

Methodological Note

ADVANZ PHARMA is committed to ensuring transparency of relationships with healthcare professionals (HCPs), healthcare organisations (HCOs), patient organisations (POs), other relevant decision makers (ORDMs) and other disclosable parties (ODPs) by operating within the Association of British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on Disclosure on Transfers of Value.

Transfers of Value (ToV) i.e. payments or benefits received by HCPs, HCOs, POs, ORDMs and ODPs during the 2022 calendar year will be disclosed on a central platform managed by the ABPI and made public on 30th June 2022.

Impact of acquisition by Advanz Pharma Corp. Limited

On July 2, 2022, the Advanz Pharma Corp. Limited acquired the ex-US entities of Intercept Pharmaceuticals, Inc. As a result, the transfers of value made during 2022 have been disclosed against the following entities:

- For the period of 1 January 2022 – 1 July 2022, all non-research related payments made to HCP, HCO, PO or ODPs are disclosed under Intercept Pharma UK & Ireland Ltd.
- For the period 2 July 2022 – 31 December 2022, all non-research related payments made to HCP, HCO, PO or ODPs are disclosed under Advanz Pharma UK & Ireland Ltd.
- For the period 1 Jan 2022 – 31 December 2022, all research related payments are disclosed under Intercept Pharma UK & Ireland Ltd.

The principles applied in this methodological note are relevant to the UK only.

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”). ADVANZ PHARMA 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 ADVANZ PHARMA (including employees or contractors of ADVANZ PHARMA’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 ADVANZ PHARMA. For example, if an employee or contractor is providing full time services to ADVANZ PHARMA (or to ADVANZ PHARMA’S appointed agencies or third-party vendors) and they are not also employed by an HCO then this would not be considered as reportable.

HCPs who have worked with ADVANZ PHARMA may ask for their fee to be paid to charity. ADVANZ PHARMA does not encourage this type of fee payment and all payments are normally made directly to the HCP; where payment to a charity may occur the disclosure is still made against the individual HCP.

- “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 Parties (ODP)”: 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).

Disclosure Categories

In 2022 ADVANZ PHARMA has disclosed the following financial & non-financial payments:

1. Transfers of value to healthcare professionals (HCPs):
 - i. Receipt of support for attendance at third party led educational meetings including registration fees and logistics (travel and accommodation). Costs related to subsistence (food) are not declared but the meal costs are regulated by strict industry guidelines;
 - ii. Contracted services and expenses relating to the consultancy services;
 - iii. Market access and market research costs where the identify of the individual is known to ADVANZ PHARMA, where these activities are “blind” or unknown to ADVANZ PHARMA, these disclosures are not made.
2. Transfers of value to healthcare organisations (HCOs):
 - i. For payments made to medical associations, healthcare organisations or institutions in relation to educational or scientific meetings. This includes direct funding such as sponsorship fees, fees paid for exhibition stands and indirect support such as logistics agency or subsidising the cost of registration fees;
 - ii. Fees for service paid to institutions, organisations or associations;
 - iii. Donations and grants for medical educational projects. ADVANZ PHARMA’s funding policies in these circumstances require that ADVANZ PHARMA has no influence over the details of the project. As ADVANZ PHARMA would not influence or select HCPs involved in such projects, ADVANZ PHARMA would disclose such payments under an HCO category where such definition is met by the independent company;

Note: Where ADVANZ PHARMA is requested by an HCO to provide a financial grant to assist its employees to attend third party medical meetings, where possible the payment will be disclosed against a named individual HCP. Where ADVANZ PHARMA is not aware of the identity of recipient HCPs, the grant is declared against the named healthcare organisation.
 - iv. Collaborative or joint working projects;
 - v. Benefits in kind will be disclosed against the HCO and must be supported by a written contract detailing the value of the benefit provided for disclosure purposes.
3. Transfers of value to patient organisations (POs):
 - i. Contracted services and expenses relating to the consultancy services;

- ii. For payments made to support funding of a medical or educational event or meeting. This includes direct and indirect support;
- iii. Donations and grants for medical educational or scientific projects;
- iv. Collaborative or joint workings.
- v. Benefits in kind will be disclosed against the PO and must be supported by a written contract detailing the value of the benefit provided for disclosure purposes.

The following categories were deemed out of scope for disclosure:

1. All costs associated with meetings run solely by ADVANZ PHARMA except for fees paid to individual HCPs providing services as speakers;
2. All costs associated related to OTC medicines and Medical Devices.

Data Privacy & Consent Methodology

In accordance with Data Privacy law, ADVANZ PHARMA has obtained and retained records of consent from HCPs on an individual activity basis prior to disclosing personal data such as individual transfers of value. Where permission has not been obtained or where HCPs have refused consent, ADVANZ PHARMA has declared the total spend as an aggregate figure given on a separate line entry within the relevant disclosure category and the % of non-consenting HCPs given as a percentage of the total HCPs receiving a ToV.

UK HCPs have the right to withdraw consent at any time. If ADVANZ PHARMA receives such a withdrawal of consent, ADVANZ PHARMA 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.

ODP disclosures are not made on a named basis and therefore consent is not required.

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

ToV Transaction Principles

Payments to Third Party Organisations for Services Provided by Individual HCPs

In some cases ADVANZ PHARMA contracts with HCPs through a third party agency. In such cases, ADVANZ PHARMA will disclose any payments made to the individual HCP by the service agency as if the payment had been made directly by ADVANZ PHARMA to that HCP.

VAT & Fees

For all ToVs, VAT and other applicable taxes and business-related fees (e.g. administration fees) are excluded.

Transaction Date

ToVs are reported based on payment date or transfer of value date (e.g. the date a flight was taken). Where an interaction with a UK HCP, HCO, PO or ODP runs for more than one year, ADVANZ PHARMA will disclose ToVs made in the year of payment or transfer.

Transfer in foreign currencies

ADVANZ PHARMA discloses ToVs in GBP (£). Where ToVs are made in another currency, the invoice amount will be converted into GBP using a monthly exchange rate. Amounts disclosed may therefore vary slightly from the exact amounts paid.

Multi-Year Projects

Where projects run for several years ADVANZ PHARMA will declare the amount paid relevant to the year in which each part of the payment was made. Thus a project which spans 4 calendar years and includes several individual transfers of value during that time will have four associated disclosures; one for each calendar year showing the value of the transfer made in that specific calendar year.

Cross-Border Payments

All disclosures are made in the country in which the HCP or HCO practice is located. Payments made to UK-based HCP or organisations by ADVANZ PHARMA overseas operations are disclosed within the UK.

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 ODP does not receive the benefit due to non-participation, ADVANZ PHARMA will not disclose ToVs against such HCP, HCO, PO or ODP.

Co-Marketing Projects

Where ADVANZ PHARMA jointly markets a product with another pharmaceutical company, ADVANZ PHARMA will only declare those payments made directly from ADVANZ PHARMA bank accounts and listed in the company records as part of its normal business operations. Transfers of value made by its co-marketing partners will be disclosed separately by those organisations.

Disclosure Principles

All transfers of value to UK based HCPs and HCOs, including research related spend is disclosed on the Disclosure UK website (<https://www.abpi.org.uk/reputation/disclosure-uk/>).

All transfers of value to UK-based POs and ODPs are disclosed directly on ADVANZ PHARMA's Website (<https://www.advanzpharma.com/ethics-transparency>).

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 ODPs are not disclosed by name and include for each category the total number of ODP, the total monetary value and a description of the support provided.

ADVANZ PHARMA 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.