

## **AbbVie Romania 2016 Transparency Disclosure Methodological Notes**

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 ToVs provided directly or indirectly to HCPs or HCOs in calendar year 2016.

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 2016 disclosure includes applicable ToVs provided between 1 January 2016 and 31 December 2016 related to 2016 activities. Transactions processed after the 2015 cut-off date may be included in the 2016 report.

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

Agreements between AbbVie Romania and HCPs/HCOs relating to 2016 ToVs may have included a Transparency section where HCPs and HCOs were notified of AbbVie's Transparency obligations.

### **Cross borders interactions:**

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

### **Date Methodology:**

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

**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 2016 to 31 December 2016).

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

Note:

### **VAT:**

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

### **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 transfers of value were captured in foreign currency, amounts were converted to local currency based on Monthly Average Rates.

**Rounding:**

For each HCP/HCO, ToVs 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 contacts:**

Activities with ToVs 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) 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 Romania to HCOs, as well as those made by its parent company, subsidiaries and joint ventures.

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.

**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.