

AbbVie Romania Transparency Disclosure Methodological Notes for Reporting Year 2019

As a member company of EFPIA and ARPIM, AbbVie Romania is committed to ensure that the nature and scope of transfers of value (ToV) 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 2019.

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 2019 disclosure includes applicable ToV during the period between 01 January 2019 and 31 December 2019. Transactions processed after the 2019 cut-off date will be included in the 2020 report.

Transparency Acknowledgment from Covered Recipients (where applicable):

Agreements between AbbVie Romania and covered recipients relating to ToV include language informing them of AbbVie's transparency disclosure obligations.

Cross Border Interactions:

Reportable ToV provided by AbbVie affiliates (worldwide) to Romanian covered recipients have been included.

Multiple Licensed HCPs:

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

Date Methodology:

AbbVie followed the date methodology when determining which ToV are in scope for the 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 data collection period 1 January 2019 to 31 December 2019).

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

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

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:

Transfers of value in a foreign currency (non-Leu) originating outside of Romania were converted to Leu using a monthly average conversion rate. Transfers of value in a foreign currency (non-Leu) originating from a Romanian entity in Romania were converted to Leu using the currency conversion rate effective on the paid date.

Rounding:

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

Multiyear contacts:

Some contracts with multiyear payments may be completely disclosed in calendar year 2019.

Research and Development:

For the purpose of disclosure, research and development (R&D) ToV are ToV to covered recipients 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 covered recipients specifically for the study.

The total aggregate disclosure includes ToV made by AbbVie Romania to covered recipients, as well as those made by its parent company, subsidiaries and joint ventures.

ToV related to retrospective portions of clinical trials have been included as individual fee for service payments.

Biological samples and investigational compounds are 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 is not included in the R&D aggregate amount disclosed.

Post Publication Disputes

AbbVie will review and investigate disputes with covered recipients related to our Transparency reports. Any changes resulting from this review will be published in an updated report.