

## 2016 EFPIA Methodological Note – Eli Lilly Malta

This Methodological Note describes the methods utilized to meet the requirements outlined in the **EFPIA HCP/HCO Disclosure Code**.

The report excludes Patient Organisations, as reporting obligations will be fulfilled via the **EFPIA Patient Organisation Code**.

With respect to **treatment of multi-year contracts**, reports include Transfers of Value (ToV) provided during the given calendar year. Reports are disclosed in local **currency**. VAT, as well as other **taxes** are excluded when administratively feasible. For HCPs/HCOs who pay their own withholding taxes, the tax amount is included in the total amount paid.

This report includes ToV associated with respective local **foundations** as well.

In regards to **date of recognition** of ToV, the **Fee for Service** ToV date is equal to the payment date. For **Contribution to Cost of Events**, ToV date is equivalent to the day(s) relating to the event/meeting.

With respect to **ToV amounts** for **Fee for Service** and **Contribution to Cost of Events**, actual amounts are applied to payments and/or related reimbursable expenses, as well as flights, long-haul bus, rail and private transport. Averages are applied to registration fees, accommodation and group transports. Complimentary registration fees are not used for the calculation of the average amount. Complimentary accommodation is not included in the average amounts for ToV.

With respect to **HCP/HCO Definitions**, as a general rule, EFPIA definitions are followed, and any ToV provided to HCPs/HCOs are reported within the relevant categories.

Regarding **HCP/HCO Consent**, consent determines the relevant category where the ToV are disclosed. As a general rule, HCP consent is required, and HCO consent is not required for disclosure. Certain countries also require HCP consent to properly report self-incorporated HCP ToV in the HCO section to appropriately reflect local treatment of self-incorporated HCPs.

If consent is granted, all ToV are disclosed at the individual named level. If consent is not granted, all ToV are disclosed in the aggregate unnamed section of the report. **Partial consent** (ToV disclosed on an engagement by engagement basis) is not an option.

With respect to **country unique identifiers**, applicable alternate identifiers are included in specified reports.

Regarding **cross-border transfer**, whether the ToV occur in or outside that country, ToV are disclosed in the country where the recipient has its principal practice address for HCP or country of origin for HCO.

**Donations and Grants to HCOs**, in cash or in kind or otherwise (i.e., product donations) that are comprised of healthcare professionals and/or that provide healthcare, are included in the report.

**Sponsorship Agreements with HCOs** or Third parties appointed by HCOs to manage an Event organised by HCOs, are included in the report.

**Registration Fees**, for Lilly Sponsored HCPs, are disclosed in the HCP section of the report. The ToV amount is equal to the average amount of registration fees purchased by Lilly for HCP meeting attendees.

For **Travel and Accommodation**, travel includes actual amounts for flights, long-haul bus, rail and private transport; and average amounts for group transports. The accommodation ToV amount is equal to the average room rate for hotel rooms purchased by Lilly for HCP meeting attendees. Travel and Accommodation ToV are reported in the HCP section of the report.

With respect to **HCP Fee for Service & Consultancy**, Speaking & Consulting related engagements are included in the report.

With respect to **HCO Fee for Service & Consultancy**, Consultancy related engagements such as Consultantships, Fellowships, Retrospective Non-Interventional Studies, Healthcare Partnerships and Educational Services are included in the report.

**Related Expenses** agreed in the fee for service or consultancy contract include miscellaneous travel & accommodation expenses relevant to the contract. These expenses are included in the report unless the related expense is part of the fee and not administratively feasible to separate.

**Research & Development** disclosure includes Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the HCP Code). The disclosure includes both Lilly and CRO managed studies, and is included in the R&D section of the report.

Regarding **report corrections**, once reports have been published, HCP/HCO consent change requests or data corrections may require updates to reports that are publicly available. Once revisions have been made, the publicly available reports may need to be updated to reflect the changes.

**Published Date:** The publication date equals the date the report is generated via internal systems.