

Methodology note

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) and healthcare organizations (HCOs) 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 and HCOs, and therefore fully supports the EFPIA disclosure code.

- Roche works with HCPs and HCOs 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.
- 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 Disclosure Code?

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

The 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 first disclosure report was published in June 2016 and pertains to transfers of value made in 2015.

Further information about the EFPIA Disclosure Code and the Icelandic code can be found here: www.frumtok.is

To which countries does the EFPIA Disclosure Code apply?

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

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

What types of payments are disclosed?

Roche's 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 Disclosure Code and may include situation such as anonymous participation of a HCP in market research.

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 will be disclosed on company websites. In some countries the report will be published on a central platform.

Here in Iceland Roche's disclosure report has been published on a central platform www.frumtok.is.

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 Iceland was published June 30th 2016, and reports transfers of value made in 2015. Data will remain in the public domain for a period of three years.

What is the definition of HCP and HCO in the context of Roche's EFPIA disclosure report?

The EFPIA Disclosure Code 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.

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 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.

To which Roche companies does the EFPIA disclosure code 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. Transfers of value made by Chugai are disclosed separately.

Have HCPs/HCOs consented to Roche disclosing this information?

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

Roche has sought to secure consent of all 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).

How is Roche's disclosure report affected if an HCP/HCO withdraws consent?

Consent is voluntary and can be withdrawn at any time, which might require Roche to update already published disclosure reports. The absence or refusal of consent of an HCP or HCO will result in the ToV data being disclosed in aggregate.

Have HCPs/HCOs been given access to the transfer of value information?

Yes, a preview of the actual transfer of value data, in the format in which they will be disclosed, has been sent to each of our HCP/HCO partners.

How are corrections of errors handled?

Errors detected in Roche's EFPIA Disclosure reports will be corrected in a timely manner. This applies to all Disclosure reports available in the public domain. This is also valid for consent withdrawal of HCPs/HCOs.

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. 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 Disclosure Code, 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.

How are transfers of value in kind benefits valued?

In the context of the EFPIA Disclosure Code, 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 Disclosure Code does not require for the cost for drugs or study materials used in research & development to be reported as ToV.

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 May 25th 2016 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 June 2017.

For further information about the EFPIA Disclosure Code and the Frumtök code can be found here: www.transparency.efpia.eu and www.frumtok.is/sidareglur

HCPs/HCOs contact Roche at Icepharma: Áslaug G. Jónsdóttir, Business Unit Lead, aslaug@icepharma.is, to 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 and HCOs shall be directed at Frumtök - The Icelandic Association of Pharmaceutical Industry, contact person is Jakob Falur Garðarsson, managing director, jfg@frumtok.is, mobile: 00354 862 4272, phone: 00354 855 8955.
