

## **VJ Salomone Pharma, on behalf of AbbVie Transparency Disclosure Methodological Notes for Reporting Year 2018.**

As a member company of EFPIA and in accordance with the corresponding national code, AbbVie and VJ Salomone Pharma, as the distributor of AbbVie products in Malta (“VJ Salomone Pharma”) 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, VJ Salomone Pharma, on behalf of AbbVie, has published applicable ToV provided directly or indirectly to HCPs or HCOs for the 2018 calendar year.

This Methodological Note provides guidance on how VJ Salomone Pharma, on behalf of AbbVie, has recorded and publicly reported this information in accordance with the current editions of EFFPIA Transparency Code.

### **Reporting period / Reportable ToV:**

VJ Salomone Pharma, on behalf of AbbVie, 2018 disclosure includes applicable ToV during the period between 1 January 2018 and 31 December 2018.

Transactions processed after 8 February 2019 will be considered for the next report.

### **Transparency Acknowledgment from HCPs or HCOs (where applicable):**

Agreements between VJ Salomone Pharma, on behalf of AbbVie, and HCPs/HCOs relating to ToV may have included a Transparency section where HCPs and HCOs were notified of AbbVie’s Transparency disclosure obligations.

### **Consent Approach:**

HCPs or HCOs received correspondence explaining AbbVie’s commitment to Transparency and the options and rights they have in accordance with the data protection legislation.

AbbVie will publish the total value of the ToV for those HCPs or HCOs that have provided express consent for such individual disclosure. HCPs or HCOs not providing consent will have their amounts included in an aggregate amount published per EFFPIA requirements.

If an HCP or HCO would like to withdraw a consent already provided, they can do so in writing to AbbVie addressed to VJ Salomone Pharma, on behalf of AbbVie.

### **Partial Consent:**

VJ Salomone Pharma, on behalf of AbbVie, supports full disclosure. If only partial consent is given by an HCP or HCO, all the ToV of this HCP or HCO will be disclosed in aggregate.

### **Multiple Licensed HCPs:**

HCPs with licenses authorizing them to practice in more than one country, including Malta, may have ToVs disclosed in multiple country reports.

### **Non Duplication:**

Whenever possible, ToV are disclosed to the respective 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 ToV 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.

**Cross Border Interactions:**

Reportable ToV provided by AbbVie affiliates (worldwide) to Maltese HCPs/HCOs have been included.

**Sponsoring Payments Made to More Than One HCO:**

In the case of sponsorship agreements where different HCOs have participated, it was assumed that each HCO received an equal share and was published for each HCO.

**ToV Definitions:**HCPs 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, 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)

HCOs 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 and any other forms of funding (e.g. logistical costs) as part of a sponsorship package these are disclosed as a ToV (sponsorship).
  - Where indirect sponsorship of an HCP occurs through an HCO, the ToV will be disclosed in the name of the HCO recipient.
  - Where the AbbVie sponsorship is provided through a conference organizer, the ToV will be disclosed in the name of the recipient HCO.
  - Where a vendor is organizing an event (via AbbVie provided sponsorship) on behalf of more than one HCO, then the ToV 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 ToV 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 2018 to 31 December 2018).

- 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. ToV 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 2018 to 31 December 2018).

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

Note: Any ToV occurring prior to the EFPIA Disclosure Code Requirements' effective date (01 January 2015) will not be included in the disclosure report.

**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 payments does include VAT. Cross border ToV may or may not include VAT depending on the submitting source.

**Social Benefits:**

Where applicable, disclosure of payments does not include Social Benefits.

**Withholding Taxes:**

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

**Currency:**

All information is reported in Euro.

**Exchange Rate:**

Where ToV were captured in foreign currency, amounts were converted to local currency based on Monthly Average Rates.

**Rounding:**

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

**Multiyear Contracts:**

Activities with ToV, crossing calendar years may have the contracted full amount disclosed using the date of last payment.

**Research and Development:**

For the purpose of disclosure, research and development (R&D) ToV are ToV 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 ToV made by AbbVie VJ Salomone Pharma, on behalf of Abbvie, to HCPs/HCOs, as well as those made by its parent company, subsidiaries and joint ventures (as required by the partner agreement).



Clinical trials with retrospective elements, including ToV direct or indirect to HCPs/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.

**Post Publication Disputes**

AbbVie will review and investigate disputes with HCPs/HCOs relative to our transparency reports. Any changes resulting from this review will be published in an updated report.