**, event IDs must be consequently used and passed on to SAP.

Lastly (**step 04**), cost should be booked against unambiguous spend types (possibly requiring adjustments of available G/L codes).

To ensure step 01, a Unique Customer Identifier (UCI) must be assigned to all relevant recipients of ToVs by the UCI manager of the reporting affiliate in the country where the HCP/HCO has his/her/its primary practice/place of incorporation. UCIs shall be assigned to all HCPs/HCOs as per the respective local definition as well as to all ToV recipients, for which cross-border engagement owners request approval via iHCP. See section 6.2 for data capture of cross-border ToV to HCOs.

The UCI will be saved in the respective affiliate's Unite CRM as single source of this information. In case of larger HCOs, different UCIs may be assigned to different departments to allow for more detailed analyses. UCIs can be grouped to allow for all ToVs to be reported against the HCO rather than individual departments in line with the EFPIA Code of Practice. Unite CRM should also be cleaned of duplicate entries. While local affiliates have visibility into their own CRM, cross-border engagement owners currently don't. The Global Customer View (GCV) system allows cross-border engagement owners to identify an HCP's UCI and to include it in the respective iHCP approval request.

UCIs might also have to be generated to enable the identification other types of ToVs not captured in iHCP.

For step 02, EFPIA Reporting Affiliates should classify all reportable vendors (using industry keys in SAP) according to Pharma Core [ref. 12] in an as detailed as possible way.

For step 03, event codes are used to flag payments for disclosure in case of local indirect ToVs by EFPIA affiliates. For cross-border engagements, event types in iHCP shall be used.

For step 04, a cost element structure and list of G/L accounts has been suggested for local ToVs to identify the relevant EFPIA categories, but requires further alignment.

For details about data cleansing (also partially applicable to Non-EFPIA Affiliates), please refer to the latest version of the Data Cleansing Guideline [ref. 13] and a comprehensive slide deck [ref. 16].

Roles involved:

ToV data validator, UCI manager and transparency manager of each EFPIA Reporting Affiliate. ToV data validator of Non-EFPIA Affiliates/Global Functions.

Localization:

Event ID is entered directly to SAP as "RefKey2" for non-PO Invoices and "Event ID" for PO based Invoices.

6.2 ToV data capture

In order for Roche to disclose in line with the EFPIA Code of Practice, ToV data must be captured from multiple sources.

Cross-border ToV data will be captured as follows:

1. **CRO payments**

   Cross-border CRO payments (i.e. payments by global or regional clinical research organizations on behalf of Roche) shall be captured in the CRO Data Excel template [ref. 15]. All global and relevant regional CROs are aware of this process and will provide data quarterly (by 31 Jan., 30 Apr., 31 Jul., 30 Nov.).

   Roles involved:

   CRO employees. ToV data validator of the relevant Global sites. The main sites expected to be involved are Basel, South San Francisco, Welwyn, Mississauga and Warsaw.

2. **HCP engagements**

   iHCP is used to approve cross-border HCP engagements and to record the corresponding actual spend. The iHCP SOP [ref. 17] and User Guide [ref. 18] can be accessed via the respective links. Data transfer from iHCP to Transparency Spend Reporting Tooloccurs continuously and automatically.

   Roles involved:

   Global ToV data validator liaising with ToV data validators of Global Functions, Non-EFPIA Affiliates and EFPIA Reporting Affiliates.

3. **HCO interactions**
4. **Collaborations & clinical studies with AROs**
5. **Fellowships**
6. **Partnering**
7. **Memberships**

8. **Other direct payments**
9. **Medical writing**

Cross-border ToV of the above categories (3 – 9) is typically captured in the SAP instance of the site employing the cross-border engagement owner. Low Volume payments (i.e., payments by global or regional clinical research organizations on behalf of Roche) are captured via the Low Volume Excel template [ref. 16] and uploaded using the file import functionality of TSR tool. Uploads of these data are due twice per year (due 31 Jan. and 31 Jul.)

Roles involved:

ToV data extractor and ToV data validator of the relevant Global Functions, Non EFPIA Affiliate and EFPIA Reporting Affiliates. The main non-EFPIA sites expected to be involved are Basel, South San Francisco and Mississauga. However, there may also be reportable transactions in other Affiliates hosting global functions and in Pharma Affiliates belonging to various regions.

Local ToV data will be captured as follows:

1. **CRO payments**

Local CRO payments are captured via a process defined by each EFPIA Reporting Affiliate individually.

Roles involved:

CRO employees; ToV data validator of each EFPIA Reporting Affiliate.

2. **HCP engagements**
3. **HCO interactions**
4. **Collaborations & clinical studies with AROs**
5. **Fellowships**
6. **Partnering**
7. **Memberships**
8. **Other direct payments**
9. **Medical writing**

Local ToV of the above categories (2 – 9) is typically captured in the local SAP instance and automatically transferred to Transparency Spend Reporting Tool, from where data can be processed provided data cleansing has been performed as outlined in section 6.1.

Roles involved:

ToV data extractor, UCI manager and ToV data validator of each EFPIA Reporting Affiliate.

Localization:

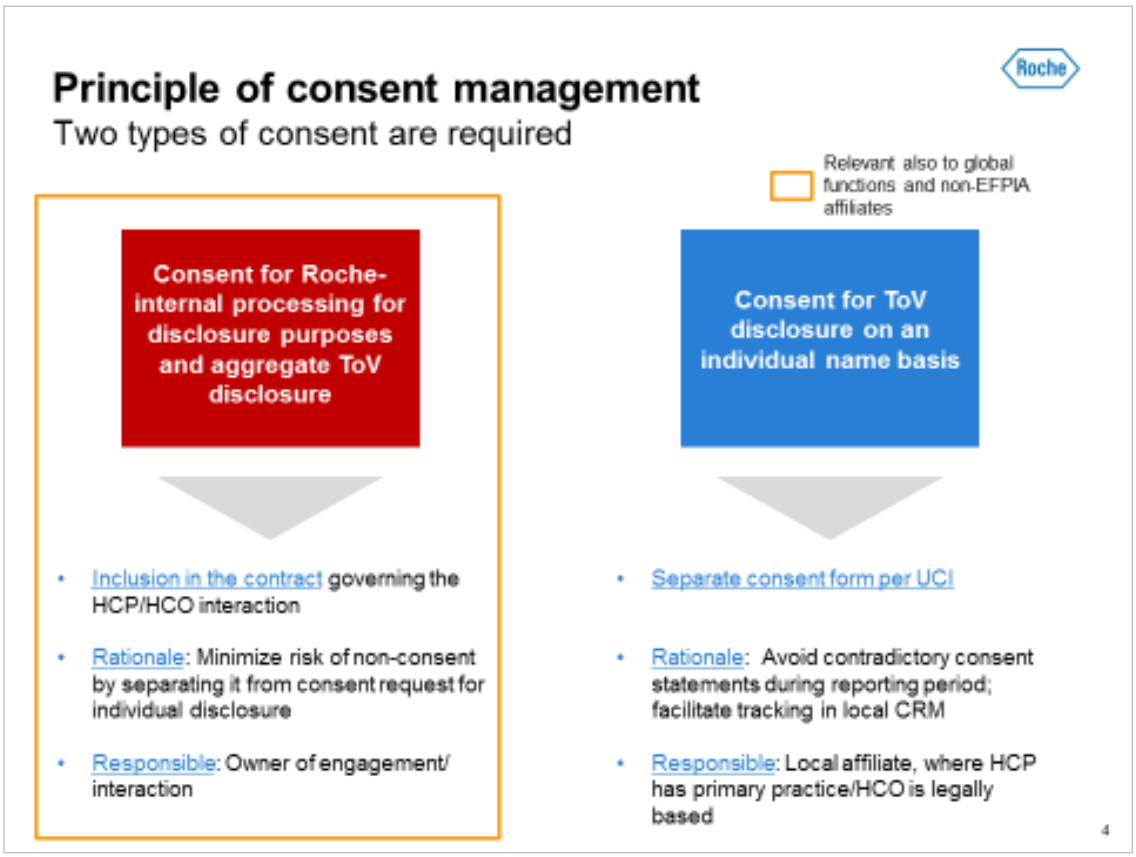
All ToVs are allocated to HCP/HCO internally in TSR. No external users are allowed access TSR.

6.3 Consent management process

The basic principles about consent in the context of EFPIA disclosure are discussed in section 5.6.

On this basis, each affiliate is responsible to determine whether or not the local interpretation of laws and regulations requires the consent of the HCP for disclosure. In case of doubt; consent should be obtained. In the (few) countries where data protection laws expand to (some or all) legal entities, the consent of the HCO might also be necessary to disclose ToVs to HCOs on an individual basis.

Informed consent needs to be obtained for individual disclosure of ToV-related data for the purpose of enabling Roche to comply with EFPIA requirements. This pertains to both direct and indirect interactions with HCPs and/or HCOs.



Ad a: Consent for individual disclosure should be obtained via a separate form per HCP/HCO by Roche – also in the case of indirect interactions. Because EFPIA does not allow for partial disclosure, consent should not be obtained per engagement contract.

Consent for individual disclosure should always be obtained by the local EFPIA Reporting Affiliate of the country where the HCP has his/her principal practice or where the HCO is legally based.

Ad b: Information regarding general data processing for the purpose of compliance with reporting obligations should be mentioned in the common declaration on processing of personal data in each contract or other agreement covering a ToV to an HCP or HCO. It is important to keep this information separate from the consent to individual disclosure to prevent the risk that withdrawal of consent to individual disclosure also removes the legal basis to processing data for aggregate disclosure.

The respective HCP's/HCO's consent status will be tracked in Unite CRM and this consent status upon report generation determines whether the ToV benefiting an HCP/HCO will be reported individually or on aggregate.

Detailed operational guidance (incl. roles & responsibilities and suggested contract wording) how to manage consent for local, cross-border, direct and indirect interactions is provided in the Consent Management Guideline [ref. 19].

This document also details how consent withdrawal should be handled.

Roles involved:

Engagement owners and consent managers of EFPIA Reporting Affiliates. Engagement owners of Non-EFPIA Affiliates and Global Functions (for iHCP data).

Localization:

For periods until 2019:
Consent for disclosure is included in to each single agreement with HCP prior interaction. Without consent interaction with HCP is not started.
In case of indirect interaction (cross border) separate consent is received where possible as soon as we have information on interaction and HCP could be identified. In all other cases ToV are reported in aggregate level.
For periods starting with 2020:
As report is legal required, no consent is necessary for individual disclosure.

6.4 Internal ToV data validation

Roche-internal validation of ToV data is a mandatory step towards accurate EFPIA Disclosure.

Validation of local ToV data

Local ToV data are validated as described in the Transparency Spend Reporting Guideline [ref. 20].

Roles involved:

ToV data validators and engagement owners of EFPIA Reporting Affiliates.

Validation of cross-border ToV data

iHCP data should be confirmed by respective engagement owner upon entry of actual spend data, which is due to be entered within 60 days of the engagement. iHCP generates automatic reminders if actual spend information is missing. Missing or incorrect UCI data is handled as detailed in a separate slide deck [ref. 16]. iHCP data are uploaded continuously into Transparency Spend Reporting Tool.

CRO data are uploaded quarterly. Validation take by the respective TOV data validator takes place twice per year before being transferred to the Transparency Spend Reporting Tool.

The respective ToV data validator checks low volume data once they have been extracted from the local source system or manually transferred (twice per year). However, no additional validation step is performed upon upload of these data. Other than ensuring best possible data quality, Affiliates do not need to certify the accuracy of cross-border data in the context of the EFPIA Disclosure. Further details can be found in the Transparency Spend Reporting Guideline [ref. 20].

Roles involved:

For iHCP data, Global ToV data validator. For small volume and CRO data, ToV data validators of Non-EFPIA Affiliates, Global functions and select EFPIA Reporting Affiliates (e.g., Roche Poland).

Localization:

No local differencies.

6.5 Data consolidation & report generation

The systems used for data consolidation and report generation depend on the EFPIA Reporting Affiliate. For data consolidation, 2 tools are available (TSR, Naya). For report generation, 2 tools are available (TSR, Naya) and the following system configurations exist:

EFPIA Reporting Affiliates	Data consolidation system	Report generation system
Belgium, France	TSR	TSR
Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, (Malta), Russia, Serbia, Ukraine	TSR	TSR
Iceland, Portugal	Custom/manual	Custom/manual

The end-to-end cross-border and local data flows are described in section 6.2. The data aggregation step is shown below and described in more detail in the Transparency Spend Reporting Guideline [ref. 20].

Roles involved:

ToV data validators, report generators and EFPIA transparency managers of all EFPIA Reporting Affiliates.

Localization:

No local differences.

6.6 External ToV data validation & dispute management

6.6.1 External ToV data validation

It is strongly recommended that EFPIA affiliates allow HCPs/HCOs to validate the ToV to be disclosed against their name. While this step is not mandatory, experience from affiliates that have conducted this step (e.g., France) has shown that this increases HCPs'/HCOs' support of public ToV disclosure and also strengthens Roche's relationship with them.

To allow for resolution of data correction requests by HCPs/HCOs prior to initial disclosure, ToV data should be provided 8 weeks prior to the initial disclosure data for external validation by them.

In the absence of an online platform for external validation, mail is the delivery method of choice. As part of this external data validation process, HCPs/HCOs shall be provided with information about how to submit requests for information and data correction.

It is recommended to include the following items when requesting HCPs/HCOs to validate their ToV:

1. Cover letter containing 4 key elements:
    - Brief outline of the EFPIA Code of Practice incl. a reference to a relevant external source (e.g., local industry association website)
    - Explanation of the ToV data attached
    - Information on next steps (disclosure timeline and contact details in case of further queries/a request for data correction)
    - Request for consent for individual disclosure for those HCPs/HCOs that didn't provide consent yet. It is recommended to omit this topic from the cover letter with the HCPs/HCOs who already provided consent.
2. Demographic information about the respective HCP/HCO incl. consent status.
3. Preview of the actual ToV data in the format in which they will be disclosed by Roche (see EFPIA example in section 5.4. or refer to the respective national template). For HCPs/HCOs, that haven't provided consent yet, it is recommended to still show them the ToV data as if they would be disclosed individually while clearly

indicating that without explicit consent, the HCP's/HCO's ToV data will be disclosed in the aggregate spend section.

4. Detailed breakdown of the ToV data by line item as basis for an in-depth external validation [ref. 20]. While EFPIA affiliates are not required to provide this information upfront, doing so is expected to help to build trust of HCPs/HCOs in the ToV data to be disclosed and thereby increase consent rates for individual disclosure.
5. Consent form to allow for individual disclosure (for the HCPs/HCOs who did not provide consent), but from whom it is required.

The respective EFPIA reporting affiliate's transparency manager should assume responsibility for these process steps.

Roles involved:

Report generators and EFPIA transparency managers of all EFPIA Reporting Affiliates.

Localization:

As all payments to HCPs are subject of PIT (Personal income Tax) and these are reported to RSS (Revenue State Service) on individual basis, there is no validation required for HCPs for local reporting event. At least two month before local reporting event on 30st June PIT statements for each single payment are sent to HCPs. Taxable items are not subject for discussions with HCPs.

6.6.2 Dispute management

Roche is required to respond to requests for information and correction of HCPs/HCOs regarding the ToV data against their name in a timely manner. Roche aims to close out all data correction requests within 4 weeks upon receipt. Erroneous data have to be corrected by Roche amendments to the respective EFPIA disclosure report within 24 hours. In some countries, local laws and regulations might require a significantly faster turnaround time. In case of cross-border requests, EFPIA reporting affiliates shall notify other affiliates involved in the dispute management process in cases where the timelines are shorter than 4 weeks.

On the other hand, neither the EFPIA Code of Practice nor the GDPR allow Roche to correct ToV data without clear evidence of them being erroneous.

To enable Roche to resolve potential disputes and to correct erroneous ToV data prior to their initial disclosure, external data validation is strongly recommended (outlined in section 6.6.1).

Any requests for information or data correction by HCPs are considered Data Subject Requests as per the GDPR as well as the Roche Global Data Privacy SOP – Data Subject Request Process (Doc ID: 19257941; hereinafter "Data Subject Request SOP"). Therefore, all HCP requests must be handled pursuant to the procedure provided in the Data Subject Request SOP.

Although requests for information/data correction might be received in any format and via multiple channels, the preferred channel to receive requests is in writing including a signature of the HCP/HCO representative. Additional communication channels (e.g. a phone number) can be set up based on local needs. Each EFPIA reporting affiliate is recommended to set up a dedicated email address managed by the EFPIA Reporting Affiliate's dispute manager (rather than the dispute manager's individual email address). For HCP requests, the dedicated email address for data privacy matters or the contacts of the local DPO / DPC can be provided instead. However, if the dedicated email address managed by the dispute manager is nevertheless provided also for HCPs, all requests the dispute manager receives from HCPs must immediately be re-directed to the local DPO / DPC or (depending on the circumstances) to the Global Privacy Office.

This email address (and any other communication channels offered by the respective affiliate for this purpose) shall be communicated to HCPs/HCOs in the following ways:

- Inclusion in the cover letter accompanying the ToV data provided to HCPs/HCOs for external validation
- Inclusion in the external methodology note (see section 7) to be published

- If possible, inclusion in the online platform, via which the EFPIA reporting affiliate publishes its disclosure report

EFPIA reporting affiliates are requested to post their channels for information/data correction requests in a central repository on the Pharma Healthcare Compliance Office Touchpoint site and to keep the information up-to-date to allow other affiliates to direct cross-border HCP/HCO requests to the appropriate channel.

HCPs/HCOs shall be provided with an information/data correction form (see template) [ref. 21] upon request by email, but ideally also via the online platform, via which the EFPIA reporting affiliate publishes its disclosure report.

HCPs/HCOs will be asked to complete, sign and submit the information/data correction form. If the HCP/HCO does not have access to the itemized ToV data, the Roche EFPIA reporting affiliate will provide the details required to specify the request for data correction. In the case of HCPs, the Data Subject Request form as referred to in the Data Subject Request SOP should be provided instead.

Details of the Roche-internal dispute management process can be found in the Dispute Management Guideline [ref. 22] and a detailed flow chart [ref. 23].

Within Roche, the progress of each data correction request by HCOs should be tracked using a structured form (see example [ref. 24]). Requests from HCPs have to be tracked as set out in the Data Subject Request SOP.

In case of data correction requests from HCOs pertaining to cross-border ToV, the local dispute manager shall use the externally available email address to seek assistance from his/her counterparts in other EFPIA reporting affiliates (see respective list [ref. 3]). For assistance in case of cross-border ToV from non-EFPIA affiliates, the respective finance managers serve as the first point of contact (see respective list [ref. 3]]), who can designate another individual as contact person.

In countries where consent is required for individual disclosure, the HCP/HCO might typically decide in favor of one of the following courses for action:

1. Request information without requesting correction of data (yet). In this case, HCP/HCO shall be provided the detailed breakdown of the ToV data by line item.
2. Request data correction and temporarily suspend consent until dispute resolution. In this case, the dispute flag in the CRM shall be ticked resulting in the entire ToV against the respective HCP/HCO to be disclosed as part of the aggregate spend (over-ride of the consent status). In this scenario, the HCP/HCO is required to confirm acceptance of the dispute resolution in writing, which triggers the dispute flag in the CRM to be unticked following which the ToV against the respective HCP/HCO will be displayed in line with the consent status.

It is suggested that EFPIA reporting affiliates establish local rules regarding their acceptance of a data correction request by HCOs along the lines of:

- Clearly justified requests to be handled by the dispute manager
- Requests requiring a judgement call to be handled by local HCO contact or another individual with delegated authority

Data correction requests by HCPs are handled as per the Data Subject Request SOP.

Affiliates are encouraged to consider a tiered escalation process taking into account the materiality of a dispute.

Roles involved:

For HCP requests, local DPOs / DPCs. For HCOs, foremost dispute managers and ToV data validators of EFPIA Reporting Affiliates. For requests pertaining to cross-border data, ToV validators and potentially engagement owners of Global Functions and Non-EFPIA Affiliates. Local decision might involve engagement owner, local HCO contact, GM the EFPIA Reporting Affiliate and potentially the regional HCO contact.

Localization:

No local differences.

6.7 Errors and omissions

Errors detected in Roche's EFPIA Disclosure reports should be corrected in a timely manner. This applies to all Disclosure reports available in the public domain (where ToV data typically have to be kept for 3 years following their initial publication). The correction process of errors identified by Roche itself is identical to the one outlined in the dispute management section (6.6.2).

Other than updates resulting from data correction requests and consent withdrawals of HCPs/HCOs, omissions (=late data) shall only be included in the disclosure report during the next disclosure cycle. Entry of actual spend data in iHCP after the respective cut-off date is expected to constitute a typical reason for omissions. For 2015 engagements, the respective ToV will be added to 2015 disclosure report (=not rolled into the 2016 disclosure report), which will be updated and published simultaneously with the 2016 disclosure report in early 2017. Details about the correction process for the different data sources can be found here [ref. 20].

Roles involved:

ToV validators of EFPIA Reporting Affiliate and Global Functions and Non-EFPIA Affiliates to drive corrections.

Localization:

No local differences.

6.8 Disclosure

Disclosures are made or arranged for by each EFPIA Reporting Affiliate on a local level in the light of the local rules re. the disclosure timing and channel/platform (local Roche website, national government body or industry association online platforms). If several disclosure channels are permissible in an EFPIA country, the respective reporting affiliate is recommended to only disclose via one single channel. The recommended channel is the local Roche website.

As outlined in section 5.5.8, disclosure will occur in 3 "waves" in January, March and June and disclosure within each wave will be synchronized. Prior to the actual disclosure, spend analytics will be performed and key communication/perception risks identified, which will be shared with the Pharma Healthcare Compliance Office that will lead the overall risk management approach. Details can be found here and the respective document will continue to be updated on a regular basis [ref. 20].

The list of POs supported or engaged for services by Roche is published on a central platform: https://www.roche.com/sustainability/patientorganisations/patient-groups-list.htm (see also section 3.3)

Roles involved:

Transparency managers of all EFPIA Reporting Affiliates.

Localization:

Local legal report to the Health Inspectorate via www.latvija.lv, information reported is publicly available, due by 30 June.

6.9 External communication

Consistency of communication is of key importance. Roche's external communication strategy is targeting several important stakeholder groups:

1. HCPs/HCOs

2. Healthcare policy makers
3. Payers
4. Patients and patient organizations
5. The general public
6. Media

With regards to HCPs/HCOs, information and pre-disclosure/external validation of ToV data are the most important communication elements along with a timely response to requests for information and transparent decision-making re. data correction requests.

With regards to the other stakeholder groups, the external methodology note (section 7) is expected to serve as the main communication vehicle.

With regards to media, the following is recommended:

- Avoid or prepare for potential inconsistencies or areas of concern between countries and companies, and establish robust explanations for significant individual payments and our total spend
- Make sure to introduce monitoring systems that enable early awareness of potential spend outliers
- Explain the value that pharma interactions with HCPs and HCOs bring

External communication is an essential part of how our work with the EFPIA Code of Practice will be perceived. It is therefore critical to make this an important part of the total effort. Further details about recommended external communication strategy can be found here [ref. 25].

Roles involved:

Transparency managers of all EFPIA Reporting Affiliates supported Roche's communications team.

Localization:

No local differences.

7. Methodology note for external publication

EFPIA requires the disclosure report to be accompanied by a public "methodology note" outlining how specific aspects of reporting are handled. Disclosures shall be made in the language(s) prescribed in the national code by the relevant Member Association. While EFPIA encourages companies to make disclosures in English in addition to the mandatory local language(s), Roche affiliates are recommended to publish their methodology note only in the mandatory local language(s).

EFPIA does neither prescribe a length of the methodology note nor an update frequency.

EFPIA Reporting Affiliates are responsible to ensure that their public methodology note reflects the latest global master template. Local Roche methodology notes should be as short and concise as possible to be easily understandable (approx. 5 pages DIN A4):

Localization:

This document explains the methodology underlying Roche's EFPIA disclosure

It is common in many innovation-led industries for companies to engage independent experts or specialist organizations. Collaborations between the pharma industry, healthcare professionals (HCPs), healthcare organizations (HCOs) and patient organizations (POs) are crucial in the development of innovative medicines that help patients live longer, healthier lives. Such collaborations have delivered numerous innovative medicines and have re-written the pathway of many diseases.

Roche believes it is only fair and appropriate to compensate such groups for their time and expertise. The company is committed to ensuring people understand the nature of and value of our work with HCPs, HCOs and POs, and therefore fully supports the EFPIA Code of Practice.

- Roche works with HCPs, HCOs and POs in a number of ways. The figures published reflect transfers of value made for a number of activities including HCP/HCO involvement in developing and running educational programmes focused on sharing new information about diseases or their treatment.
- Collaborating with POs enables Roche to understand how best we can incorporate the patient perspective while developing our medicines and diagnostics. Roche works with POs for example to include the patient input in our clinical trial design to ensure meaningful clinical trial endpoints or to discuss healthcare related topics like access and value of our innovative medicines as well as diagnostics and new approaches in health systems like personalized healthcare (PHC).
- Resource support for healthcare institutions enabling them to conduct activities such as patient support. We also support the exchange of experiences encouraging the adoption of best in class clinical practices.
- Engagement of leading HCPs as consultants and advisors. In this capacity they help to ensure that our clinical studies and programme are equipped to enable HCPs to make informed treatment decisions.

What is the EFPIA Code of Practice?

The EFPIA Code of Practice is a set of rules by the European Federation of Pharmaceutical Industries and Associations (EFPIA) that, among other rules and standards, requires its member companies and the member companies of its member associations to disclose transfers of value made to healthcare professionals (HCPs),healthcare organizations (HCOs) and patient organizations (POs). Under this Code, Roche as an EFPIA member company will disclose the names of HCPs, HCOs and POs to whom it has made payments or other transfers of value.

The HCP/HCO disclosure report details the total value transferred to each of the HCPs or HCOs with whom the company has worked. It also provides information regarding the type of activity or support provided by the HCP or HCO. This could consist of, for instance, a grant to an HCO, a consultancy fee for speaking, payment for travel, or

registration fees to attend a medical education congress. The list of POs that Roche has supported includes the names of such POs that have received funding or non-monetary support from Roche, as well as those POs that Roche has engaged to provide contracted services. The list also includes a description of the nature of each support to, or services provided by the PO. A description of the data collection process as part of the Sustainability Reporting is detailed here.

The first HCP/HCO disclosure report was published in June 2016]and pertains to transfers of value made in 2015. The list of POs supported or engaged for services was first published by the end of the first quarter of 2013, covering activities that had commenced as of or ongoing on 1 January 2012.

Further information about the EFPIA Code of Practice can be found here: SIFFA

To which countries does the EFPIA Code of Practice apply?

The EFPIA Code of Practice applies to: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom. Some other countries have adopted a comparable disclosure code without being EFPIA members including Iceland and Israel.

This particular HCP/HCO disclosure report contains details of the transfers of value made by Roche to HCPs and HCOs whose primary practice/place of incorporation is Latvia.

In the list of POs supported or engaged for services by Roche, such POs can be filtered by the country in which such POs are based or located in, including Latvia.

What types of payments are disclosed?

Roche's HCP/HCO disclosure report includes payments and transfers of value in kind made to HCPs and HCOs such as sponsorship to attend meetings, speaker fees, consultancy and advisory boards.

More specifically, transfers of value can be categorized as follows:

- Donations and Grants to HCOs (grants and donations are not allowed to individual HCPs under the EFPIA HCP Code)
- Sponsorship agreements with HCOs
- Registration fees for events
- Travel & accommodation to attend events
- Fees for service & consultancy, where a contract is in place for activities such as speaking at, or chairing meetings and attending advisory boards
- Related expenses agreed in a fee-for-service or consultancy contract including travel & accommodation and media consultancy and
- Research & development (fees for service, travel & accommodation)

Roche's disclosure report includes details of transfers of value made to HCPs/HCOs by Roche directly as well as transfers of value made on behalf of Roche by third parties such as event agencies. A few transfers of value via third parties are not reportable. Such rare cases are in line with the EFPIA Code of Practice and may include situation such as anonymous participation of a HCP in market research.

The list of POs supported or engaged for services by Roche includes, in addition to the names of the POs, the following elements:

a. The form of the support:
   i. Financial Support
   ii. Non Financial Support

b. The description of the purpose :
   i. Education of patients / General Public
   ii. Infrastructure
   iii. Consultancy fees
   iv. Sponsorship

Why are the amounts spent on meals and drinks not disclosed?

A threshold is being applied in each country, limiting hospitality under a certain amount. These amounts are outlined in country national codes of practice. Very often these transfers of value are for small amounts such as a coffee or sandwich. Disclosing these small transactions would place a disproportionate administrative burden on industry and HCPs, for little value.

Where is Roche's disclosure report published?

In the majority of participating countries, payments to HCPs/HCOs will be disclosed on company websites. In some countries the report will be published on a central platform.

Here in Latvia, Roche's disclosure report has been published on a central platform www.latvija.lv .

The list of POs supported or engaged for services by Roche is published on a central platform: https://www.roche.com/sustainability/patientorganisations/patient-groups-list.htm

When does publication occur?

Roche will disclose information regarding transfers of value to HCPs and HCOs in EFPIA reporting countries on an annual basis. Transfers of value made to HCPs and HCOs are recorded throughout the year and publically disclosed by 30 June of the following year. The first report in Latvia was published in June 2016, and reports transfers of value made in 2015.

As of 2021 reporting (data 2020), the list of POs supported or engaged is published at harmonized dates with the EFPIA disclosure and the publication will be by 30 June.

Data, in both cases, will remain in the public domain for a period of three years, except it is specified differently in the local laws

What is the definition of HCP, HCO and PO in the context of Roche's HCP/HCO disclosure report and the list of supported or engaged POs?

The EFPIA Code of Practice defines healthcare professionals as any 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 or administer a medicinal product.

An HCO is any legal entity that is a healthcare, medical or scientific association or organization such as a hospital, clinic or learned society through which one or more HCPs provide services. Patient organizations (POs) are not considered HCOs.

A PO is a non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

In the HCP/HCO disclosure report, Roche discloses transfers of value made to HCPs/HCOs whose primary practice, principal professional address or place of incorporation is in an EFPIA country.

In the list of POs supported or engaged by Roche, both POs with their place of incorporation or primary place of operation in Europe and outside Europe are published.

In which countries are transfers of value for an individual HCP/HCO reported?

Roche discloses information regarding each of the HCPs and HCOs it works with in one country only. Specifically, the company will report the transfers of value in the country where the HCP or HCO has his/her primary practice, principal professional address or its place of incorporation. This rule continues to apply even when the HCP or HCO receives a transfer of value from a Roche entity in a country that is different to their primary location or if the HCP/HCO practices in several EFPIA countries.

POs supported or engaged by Roche around the world are published on a country-by-country basis in the list of supported or engaged POs.

To which Roche companies does the EFPIA Code of Practice apply?

Roche discloses information regarding transfers of value made by Roche Pharma (including Genentech). Transfers of value made by Roche Diagnostics are in most cases not included (except in the case of POs). Transfers of value made by Chugai are disclosed separately.

Have HCPs/HCOs consented to Roche disclosing this information?

Disclousures for data until 2018:

The consent of each HCP is required before individualized data can be released.

Roche has sought to secure consent of all the HCPs with whom we work but consent is voluntary and can be withdrawn at any time. Roche believes it is important to make sure our relationships with HCPs are transparent and as such will continue working to encourage our partners to provide consent for full disclosure.

Where we have not been able to secure consent from an HCP , the respective ToV data is disclosed in aggregate.

Transfers of value to HCOs, from which no consent is required, are disclosed individually (with the exception of payments for research & development).

Disclosure in 2020 for data collected in 2019:

Due to the exceptional circumstances related to COVID-19 and taking in to consideration that it is inappropriate for companies to contact HCPs and HCOs to obtain consent and/or complete pre-disclosure activities, we cannot satisfy the requirements of the data protection regulations and therefore disclose the data for HCPs in aggregate level, HCOs - without pre-disclosure communication. The consents of each HCP will be not be obtained later and publication of disclosure with individualized data will not follow for Year 2019.

Disclosure starting from 2021 for data collected in 2020:

In Latvia disclosure of transfers of value to HCPs and HCOs is a legal requirement.

Hence, all transfers of value (with the exception of payments for research & development) are disclosed individually.

How are corrections of errors handled?

Errors detected in Roche's HCP/HCO Disclosure reports and the list of supported or engaged POs will be corrected in a timely manner. This applies to all HCP/HCO Disclosure reports and lists of supported or engaged POs available in the public domain.

How does Roche define the date of a transfer of value?

In general, the date of payment of the HCP/HCO by Roche is considered as date of the respective transfer of value for EFPIA disclosure purposes rather than the date, when an HCP/HCO delivered a service to Roche.

In the case of POs, the posting date [the **date** that determines in which **posting** period a document or journal entry is added to the database] is considered as the date of the respective transfer of value. For the purpose of Roche's disclosure report, this distinction is only relevant, when both dates lie in different calendar years. In the case of an HCP's attendance of an international event, Roche discloses all transfers of value as if they occurred on the date of the event even if flights and accommodation were paid in advance and cost for ground transportation reimbursed after the event.

How are taxes considered in Roche's disclosure of transfers of value?

In the context of the EFPIA Code of Practice, Roche defines value (that is transferred to HCPs/HCOs) as a cost to Roche. Hence, transfers of value shown in Roche's disclosure report are net of sales tax (VAT), where the respective amount is recoverable by Roche. For payments that are subject to withholding taxes, the value of the tax is included in the transfers of value disclosed.

How are transfers of value in foreign currencies handled?

Transfers of value are published in the local currency of country of primary practice or incorporation of the respective HCP/HCO. However, as some transfers of value are made in foreign currencies, they need to be converted in the respective local currency. For the sake of simplicity and comparability, a constant exchange rate has been applied to transfers of value in foreign currencies made during the reporting year. This constant exchange rate corresponds to the actual average exchange rate of the preceding 12 months.

For POs, the local currency is the basis for the reporting as this is being reflected in the legacy system according to the local tax and accounting principles

How are transfers of value in kind benefits valued?

In the context of the EFPIA Code of Practice, Roche defines value (that is transferred to HCPs/HCOs) as the cost to Roche. Hence, benefits in kind are valued according to purchasing price paid by the Roche entity providing the respective transfer of value net of sales tax (VAT). This also applies to Roche's own products. The EFPIA Code of Practice does not require for the cost for drugs or study materials used in research & development to be reported as ToV.

Same approach is followed for POs as well.

How are transfers of value to HCOs handled, from which HCPs benefit?

The HCO receiving a transfer of value is always reported as sole beneficiary of this transfer of value, irrespective of the extent to which HCPs employed by the HCO or owning the HCO benefit from this transfer of value. In most of these cases an accurate representation of the benefit to individual HCPs is not possible.

How are "late data" reported?

To be able to accurately disclose transfers of value for the respective reporting year by 30 June of the following year and to allow HCPs/HCOs to review the information prior to publication, only data available by 28/29 February are included in Roche's initial publication of the respective disclosure report. Data becoming available only after the cutoff date (e.g., due to late submission of an invoice related to a transfer in the reporting year) will be included in

an update of the respective disclosure report published together with the disclosure report for the next reporting period in by 30 June of next year.

For further information about the EFPIA Code of Practice can be found here: SIFFA

HCPs/HCOs/POs contact Roche at riga.info_Latvija@roche.com or 67039831to request further information about or correction of transfers of value disclosed by Roche.

General inquiries about Roche's disclosure of transfers of value to HCPs, HCOs and POs shall be directed at riga.info_Latvija@roche.com or 67039831.

8. Definitions

Term	Definition
CER	Constant exchange rate
CRM	Customer relationship management
DPC	Data Protection Coordinator
DPO	Data Protection Officer
EFPIA	European Federation of Pharmaceutical Industry Associations
GCV	Global Customer View
GDPR	EU Regulation 2016/679 (the "General Data Protection Regulation" or "GDPR")
GSD	Grants, sponsorships and donations
HCO	Healthcare organization
HCP	Healthcare professional
iHCP	Roche's HCP engagement approval system
IT	Information technology
OECD	Organization for economic cooperation and development
Pharma HCO	Pharma healthcare compliance office
POMs	Prescription-only-medicines
POs	Patient organizations
R&D	Research & development

Term	Definition
ToV	Transfer of value
UCI	Unique customer identifier
US	United States of America
VAT	Value-added/sales tax

9. References

Reference No.	Available Location
1	EFPIA Code of Practice Disclosure Methodology
2	Countries in scope of the EFPIA Code of Practice Reporting
3	EFPIA Reporting Affiliates Contact List
4	EFPIA Code of Practice
5	Roche EFPIA Code of Practice iHCP Information
6	Pharma Directive on Grants, Sponsorship and Donations
7	Decision Memo R&D
8	Decision Memo ToV Date
9	Decision Memo Exchange Rates
10	Decision Memo VAT and Withholding Tax
11	Disclosure Due Dates
12	Pharma Core
13	Data Cleansing Guideline
14	UCI Slide Deck
15	CRO Excel template
16	Low Volume Excel template
17	iHCP SOP

Reference No.	Available Location
18	iHCP User Guide
19	Consent Management Guideline
20	Transparency Spend Reporting Guideline
21	Information and Data Correction Request Form
22	EFPIA Transparency Dispute Management Guideline
23	Dispute Management Process
24	Data Correction Tracking Form
25	External communication guidance
26	Sustainability Reporting Guidance (Economic Performance)

10. Revision History

Version	Dates Active	Reasons for Changes
2.6	31-Jan-2019	Update according GDPR and to reflect current approach
2.7	31-Dec-2020	Update in light of the revised EFPIA Code of Practice and changes introduced to PO reporting

11. Authorship, Review and Approval

	Name	Global Function/Role
Author	Barbara Brunner	GBPS
Reviewers		
Approver		