

Angelini Pharma UK-I Limited

Methodology

**on Disclosure of Transfers of Value to HCPs, ORDMs and HCOs in
accordance with the Association of the British Pharmaceutical
Industry (ABPI) Code of Practice**

Disclosure reporting period: 2022

Angelini Pharma UK-I Limited – 6th floor Napier House – 24 High Holborn – London – United Kingdom
– WC1V 6AZ

Company number: 13473950 – VAT number: GB387249551

Contents

- 1. Introduction**
- 2. Definitions**
Events: details
- 3. Disclosure Methodology**
- 4. Data Protection and Consent Management**
HCPs
HCOs

1. Introduction

Angelini Pharma UK-I, is part of the Angelini Pharma Group. Angelini Pharma acts with Integrity, Trust, Respect and Transparency as per its core behaviours, and it collaborates with various stakeholders including Healthcare Professionals (HCPs), Healthcare Organizations (HCOs), Patient Organizations (POs) and Other Relevant Decision Makers (ORDMs) on a range of activities in the interest of patients.

Our full commitment to the highest ethics and integrity standards is a cornerstone of our values and our actions; transparency and openness of the interactions with Healthcare Professionals (HCPs), Healthcare Organizations (HCOs), Patient Organizations (POs) and Other Relevant Decision Makers (ORDMs) is one of the key Angelini core behaviour, leading our way of conducting ourselves and our business.

Angelini Pharma UK-I is committed to ensure that Transparency is respected, demonstrating the integrity of our relationships by disclosing transfers of value to HCPs, HCOs, ORDMs and POs. These requirements extend to contracted services provided by the public including patients and journalists.

Angelini Pharma UK-I is accountable for compliance with laws, regulations and industry codes in accordance with the Association of the British Pharmaceutical Industry (ABPI) Code of Practice and Transfers of Value (ToV) tracking and disclosure.

This methodological note describes the key aspects and clarifications on the nature of the Transfers of Value included in the disclosure.

2. Definitions

Healthcare Professional (HCP)

The term ‘healthcare professional’ includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine.

Healthcare Organisation (HCO)

The term ‘healthcare organisation’ means either a healthcare, medical or scientific association or organisation such as 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 health professionals or other relevant decision makers provide services.

Other Relevant Decision Maker (ORDM)

The term ‘other relevant decision makers’ particularly includes those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals.

PCO – Professional Conference Organisers:

Companies/individuals that specialise in the organisation and management of congresses, conferences, seminars and similar events (all “Events”). Commercial companies involved in organisation of travel (travel agencies) or accommodation (hotels, hospitality functions in hotels, etc.) are not considered PCOs.

ToV – Transfer of Value:

Economic transfers whether direct or indirect, both in cash or kind, carried out for either promotional aims or for the development and commercialisation of pharmaceuticals for human use subject to medical prescription.

The direct transfers are those carried out directly by Angelini Pharma for the benefit of the recipient. The indirect transfers are those carried out on behalf of Angelini Pharma by a third party. When ToV are made through a “Third party”, necessary arrangements have been made with third parties to ensure the obligations are fulfilled (Third parties representing Angelini Pharma or acting on behalf of Angelini Pharma, provide Angelini Pharma with a detailed tracker of the ToV made to HCPs and HCOs).

The following table illustrates activities reported according to the specific ABPI category and subcategory.

ABPI category	ABPI subcategory	Angelini Pharma UK-I Activities
Donations and Grants	n/a	Funds, assets, or services freely given to HCOs for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return. <u>Examples:</u> <ul style="list-style-type: none"> • Donations and grants • Independent investigator trials IIT (no-profit studies)
Contribution to Cost of Events	Sponsorship agreements	Sponsorship agreements with HCOs or with Third Parties (PCOs) to manage an Event. <u>Examples:</u> <ul style="list-style-type: none"> • Rental of booths • Advertisement (in paper, electronic or other format) • Sponsoring of speakers/faculty
	Registration Fees	<ul style="list-style-type: none"> • Fees paid for the HCP/HCO to attend events
	Travel and Accommodation	<ul style="list-style-type: none"> • Travel (e.g., flight, train, taxi, car hires, tolls, mileage reimbursement, parking) • Accommodation
Fee for services and consultancy	Fees	ToVs resulting from or related to contracts between the Company and HCOs / HCPs under which such HCOs / HCPs provide any type of services to the Company or any other type of funding not covered in the previous categories. <u>Examples:</u> <ul style="list-style-type: none"> • Speaker fees • Post-marketing surveillance studies • Retrospective Non-Interventional Studies • Development of education materials • General consulting / advising
	Related Expenses	ToVs relating to expenses agreed in the written agreement for consultancy / professional service, including: <ul style="list-style-type: none"> • Travel (e.g. flight, train, taxi, car hires, tolls, mileage reimbursement, parking) • Accommodation
Research and Development Transfers of Value	n/a	Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation N° 536/201412); or (iii) non-interventional studies that are prospective in nature, including relevant ToVs, e.g. for Investigator meetings.

Excluded from the list are hospitality related costs (cost of meals and drinks, except if its inseparable), informal and educational materials, logistical costs (room hire, technics etc.).

Events: details

Where an HCP/HCO does not receive the benefit due to a “no show” (occurring when a HCP fails to attend a meeting they were supposed to), the associated costs are not reported, such as the cost of cancelling a hotel booking or accommodation.

In case of partial attendance, only the benefits received are disclosed.

In case of cancellation of an Event, possible penalties for annulling a confirmed arrangement or order and cancellation fees are not disclosed.

3. Disclosure Methodology

Disclosure Scope	<p>Angelini Pharma UK-I documents and discloses Transfers of Value that are related to prescription-only medicines and that are made, directly or indirectly, to or for the benefit of a Recipient.</p> <p><u>Excluded ToVs:</u></p> <ul style="list-style-type: none"> • transfers of value that are solely related to over the counter (OTC) medicines or medical devices • costs of meals & drinks are excluded. However, where meals and drinks make up an integral and inseparable part of contributions to the cost of events or sponsoring as part of Sponsorship Agreements, they have been included in Contributions to Cost of Events. • items of medical utility for HCPs, informational and educational material and samples are not disclosed • ToVs to Patient Organisations are out of scope for this reporting and disclosed separately on the Angelini Pharma website • Group Calls
Date of ToVs	<p>The 2022 (January 1st – December 31st 2022) report discloses ToVs according to -cash principle; following some details:</p> <ul style="list-style-type: none"> • Where the ToV is a payment values are reported on the date of payment • Where the ToV is a benefit in kind, values are reported on the date the recipient received the benefit
Multi-year contracts	Where contracts are valid for more than one year, only ToVs made in the reporting period are captured and disclosed
Treatment of Value Added Tax (VAT) and other taxes	All transactions are reported in the net amount excluding the VAT and including the withholding tax (if any).
Currency	<p>The currency of the amounts disclosed in the report is the currency of the country where the disclosure is made, even if the payment of the ToV has been done in a different currency.</p> <p>In the case where ToV have been made in a different currency, the value is converted in local currency, based on www.oanda.com currency converter accessed on 29th March 2023.</p>
Language of disclosure	Disclosure is made in English
Retention of Records	Relevant records of the disclosure are retained for a minimum of 5 years after the end of the relevant Reporting Period
Cross border activities (ToVs made by other Angelini Pharma legal entities)	Angelini Pharma UK-I report includes also ToVs to HCPs whose address of principal practice and to HCOs whose address of registration is UK made by any other Angelini Pharma Companies in other countries

4. Data Protection and Consent Management

HCPs

To process HCP personal data for the disclosure, it is needed to obtain explicit consent from the healthcare professional to process his/her personal data.

- If the HCP provides consent for disclosure, the sum of all ToVs to that HCP during the reporting period is disclosed under his/her name according to the specific ToV category
- If the HCP does not provide consent to disclosure, all the ToVs in the reporting period are reported in the “aggregate” section, without stating the details of HCP.

Angelini Pharma UK-I requires HCP to provide the consent information once per reporting period / for each transaction with the HCP during the reporting period.

If the consent of HCP was withdrawn, relevant ToVs have been disclosed on an aggregated basis.

HCOs

Angelini Pharma UK-I does not obtain consents from HCOs to the disclosure of the transfers of value made to them because legal entities are not subject to personal data protection under the law and therefore the consent collection is not required.

Indirect ToV to HCPs via a third-party: Where HCPs have requested that their payment is made to a third-party such as their employer, the ToV has been reported as being received by the HCP.