

Amicus Therapeutics UK Limited 2016 Transparency Disclosure Methodological Notes

As a reporting non-member of ABPI, an EFPIA affiliated organization, Amicus is committed to ensure that the nature and scope of transfers of value (ToV) with healthcare professionals (HCPs) and healthcare organizations (HCOs) are transparent to the public. Therefore, Amicus has published applicable ToVs provided directly or indirectly to HCPs or HCOs in calendar year 2016.

This Methodological Note provides guidance on how Amicus has recorded and publicly reported this information in accordance with the current edition of ABPI's Transparency Code.

Reporting period / Reportable ToV:

The Amicus 2016 disclosure report includes applicable ToVs provided between 1 January 2016 and 31 December 2016. Cross border transactions have been included as appropriate and in accord with the ABPI and any transaction submitted after 31 December 2016 will be considered for the next annual report.

Consent Approach:

To satisfy the reporting requirements of the ABPI, Amicus complied with the governing data protection laws of [enter country name]. Amicus will publish the total value of the ToVs for HCPs and HCOs, as appropriate that have provided express consent for such individual disclosure. HCPs or HCOs, as appropriate, not providing consent will have their amounts included in an aggregate amount published per ABPI requirements.

HCP/HCO number of recipients reported at an aggregate level:

Each category of ToVs reported at an aggregate level includes the number of HCPs/HCOs provided with a ToV. Each HCP/HCO that received a ToV is counted as one recipient in each category. The total number of recipients may therefore include individual HCPs/HCOs that received one or more ToVs during the reporting period.

Cross borders interactions:

Amicus affiliates (worldwide) that have provided United Kingdom HCPs/HCOs with a reportable ToV have been included.

ToV Definitions:

HCP ToV Definition, such as:

- Fee for Service and Consultancy
 - Speaking 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)

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)

HCO ToV Definition, such as:

- Fee for Service and Consultancy
 - Speaking 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)
- 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 ToV (sponsorship).
 - Where indirect sponsorship of an HCP occurs through an HCO, the ToVs will be disclosed in the name of the HCO recipient.
 - Where the Amicus 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 Amicus 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

Date Methodology:

Amicus followed the date methodology below when determining which ToVs are in scope for the 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

VAT:

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

Withholding Taxes:

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

Currency:

All information is reported in **[local currency]**.

Exchange Rate:

Where transfers of value were captured in foreign currency, amounts were converted to local currency based on Monthly Average Rates. Month determined by ToV date.

Rounding:

For each HCP/HCO, ToVs for each reporting category are rounded to the nearest GBP amount. 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 2016 and 31 December 2016).

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 clinical trials and research. The total aggregate disclosure includes transfers if value made by Amicus clinical trial sites.

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 Amicus 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.

Post Publication Disputes

Amicus will review and investigate disputes with HCPs/HCOs relative to our transparency reports. Subject to Amicus' internal review and approval, any changes resulting from disputes will be published from time to time.

Enquiries relating to Amicus transparency reports should be addressed to compliance-review@amicusrx.com