

AbbVie ROMANIA 2015 Transparency Disclosure Methodological Notes – Aggregated R&D

Following legal requirement by the Healthcare Reform Law no 95/2006 as amended (EO no 2/2014), and the Order of the Ministry of Health no. 194/2015, AbbVie Romania will publish Transfer of Value (ToV) to HCPs and HCOs according to the local law by 27 June 2016 on the platform <http://abbvietransparenta.ro>.

As a member company of ARPIM, R&D transactions have to be disclosed on an aggregated level for the calendar year 2015.

This methodological note provides guidance on how AbbVie ROMANIA has recorded and publicly reported this information in accordance with the current editions of ARPIM Disclosure Code.

Reporting period / Reportable ToV:

The AbbVie ROMANIA 2015 aggregated R&D disclosure includes applicable ToVs provided between 1 January 2015 and 31 December 2015 related to 2015 interactions.

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

Cross borders interactions:

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

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 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.

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 2015 to 31 December 2015).

- Fee For Service and Consultancy: Fee
- Contribution to Cost of Events: Sponsorship Agreements
- Grants and Donations (including donations of medicinal products)
- 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.

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

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 Invoice Exchange Rate or Monthly AbbVie Average Rates. Month determined by ToV date.

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:

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