

Intercept Pharma – UK Transparency Disclosure Methodology Statement 2016

The EFPIA Disclosure Code 2014 requires all member companies to document and disclose certain Transfers of Value (“ToVs”) they make, directly or indirectly, to or for the benefit of, healthcare professional (“HCPs”) or healthcare organisations (“HCOs”). The EFPIA Code is implemented in the UK by the Association of the British Pharmaceutical Industry (“ABPI”) Code of Practice.

As a member company of the ABPI, Intercept Pharma Europe Ltd. (“Intercept”), is committed to ensuring transparency around interactions with UK HCPs and HCOs including the nature and scope of our ToVs. Intercept discloses these in accordance with its commitment to the ABPI Code and the relevant data privacy legislation.

This note describes the methodologies and business rules used by Intercept to meet its reporting and disclosure obligations in line with the ABPI Code of Practice.

Definitions:

“Healthcare Professional (HCP)”: A member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in the UK.

In the UK, HCP includes ‘other relevant decision makers’ (“ORDMs”).

If an HCP has set up a private company, as a sole-director, they will be considered an HCP for disclosure purposes.

- “Healthcare Organisation (HCO)”: A healthcare, medical or scientific association or organisation (e.g., a hospital, clinic, foundation, university or other teaching institution or learned society) whose business address, place of incorporation or primary place of operation is in the UK; or an organisation through which one or more HCPs provide services.
- “Research and Development (R&D)”: HCP/HCO transfers of value that relate to the planning and conduct of
 - Non-clinical studies (as defined in OECD Principles on Good Laboratory Practice);
 - Clinical trials (as defined in Directive 2001/20/EC);
 - Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study. This also includes investigator sponsored research (IIRs).

Transfers of Value

ToVs made directly to an HCP/HCO or indirectly on behalf of Intercept through a third party will be disclosed within this report.

ToVs are reported based on payment date or transfer of value date (e.g. the date a flight was taken).

The following ToVs made to HCPs and HCOs will be included within our disclosure report:

	Example activities	HCP*	HCO
<u>Fees for Service</u> ToVs resulting from or related to a contract where the HCP / HCO provides services.	Advisory Boards Speaker services Consulting services	✓	✓
<u>Related expenses to the fees for service contract</u> ToVs directly related to a fee for service contract.	Travel (incl. flights, taxi, train, parking) Accommodation	✓	
<u>Sponsorship agreements</u> ToVs made to either the HCO directly or to an event organizer or other third party appointed by the HCO to manage an educational or scientific event.	Congress sponsorship Stand / booth sponsorship		✓
<u>Registration fees</u> ToVs related to the registration of an HCP / HCO to attend a congress or educational event.	Registration fees	✓	✓
<u>Travel and accommodation relating to a congress or educational event</u> ToVs related to travel and accommodation in support of an HCPs attendance at a congress or educational event.	Travel (incl. flights, taxi, train, parking) Accommodation	✓	
<u>Donations</u> Funding provided for an unspecified purpose.	Donations		✓
<u>Grants</u> Funding provided to support a specific activity that provides educational benefit or enhances patient care.	Grants		✓
<u>Research and development</u> ToVs related to non-clinical studies, clinical studies and non-interventional studies.	Investigator site fees Advisory boards related to R&D Expert meeting services Data safety monitoring boards Steering Committee meetings Investigator sponsored research	✓	✓

*HCP disclosure will be made based on named individual if consent has been obtained, refer below for further information on our consent methodology.

Research and development will be disclosed in aggregate for all UK transfers of value.

Consent

Data protection law requires Intercept to collect consent from UK HCPs to disclose ToVs against named individuals. Intercept has contacted relevant UK HCPs to seek their consent to disclose all interactions entered into with Intercept. Where consent has not been granted, Intercept will disclose ToVs in aggregate and will not publish against the named individual.

Where no response has been received, Intercept has followed up with the HCP once. Where still no response is received, the ToVs have been disclosed in aggregate as we require an opt-in decision.



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UK HCPs have the right to withdraw consent at any time. If Intercept receives such a withdrawal of consent, Intercept will, within a reasonable period, move the relevant ToV data into the aggregate category.

HCO consent is not required to be collected in the UK.

Pre-disclosure validation

Intercept has made reasonable efforts to ensure completeness and accuracy of our disclosable spend and has worked closely with third party vendors and agencies to collect relevant information. In order to maintain transparency in our reporting, Intercept has provided UK HCPs, involved in non-R&D activities, a statement for review and validation prior to Intercept's report submission to the ABPI. If no response has been received to correct the data in the statement, Intercept has assumed this is accurate for disclosure purposes.

Country of disclosure

Intercept discloses ToVs based on the HCPs principal place of practice. If a UK HCP operates in more than one country, Intercept will select one country to be the primary principal place of practice and disclose in that country.

Currency

Intercept discloses ToVs to UK HCPs and HCOs in GBP. Where ToVs are made in another currency, the invoice amount will be converted into GBP using the exchange rate applied by our Finance team for the month in which the payment or ToV was made. The exchange rate used is based on data from Commonwealth Foreign Exchange. Amounts disclosed may therefore vary slightly from the exact amounts paid to HCPs and HCOs.

Tax

Intercept discloses all ToVs excluding VAT and other applicable taxes.

Timing & multi-year contracts

Intercept discloses all ToVs made between 1 January and 31 December by 30 June of the following year. Where an interaction with a UK HCP or HCO runs for more than one year, Intercept will disclose ToVs made in the year of payment or transfer.

Cancellations and non-participation

ToVs will only be disclosed where the benefit has been received. In the event of a cancellation or where an HCP does not receive the benefit due to non-participation, Intercept will not disclose ToVs against the HCP.

Disclosure and document retention periods

Intercept will maintain public disclosures for a minimum of three years and will retain records for at least five years after the end of the calendar year to which they relate.