

METHODOLOGICAL NOTE

Disclosure of transfers of value for Orphalan UK Ltd

Introduction

The interaction between the pharmaceutical industry and healthcare professionals and healthcare organisations is important for the improvement of patient care through the exchange of knowledge and experience. Orphalan UK Ltd is committed to ensure any interactions meet the high standards of professionalism, integrity and transparency that are expected.

Orphalan UK Ltd markets Prescription Only medicines and complies with the obligation to identify, collate and disclose transfers of value to healthcare professionals and healthcare organisations in accordance with the ABPI Code of Practice requirements. The ABPI Code incorporates the EFPIA Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations (EFPIA Disclosure Code). For further information on these codes please visit <http://transparency.efpia.eu> or <https://www.abpi.org.uk>

Document Purpose and Scope

This Methodological Note summarizes the processes applied by Orphalan UK Ltd when preparing its disclosure report. The report includes transfers of value by Orphalan UK Ltd to healthcare professionals and healthcare organisations based in the United Kingdom and covers activity relating only to Prescription Only Medicines. Orphalan UK Ltd have no transfers of value to healthcare professionals and healthcare organisations based in other countries.

Definitions

Transfers of Value (ToVs)

A 'Transfer of value' is a direct or indirect transfer of value, whether in cash, in-kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is one made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value. Orphalan UK Ltd discloses direct and indirect ToVs.

ToVs are reported at the level of the first identifiable recipient which falls under the definition of an HCP/HCO. All ToVs reported by Orphalan UK Ltd have a monetary value which can be attributed to an individual HCP or HCO. Non-monetary ToVs have not been made.

Healthcare professional

A Healthcare Professional ("HCP") is defined as a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product.

Healthcare organisation

A Healthcare Organisation ("HCO") is 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.

Other relevant decision maker'

An Other Relevant Decision Maker ('ORDM') is someone 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 is not a health professional.

Collectively, HCP, HCO and ORDM are classed as recipients. Orphalan have made ToVs to HCPs and HCO only, there have been no ToVs to ORDMS.

Reporting Categories

Orphalan UK Ltd uses the ABPI Code's definition of the reporting categories as well as the terms "grant", "donation" and "sponsorship". The following provides examples of the specific activities reported under each category. Where Orphalan UK Ltd has made a ToV during the reporting period, this is stated by the activity definition.

Fees for services and consultancy

Speaker engagements: 1 ToV was made to 1 HCP for a speaker engagement.

Advisory Boards and individual consulting engagements: 5 ToVs were made to 5 HCPs for participating in an Advisory Board.

Related expenses agreed in the fee for service or consultancy contract (including travel and accommodation relevant to the contract)

No related expenses were made in this category.

Contribution to costs of events – registration fees

No costs were incurred in this category.

Contribution to costs of events – travel and accommodation

Travel and accommodation: 5 ToVs were made to 5 HCPs in this category.

Donations and grants to HCOs

Research grants: 1 ToV was made to 1 HCO in this category.

Contribution to costs of events – sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event

Funding an event in return for a display booth at the event or at an online virtual event, virtual space: 7 ToVs were made to 7 HCOs in this category.

Research and Development

No costs were incurred in this category.

Transfers of Value Inclusive Dates

The disclosure report includes all ToVs to recipients during the reporting period between 01 January 2021 and 31 December 2021. ToVs for which relevant data becomes available after the cut-off date on 31 December 2021 will be included in the following disclosure report.

For multi-year contracts or contracts covering multiple ToVs, each individual ToV will be disclosed according to the reporting period in which it was received.

Consent Management

In compliance with applicable data privacy regulations, the disclosure of personal data is dependent on the explicit consent of the HCP concerned.

Orphalan UK Ltd advocates transparency and encourages recipients to grant consent to full disclosure. Orphalan UK Ltd request consent through a consent to disclose form. This form contains an opt-in statement which the HCP signs if agreeing to consent and any subsequent ToVs are recorded against the recipient's name in the Disclosure database. Orphalan UK Ltd will disclose the ToV in the aggregate section of the disclosure report if the HCP does not consent to the disclosure of the data or if a response from the HCP is not received on time. Consent is voluntary and can be withdrawn at any time in writing.

During this reporting period, Orphalan has made 11 TOVs to 11 HCPs. 5 HCPS agreed to consent to disclose, 6 either declined or did not send a response. No HCPs agreed to some ToVs being disclosed individually and some in aggregate.

Disclosure Form

ToVs are disclosed on an annual basis and within six months after the end of the calendar year. The disclosure report remains in the public domain for a minimum of three years, unless required otherwise for legal reasons.

The disclosure report is published on the ABPI central platform <https://search.disclosureuk.org.uk/>.

Financial Considerations

Orphalan UK Ltd discloses the ToV at gross or net value depending on the underlying invoice. VAT is applicable where VAT has been paid. The ToV will be calculated based on the actual amount received by the recipient, either in kind or in cash.

ToVs are disclosed in United Kingdom Sterling and are rounded up to the nearest single pound. ToVs in foreign currencies are converted into Sterling using the appropriate currency conversion rate, calculated at the time the ToV was made, which may be different to the time it was utilised.

ToVs to multiple recipients are, when possible, disaggregated. Where an exact disaggregation is not possible, the ToV is divided by the total number of recipients.