



*This Methodological Note is for 2021 Transfers of value (reported 2022)*

## **Methodological Note**

Transparency is fundamental to ensure a positive working relationship between the pharmaceutical industry and healthcare providers, relationships that best serve the interests of patients. Recordati Rare Diseases (Recordati Rare Diseases or the 'Company') has prepared this document to outline the Company's interpretations and assumptions made and methodologies used in complying with the requirements to disclose payments to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), and Other Relevant Decision Makers (ORDMs) under the Code of Practice 2021 administered by the Prescription Medicines Code of Practice Authority (PMCPA).

Recordati Rare Diseases first identified all possible sources of information within the Company's finance system and all Transfers of Value (ToV) made by the Company to HCPs, ORDMs and HCOs. This list was compared to the internal record of all contracts/agreements and payment requests related to interactions with HCPs, ORDMs and HCOs held for compliance purposes in order to omit any loss of information. Any inconsistencies between the two lists were resolved through internal consultation or by contacting the relevant payee to resolve any doubts.

Based on a complete dataset Recordati Rare Diseases has endeavoured to disclose to the ABPI for publication on its central platform all direct and indirect ToVs made between 1 January 2021 and 31 December 2021.

## **Consent**

Recordati Rare Diseases has endeavoured to seek consent from all HCPs to disclose on an individual basis, naming the recipient and identifying the ToV. To this end, the Company has incorporated a clause to this effect in the contractual templates on the basis of which all such engagements should proceed. For each activity, consent is requested at the inception of a HCP agreeing to provide services for the Company. This consent is stored electronically allowing a review of records if required in the future.

Should a HCP provide consent to disclosing ToV for one engagement but decline consent for another, those engagements with consent will be disclosed on an individual basis whilst those engagements where consent was declined will be included in the aggregate value.

In circumstances where a HCP declines to give, or subsequently withdraws consent to disclose on an individual basis of ToV during the reporting calendar year all transfers of value with no consent to disclose are included in the aggregate value.

Where a HCP provides consent for ToV disclosure for one engagement but neither provide consent nor decline to give consent, for another engagement in the same year, the HCP was contacted to request consent and ToV disclosure made as appropriate based on the response. If no response was obtained then only the transfers of value with no consent to disclose are included in the aggregate value.

### **What is a Transfer of Value (ToV)?**

The ToVs data is based on any direct or indirect ToV, whether monetary, benefit in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and/or sale of prescription only medicinal products for human use.

A ToV can be salary, fee or remuneration for a service provided by the HCP or HCO to Recordati Rare Diseases. Expenses incurred during the execution of the service (e.g. travel and accommodation) are also considered ToV. Donations and sponsorships provided by Recordati Rare Diseases are also considered to be ToV.

This includes, but is not limited to, payments of fees for services, consultancy and associated expenses, registration fees, sponsorships, grants, donations, travel, accommodation.

Examples of Transfers of Value covered under Fee for Service and Consultancy agreements:

- Speaker fees
- Webinar Faculty
- Development of case studies
- General consulting / advising
- Chairing and speaking at meetings

**Who is the recipient of the ToV?**

Recordati Rare Diseases will consider the recipient to be the contracting entity, which may be a HCP, [a legal entity owned by a HCP (which is then a HCO)] or a HCO. Hence the contracting party as stated on the legal contract executed between Recordati Rare Diseases and the counterpart will be reported as the recipient.

**When are ToVs disclosed?**

The Company has made its disclosures relating to cash payments by reference to the payment date. As a consequence, a fee for a service provided during 2020 and paid during 2021 would be registered on the 2021 ToV listing. If the exact date for a specific transfer cannot be obtained by the individuals registering the ToVs, the transfer is to be registered as close as possible to the actual payment date.

Payments made after December 31, 2021 for events that took place in 2021 will be included in the 2022 report.

**Currency**

The Company has made its disclosures in sterling. For those payments made in any other currency, the company has used the applied the current (March 2022) exchange rate with sterling. An exchange rate of £0.84: 1 euro and £0.74: \$1 were used

The Company has made its disclosures relating to direct ToVs exclusive of all applicable taxes.

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