

## **AbbVie Romania Transparency Disclosure Methodological Notes for Reporting Year 2020**

As a member company of EFPIA and ARPIM, AbbVie Romania 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. Disclosure is performed by AbbVie Romania in accordance with all requirements as set forth in law 95/2006 and Order of Ministry of Health 194/2015. Therefore, AbbVie Romania has published applicable ToV provided directly or indirectly to covered recipients (HCPs, HCOs Patient Organizations or other entities) as stipulated in OMoH 194/2015 in calendar year 2020.

This Methodological Note provides guidance on how AbbVie Romania has recorded and publicly reported this information in accordance with the current editions of ARPIM Transparency Code and Romanian Legislation.

### **Reporting Period / Reportable ToV:**

The AbbVie Romania 2020 disclosure includes applicable ToV during the period between 1 January 2020 and 31 December 2020.

Transactions processed after 29 January 2021 will be considered for the next report.

### **Transparency Acknowledgment from HCPs or HCOs:**

Agreements between Romania and covered recipients relating to ToV may have included a Transparency section where HCPs and HCOs were notified of AbbVie's Transparency disclosure obligations.

### **Multiple Licensed HCPs:**

HCPs with licenses authorizing them to practice in more than one country, including Romania, may have ToV 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.

### **Cross Border Interactions:**

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

### **Pre-Disclosure:**

During March 2021, HCPs received correspondence containing the details of ToV to be reported according to ARPIM and Romanian Legislation requirements. AbbVie's intention was to provide an opportunity for HCPs to verify and review the information to ensure it is accurate, prior to disclosure on 31 March 2021.

## 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 professional conference organizer (PCO), 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:

**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 2020 to 31 December 2020).

- 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 OMOH 194/2015 effective date (01 January 2015) will not be included in the disclosure report.

**Out of Scope:**

No specific exclusions noted; however, samples, gifts and educational items will not be reported, for these items are either banned or do not fall within the scope of this law.

**VAT:**

Where applicable, disclosure of payments does not include VAT. Cross border ToV may or may not include VAT depending on the submitting source.

**Social Benefits:**

Where applicable, disclosure of payments may include Social Benefits.

**Withholding Taxes:**

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

**Currency:**

All information is reported in RON.

**Exchange Rate:**

Where ToV were captured in foreign currency, amounts were converted to local currency based on Monthly Average Rates. TOV in a foreign currency (non-RON) originating from a Romanian entity in Romania, were converted to RON using the currency conversion rate effective on the paid date.

**Rounding:**

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

**Multiyear Contracts:**

Some contracts with multiyear payments may be completely disclosed in calendar year 2020.

**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 Romania 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, have 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.