

## METHODOLOGICAL NOTE

### Disclosure of transfers of value for Orphalan

#### **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 (“Orphalan”) is committed to ensuring any interactions meet the high standards of professionalism, integrity and transparency that are expected.

Orphalan 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://transpar-ency.efpia.eu> or <https://www.abpi.org.uk>

#### **Document Purpose and Scope**

This Methodological Note summarizes the processes applied by Orphalan when preparing its disclosure report. The report includes transfers of value by Orphalan to healthcare professionals and healthcare organisations based in the United Kingdom and covers activity relating only to Prescription Only Medicines. Orphalan 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 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 have a monetary value which can be attributed to an individual HCP or HCO. Non-monetary ToVs have not been made.

#### **Terms and Definitions**

For Orphalan’s disclosures, we applied the definitions found in the ABPI Code for all applicable terms including, but not limited to, “Healthcare Organisation (HCO),” “Healthcare Professional (HCP),” “Transfers of Value (ToV),” “Research and Development,” “Donation,” “Grant,” and “Sponsorship.”

#### **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.

### **Disclosure Categories**

For Orphalan's disclosures, we applied the standards found in the ABPI Code for all applicable Categories of Disclosure including, but not limited to, "Collaborative Working," "Donations and Grants to HCOs," "Contribution to costs of Events," and "Contracted Services."

### **Indirect Transfers of Value**

Indirect ToV made to HCPs/HCOs/ORDMs are used as defined in the ABPI Code. These indirect payments may include assignment ordered by Orphalan that is then contracted out to an individual HCP. Orphalan cooperates with the contracted service agent to obtain all necessary information for preparing our transparency disclosures.

### **Cross-border ToV**

Cross-border ToVs are if an Orphan's affiliate provides a ToV to an HCP or HCO whose country of primary practice is different than the location of the Orphan affiliate. Orphan will issue one disclosure report for each country showing all ToV made to HCPs, HCOs, and ORDMs in that country, and each report will be published by the relevant Orphan affiliate for that country in line with the regulations of the country.

Orphan discloses ToV based upon the recipient HCP's primary country of practice. If an HCP practices in more than one country, Orphan will disclose all ToV to that HCP in the HCP's primary country of practice.

### **Market Research**

The payments made to a contracted market research company will not be disclosed if the research is either (1) double-blinded or (2) single-blinded where Orphan does not know the identity of the HCP recipient. Any non-blinded Market-Research-related payments will be disclosed.

### **Sponsorships for HCPs to Attend Meetings**

Orphan supports the attendance of HCPs at educational, scientific meetings. Orphan will disclose the associated ToV linked to the individual attendee. Costs are captured in an individually itemised manner (e.g. a group costs are split per capita equally). ToVs include transport, registration fees, accommodation, and other forms of hospitality.

### **Cancellations and No-Shows**

If an invited Beneficiary does not come to such event, any payments made on the date of the event will not be included as a ToV to the Beneficiary who did not attend. No-show fees and other required payments will be disclosed aggregated.

If an event is cancelled, cancellation fees are not included in transparency declarations.

### **Contributions to Meetings**

Orphan will disclose all payments made to HCOs in relation to meetings. This includes direct support, such as sponsorship fees in return for a service provided to Orphan (booth, advertising, symposium time etc.).

### **Transfers of Value Inclusive Dates**

The disclosure report includes all ToVs to recipients during the reporting period between 01 January 2022 and 31 December 2022. ToVs for which relevant data becomes available after the cut-off date on 31 December 2022 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.

### **Data Privacy and Aggregated Disclosure**

With respect to the collection and processing of HCPs' personal data, Orphalan complies with all applicable data protection regulations. Orphalan requires consent from HCPs prior to disclosing their personal data, including details of any ToV paid by Orphalan. For ToV in which Orphalan is unable to disclose on an individual basis for legal reasons, including compliance with data protection requirements, Orphalan will disclose on an aggregate basis. HCPs have the right to withdraw their consent at any time. In such cases, any ToV to these individuals will be disclosed on an aggregate basis.

### **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 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.

### **Transfers of Value to Patient Organisations**

Disclosure data for patient organisations is published on our company website per ABPI Code clause 29.1.