

AbbVie RO “AbbVie Biopharmaceuticals” in Ukraine 2015 Transparency Disclosure Methodological Notes

As a member company of EFPIA and Association of Pharmaceutical Research and Development (APRaD), RO “AbbVie Biopharmaceuticals” in Ukraine is committed to ensure that the nature and scope of transfers of value (ToV) with healthcare professionals (HCPs) and healthcare organisations (HCOs) are clear and transparent to the public. Therefore, RO “AbbVie Biopharmaceuticals” in Ukraine has published applicable ToVs provided directly or indirectly to HCPs or HCOs in calendar year 2015.

This Methodological Note provides guidance on how RO “AbbVie Biopharmaceuticals” in Ukraine has recorded and publicly reported this information in accordance with the current editions of Association of Pharmaceutical Research and Development (APRaD) Transparency Code.

Reporting period / Reportable ToV:

The AbbVie RO “AbbVie Biopharmaceuticals” in Ukraine 2015 disclosure includes applicable ToVs provided between 1 January 2015 and 31 December 2015 related to 2015 events.

A cut-off date has been defined for transactions to be eligible for current year reporting 12 February 2016. Transactions submitted after the date will be considered for the 2016 report.

Transparency Acknowledgment from HCPs or HCOs (where applicable):

Agreements between RO “AbbVie Biopharmaceuticals” in Ukraine and HCPs/HCOs relating to 2015 ToVs may have included a Transparency section where HCPs and HCOs were notified of AbbVie’s Transparency obligations.

Consent Approach:

HCPs and HCOs received a consent package including a letter explaining AbbVie’s commitment to Transparency and the options and rights they have in accordance with data protection legislation.

AbbVie will publish the, total value of the ToVs for those HCPs or HCOs (if applicable) that have provided express consent for such individual disclosure. HCOs or HCOs not providing consent will have their amounts included in an aggregate amount published per Association of Pharmaceutical Research and Development (APRaD) requirements.

AbbVie’s approach is to seek indefinite consent. If an HCP or HCO would like to withdraw a consent already provided, they can do so in writing to AbbVie.

Partial Consent:

AbbVie RO “AbbVie Biopharmaceuticals” in Ukraine supports full disclosure. If only partial consent is given by a HCP or HCO, all the TOVs of this HCP or HCO will be disclosed as aggregate, so not on an individual level.

Non Duplication:

Whenever possible, AbbVie RO “AbbVie Biopharmaceuticals” in Ukraine ToVs are disclosed to HCPs. If ToV is provided to the company of an HCP, the ToV will be attributed to the company.

HCP/HCO number of recipients reported at an aggregate level:

Each category of ToVs reported at an aggregate level includes the number of HCPs/HCOs provided with a ToV. Each HCP/HCO that received a ToV is counted as one recipient in each category. The total number of recipients may therefore include individual HCPs/HCOs that received one or more ToVs during the reporting period.

Cross borders interactions:

AbbVie affiliates (worldwide) that have provided Ukraine HCPs/HCOs with a reportable ToV have been included.

Sponsoring payments made to more than one HCO:

In the case of sponsorship agreements where different HCO's have participated, it was assumed that each HCO received an equal share and was published at individual HCO level accordingly.

Pre disclosure:

During April-May, 2016, HCPs and HCOs that granted consent to disclose on individual level, received a statement with the details of ToVs to be reported to Association of Pharmaceutical Research and Development (APRaD) to provide an opportunity to verify and review the information to ensure it is accurate, prior to full submission to Association of Pharmaceutical Research and Development (APRaD) on 30 June 2016.

ToV Definitions:HCP ToV Definition, such as:

- Fee for Service and Consultancy
 - Speaker fee (including associated preparation work)
 - Advisory Boards and other consultancy engagements (including associated preparation work)
 - Chairing a meeting
 - Training
 - Educational/Scientific Events

Note: Where AbbVie knows the identity of a market research participant (single blind market research), the fee(s) will be disclosed under this category.

- Related expenses agreed in the Fee for Service or consultancy contract, such as:
 - Flights
 - Hotel
 - Other transportations costs (mileage, train, taxi, bus, underground, parking)

Note: Where incidental expenses are immaterial and unable to be disaggregated from the fees (due to system limitations), said expenses will be disclosed under the Fee for Service and Consultancy Fees category.

- Contribution to cost of events e.g. sponsorship for registration fees, travel and accommodation, such as:
 - Congress/Meeting registration
 - Flights
 - Hotel
 - Other transportations costs (mileage, train, taxi, bus, underground, parking)

HCO ToV Definition:

- Fee for service and consultancy, such as:
 - Speaker fee (including associated preparation work)
 - Advisory Boards and other consultancy engagements (including associated preparation work)
 - Chairing a meeting
 - Training
 - Educational/Scientific Events

- Related expenses agreed in the fee for service or consultancy contract, such as:
 - Flights
 - Hotel
 - Other transportations costs (mileage, train, taxi, bus, underground, parking)

- Contribution to cost of events e.g. sponsorship for registration fees, travel and accommodation, such as:
 - Congress/Meeting registration
 - Flights
 - Hotel
 - Other transportation costs (mileage, train, taxi, bus, underground, parking)

- Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an event, such as part funded independent education events. When sponsorship also included catering costs as part of a sponsorship package which included other forms of funding to enable the event to take place (e.g. logistical costs), then it was included as a ToV (sponsorship).
 - Where indirect sponsorship of an HCP occurs through an HCO, the ToVs will be disclosed in the name of the HCO recipient.
 - Where the AbbVie sponsorship is provided through a conference organiser, the ToV will be disclosed in the name of the recipient HCO.
 - Where a vendor is organising an event (via AbbVie provided sponsorship) on behalf of more than one HCO, then the ToVs will be disclosed in the name of each HCO recipient.

- Donations and Grants to HCOs and Benefits in Kind to HCOs

Date Methodology:

AbbVie followed the date methodology when determining which ToVs are in scope for current reporting cycle:

Event Date is defined as the date the expense occurred. ToV related to the following categories will use the Event Date when determining applicability for current year reporting requirements (e.g., did the event occur within the reporting period 1 January 2015 to 31 December 2015).

- Fee for Service and Consultancy: Expenses
- Contribution to Cost of Events: Registration Fees
- Contribution to Cost of Events: Travel and Accommodation

Paid Date is defined as the date the payment was provided to the covered recipient. ToVs related to the following categories use the Paid Date when determining applicability for current year reporting requirements (e.g., did the payment occur within the reporting period 1 January 2015 to 31 December 2015).

- Fee For Service and Consultancy: Fee
- Contribution to Cost of Events: Sponsorship Agreements
- Grants and Donations
- Research and Development

Note: For the current reporting year, any ToVs with a paid date in 2015 that relates to an event in 2014 will not be reported as the timing of the event occurred prior to the effective date (1 January 2015) of the EFPIA Disclosure Code requirements.

Out of Scope:

Transfers of value that:

(i) are solely related to over-the-counter medicines

(ii) are not listed in Article 3 of this Code, such as items of medical utility, meals and drinks and medical samples

(iii) are part of ordinary course of purchases and sales of medicinal products by and between AbbVie and HCP (such as a pharmacist) or an HCO

VAT:

Where applicable, disclosure of HCP and HCO payments include VAT

Social Benefits:

Where applicable, disclosure of HCP and HCO payments does not include Social Benefits

Withholding Taxes:

Where applicable, for services provided in locations outside of Ukraine, ToV amounts will be reported as in the contract agreement.

Currency:

All information is reported in UAH.

Exchange Rate:

Where transfers of value were captured in foreign currency, amounts were converted to local currency based on Monthly Average Rates. Month determined by ToV date.

Rounding:

For each HCP/HCO, ToVs for each reporting category are rounded to the nearest UAH. The Total Amount for each HCP/HCO represents the sum of the reporting category amounts.

Multiyear contacts:

For multiyear contracts, disclosure only includes ToVs applicable during the reporting period (1 January 2015 and 31 December 2015).



Research and Development:

For the purpose of disclosure, research and development (R&D) ToVs are ToVs to HCPs or HCOs related to the planning or conduct of:

- non-clinical studies
- clinical trials
- non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of HCPs specifically for the study.

The total aggregate disclosure includes transfers of value made by AbbVie RO “AbbVie Biopharmaceuticals” in Ukraine to HCOs, as well as those made to parent company and its subsidiaries.

Clinical trials with retrospective elements, including ToVs direct or indirect to HCOs, has been disclosed at an individual level as a fee for service.

Biological samples and investigational compounds will be excluded from R&D disclosures. These compounds are subject to provisions under the Clinical Trial Directive (their use is submitted in the clinical trial approval process).

Lending of laboratory equipment that is used exclusively for conducting a study and will be returned to AbbVie at the end of the study will not be disclosed in the R&D aggregate amount. This activity does not constitute a permanent benefit to the covered recipient.

Post Publication Disputes

AbbVie will review and investigate disputes with HCPs/HCOs relative to our transparency reports. Subject to AbbVie's internal review and approval, any changes resulting from disputes will be published from time to time.