



AbbVie Ltd 2016 ABPI Transparency Disclosure Methodological Notes

As a member company of ABPI and EFPIA, AbbVie is committed to ensure that the nature and scope of our Transfers of Value (ToV) with healthcare professionals and healthcare organisations should be clear and transparent to the public.

In order to comply with the requirements of the ABPI and EFPIA, we have published all Transfers of Value (provided directly or indirectly to any healthcare professionals or healthcare organisations via ABPI Central Disclosure Platform. The reporting period in each case will be the previous calendar year.

The aim of these guidelines is to provide a clear and simple explanation of how we have recorded and publicly reported this information in accordance with the current editions of the ABPI and EFPIA Transparency Codes and to thereby provide a basic framework for interpreting our report. In particular, we would like to outline the underlying methodology we intend to apply and to explain specific issues as to how we will apply this methodology in publishing the relevant information. In the event of any doubt over whether the details of any specific ToV needs to be published, we have assumed in the interest of transparency, that such details should be published (subject to the individual consent of the healthcare professional).

Reporting period:

The AbbVie Ltd 2016 disclosure includes applicable ToVs provided between 1 January 2016 and 31 December 2016 related to 2016 events. Transactions processed (paid) after the 2016 cut-off date, 13 January 2017, may be included in the 2017 disclosure. Any pending transactions that cannot be fully validated will be included in the next reporting cycle.

As a summary:

- 2015 ToVs with HCPs and HCOs paid after 31 December 2015 are being included in 2016 disclosure.
- 2016 ToVs with HCPs and HCOs between 1 January 2016 and 31 December 2016 have been reported at an individual level subject to consent requirements and at an aggregate level for those who have not provided consent.
- 2016 ToVs (1 January 2016 and 31 December 2016) with HCPs and HCOs paid after 13 January 2017 will be included in next year's disclosure.

Transparency Acknowledgment from HCPs:

- Agreements between AbbVie Ltd and HCPs/HCOs relating to 2016 ToVs included a Transparency clause where HCPs and HCOs were notified of AbbVie's Transparency obligations. In the particular case of HCPs, agreements stated that AbbVie Ltd will be requesting their consent declaration to disclose their ToV at an individual level

Consent Approach:

HCPs received a consent package including a letter explaining AbbVie's commitment to Transparency and the options they have in accordance with their data protection rights to disclose transfers of value between AbbVie and them. If this consent was denied, AbbVie will only publish the total value of the ToVs without specifying names of recipients.

In the majority of cases, consent declarations were sent electronically (via email) and in a very few cases by post. AbbVie's consent to approach is indefinite. If an HCP would like to opt out from the individual disclosure they will need to communicate this in writing to the company.

Partial Consent:

AbbVie Ltd supports full disclosure. If partial consent is requested by a HCP, all TOVs in respect of this HCP will be disclosed as aggregate.

Non Duplication:

Limited company payments are disclosed at HCP Level when the HCP is identifiable. If the HCP requests their ToV to be disclosed as a Limited Company, then information was reported at an individual level as an HCO.

HCP number of recipients reported at an aggregate level for Reporting:

In agreement with latest ABPI HCP aggregate guidance (March 2017) each of the four columns to which aggregate ToVs can be attributed (Registration fees, Travel and accommodation, Fees and Related expenses agreed in the fee for service or consultancy contract) had been completed independently with the three rows of information required.

- Aggregate amount attributable to transfers of value to such Recipients
- Number of Recipients in aggregate disclosure
- Number of Recipients disclosed in aggregate as a % of all Recipients (individual & aggregate disclosures)

So that for each column of spend all of this information is completed, resulting in:

- The amount of money spent on registration fees that is not individually disclosed
- The number of individuals that received this money for registration fees who are not individually disclosing
- The percentage of all of the individuals receiving ToVs that this number represents.

Abbvie Ltd has also completed the ‘Total Optional’ column for ABPI to be able to capture the correct split between aggregate and individual reporting of HCPs.

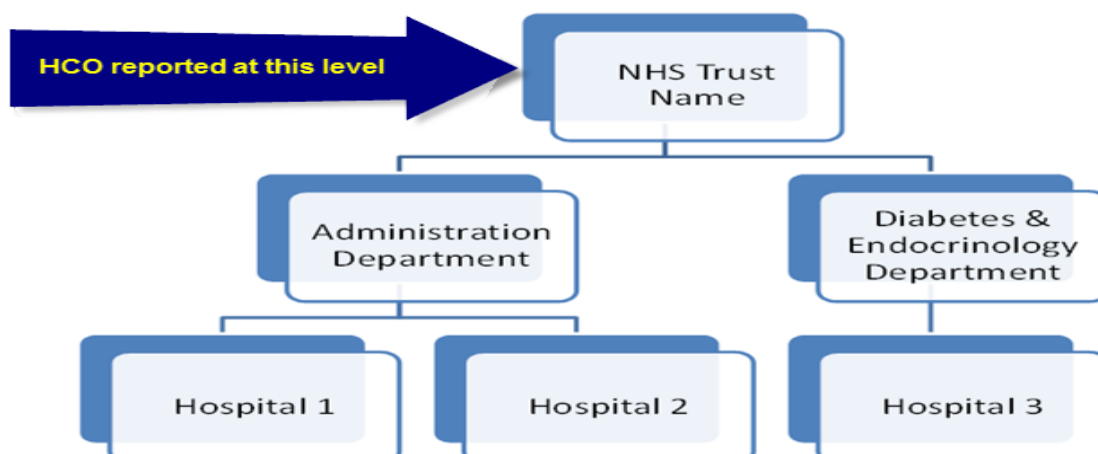
The total numbers of aggregate recipients represents number of HCPs that received a transfer of value and decided to disclose at an aggregate level.

Cross borders interactions:

All countries (worldwide) regardless of their local Transparency obligations that have provided UK HCPs with a Transfer of Value from 1 January 2016 to 31 December 2016 have been reported.

HCO disclosure:

Where it has not been possible to identify an individual hospital or department within an organisation, the HCO will be reported at the highest organizational level as displayed below:



Sponsoring payments made to more than one organisation

In the case of sponsorship agreements where different Trusts have participated, it was assumed that each organisation receives an equal share and will publish this accordingly.

Pre disclosure:

During February and March 2017, all HCPs that granted consent to disclose at an individual level, received a statement with the detail of Transfers of Value to be reported to the ABPI to provide an opportunity to verify and review the information prior to full submission to the ABPI on 31 March 2017.

Transfer of Value Definitions:

HCP Transfer of Value 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
- 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 transportations costs (mileage, train, taxi, bus, underground, parking)

HCO Transfer of Value 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 as part of a sponsorship package which included other forms of funding to enable the event to take place (e.g. logistical costs), then it was included as a transfer of value (sponsorship).
 - 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 ToVs will be disclosed in the name of each HCO recipient.
- Donations and Grants to HCOs and Benefits in Kind to HCOs
 - Funding or in-kind benefits provided to healthcare organisations which enhance patient care, or benefit the NHS and maintain patient care.
 - MEGS as defined in ABPI Code clause 19.

Date Methodology:

AbbVie followed the date methodology when determining which ToVs 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 2016 to 31 December 2016).

- 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. 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: For the current reporting year, any ToVs with a paid date in 2016 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.

Joint Working:

There were no joint working initiatives in 2016.

Out of Scope:

Meals, drinks, 'samples and starter packs' (as defined by Clause 17 of the 2016 ABPI Code), package deals, promotional aids and patient support items (all as defined by Clause 18 of the 2016 ABPI Code) are out of scope.

VAT:

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

Withholding Taxes:

Where applicable, for services provided in locations outside of the UK, Transfer of Value amounts will be reported as per the Contract agreement.

Currency:

All information is reported in GBP.

Exchange Rate:

Where applicable, all interactions in foreign currency were translated at a monthly close corporate exchange rate (source: Bloomberg)

Multiyear contacts:

For multiyear contracts, disclosure only includes ToVs applicable during the reporting period (1 January 2016 and 31 December 2016).

Non-Monetary Transfers of Value:

There are non-monetary ToVs currently in place.

Working with other pharmaceutical companies

There are currently no working arrangements with other pharmaceutical companies.

Medical devices transfers of value

There are currently no Transfers of Value in respect of medical devices.

Websites to Patients:

Benefits provided to healthcare organisations which are acknowledged to be for direct patient benefit as opposed to HCO benefit (such as patient websites) have been treated as exempt from transparency reporting requirements under Clause 24 of the 2016 ABPI Code.

R&D

For the purpose of disclosure, research and development transfers of value are transfers of value to health professionals or healthcare organisations related to the planning or conduct of:

- Non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice)
- Clinical trials (as defined in Directive 2001/20/EC)
- Non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of health professionals specifically for the study.

The total aggregate disclosure includes transfers of value made by AbbVie Ltd to UK healthcare organisations, as well as those made to parent company and its subsidiaries.

Clinical trials with retrospective elements, including ToVs direct or indirect to HCOs, have been disclosed at an individual level as a fee for service.

**Other Relevant Decision Makers (ORDM)**

In cases where consent was requested from ORDM who will not believe to be HCPs or ORDMs, their ToVs will be reported as aggregate.

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.