

Angelini Pharma UK-I Limited

Methodology

on Disclosure of Transfers of Value to Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs), Healthcare Organisations (HCOs), Patient Organisations (POs), Patients and Journalists in accordance with the Association of the British Pharmaceutical Industry (ABPI) Code of Practice and Irish Pharmaceutical Healthcare Association (IPHA)

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1. Introduction

Angelini Pharma UK-I, a company of Angelini Pharma Group is a modern group, projected into the future and always proud of the values that are at the basis of its corporate philosophy.

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 Organisations (HCOs), Patient Organisations (POs), Other Relevant Decision Makers (ORDMs), patients and journalists 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 stakeholders 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 relationship with different stakeholders. These requirements extend to contracted services provided by the public including patients and journalists.

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

ToVs made by Angelini Pharma UK-I, including ToVs made by Arvelle Therapeutics - a company of Angelini Pharma Group - and by other Affiliates of the Angelini Pharma Group to HCPs/HCOs, whose principal address is in United Kingdom are published on the ABPI and IPHA Platforms¹ and the report remains in the public domain for a minimum of 3 years after the time such information is first disclosed.

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 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 Europe or an organisation through which one or more health professionals or other relevant decision makers provide services. If a healthcare organisation consists of only one health professional or other relevant decision maker, then it would be subject to the requirements in the Code regarding individual health professionals

¹ The central platform link is also accessible in the Transparency section into www.angelinipharma.com website.

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: company/individual specialized in the organization and management of congresses, conferences, seminars and similar events (all “Events”). Commercial companies involved in organisation of travel (travel agencies) or accommodation (hotels, banqueting 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 as per the ABPI and IPHA requirements.

Category	Subcategory	Angelini Pharma UK-I Activities
Donations and Grants	n/a	<p>Funds (grants), assets, or services (donations) 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.</p> <p><u>Examples:</u></p> <ul style="list-style-type: none"> • Donations and grants • Independent investigator trials IIT (no-profit studies)
Contribution to Cost of Events	Sponsorship agreements	<p>Sponsorship agreements with HCOs or with Third Parties (PCOs) to manage an Event</p> <p><u>Examples:</u></p> <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 & Accommodation	<ul style="list-style-type: none"> • Travel (e.g., flight, train, taxi, car hires, tolls, mileage reimbursement, parking) • Accommodation

Category	Subcategory	Angelini Pharma UK-I Activities
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 it is inseparable), informal and educational materials, logistical costs (room hire, technics etc.).

Events: details

Where a service provider does not receive the benefit due to a “no show” (e.g. 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
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	<ul style="list-style-type: none"> • 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. • Group Calls
Date of ToVs	<p>The 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 made in a different currency.</p> <p>In the case where ToV has been made in a different currency, the value is converted in local currency on the date payment was made or on the last day of the month, based on an online currency converter.</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 of service providers whose address of principal practice and to HCOs and POs whose address of registration is UK made by any other Angelini Pharma Country

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 and POs

Angelini Pharma UK-I does not obtain consent from HCOs and POs 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.

Patients and Journalists

As per the rules set out in the ABPI and IPHA, disclosure of payments made to members of the public, including patients and journalists, is carried out in aggregate and displayed on www.angelinipharma.co.uk. As a result, consent 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 (this is an EFPIA and ABPI Code of Practice requirement).

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