

Intercept Pharma – UK Transparency Disclosure Methodology Statement 2021

The EFPIA Disclosure code is a code of conduct that requires all EFPIA member companies and companies that are members of EFPIA member associations to document and disclose certain transfers of value (“ToVs”). The EFPIA Code is implemented in the UK by the Association of the British Pharmaceutical Industry (“ABPI”) Code of Practice.

Intercept documents and discloses transfers of value made directly or indirectly, to or for the benefit of, healthcare professional (“HCPs”), healthcare organisations (“HCOs”) or other relevant decision makers (“ORDMS”), patient organisations (“POs”), individuals representing patient organisations, and members of the public, including patients and journalists (“Other Disclosable Entity”).

As a member company of the ABPI, Intercept Pharma Europe Ltd. (“Intercept”), is committed to ensuring transparency around interactions with UK HCPs, ORDMS, HCOs, POs and ODEs 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”). Intercept regards all employees of NHS or private HCOs as HCPs or ORDMs regardless of employment status.

If an HCP has set up a private company, as a sole director, they will be considered an HCP for disclosure purposes. Part-time employees or contractors of Intercept (including employees or contractors of Intercept’s appointed agencies and third-party vendors) who are not also an employee of an HCO would fall outside the scope of disclosure for ToVs made by Intercept. For example, if an employee or contractor is providing full time services to Intercept (or to Intercept’s appointed agencies or third-party vendors) and they are not also employed by an HCO then this would not be considered as reportable.

- “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.
- “Individuals representing patient organisations” means a person who is mandated to represent and express the views of a patient organisation.
- “Other Disclosable Entity (ODE)”: Individuals representing patient organisations, and members of the public, including patients and journalists.
- “Patient organization (PO)”: An organisation mainly comprising of patients and/or caregivers or any user organisation such as a disability organisation, carer or relative organisation and consumer organisation that represents and/or supports the needs of patients and/or caregivers.
- “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 (ISRs).

Transfers of Value

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

The disclosure of transfers of value to a PO must include both the monetary value and a description of that support to enable the reader to understand the nature of that support or the arrangements.

ToVs made to ODEs are not disclosed by name and include for each category the total number of ODE, the total monetary value and a description of the support provided.

The following ToVs will be included within our disclosure report:

	Example activities	HCP*	HCO	PO	ODE
Contracted Services ToVs resulting from or related to a contract where the HCP / HCO/PO / ODE provides services.	Advisory Boards Speaker Services Consulting Services Steering Committees	✓	✓	✓	✓
Related expenses to the contracted service ToVs directly related to a fee for service contract**.	Travel (incl. flights, taxi, train, parking) Accommodation	✓		✓	✓
Sponsorship agreements ToVs made to either the HCO/PO directly or to an event organizer or other third party appointed by the HCO/PO to manage an educational or scientific event.	Congress sponsorship Stand / booth sponsorship		✓	✓	
Registration fees ToVs related to the registration of an HCP / HCO to attend a congress or educational event.	Registration fees	✓	✓		
Travel and accommodation relating to a congress or educational event ToVs related to travel and accommodation in support of HCP attendance at a congress or educational event.	Travel (incl. flights, taxi, train, parking) Accommodation	✓			
Donations Non-financial support provided for an unspecified purpose.	Donations		✓	✓	
Grants Funding provided to support a specific activity that provides educational benefit or enhances patient care.	Grants		✓	✓	
Research and development 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	✓	✓		
Collaborative Working including joint workings	Joint Workings		✓	✓	

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

** In the event an HCP is contracted for services and is paid through an HCO that the HCP is part of, disclosure of the ToVs in respect of the contracted service will be made against such HCO that received the ToV, however, any "person" related expenses, such as travel and accommodation, will be reported on the HCP unless otherwise stated in the contract.

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

Nominal / small ToVs might be made to HCPs participating in "blind" market research. As Intercept does not (and will not) know the identities of the individual participants to such "blind" market research, Intercept has not reported any ToVs for such activities.

Consent Methodology

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



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publish against the named individual.

Where no response has been received, Intercept has followed up with the UK HCP once. Where no response is received (and an opt-in decision not provided), the associated ToVs have been disclosed in the aggregate category. 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 and PO consent is not required in order to disclose ToVs against named organisations in the UK. ODE disclosures are not made on a named basis and therefore consent is not required.

Pre-disclosure validation

Intercept has made reasonable efforts to ensure completeness and accuracy of our disclosable spend and has worked closely with appointed 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 with an individualized statement for review and validation prior to Intercept's report submission to the ABPI. If no contact is made to correct the data provided in the statement, Intercept has assumed that this is accurate for disclosure purposes.

Country of disclosure

Intercept discloses ToVs based on a HCP's or ODRM's 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 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. Amounts disclosed may therefore vary slightly from the exact amounts paid.

Taxes and Fees

Intercept discloses all ToVs excluding VAT, other applicable taxes and business-related fees (e.g. administration fees).

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, HCO, PO or ODE runs for more than one year, Intercept will disclose ToVs made in the year of payment or transfer.

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

Cancellations and non-participation

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

Disclosure and document retention periods

Intercept will maintain public disclosures for a minimum of three (3) years and will retain records for at least five (5) years after the end of the calendar year to which they relate.