



This Methodological Note is for 2022 Transfers of value (reported 2023)

Methodological Note

Transparency is fundamental to ensure a positive working relationship between the pharmaceutical industry and healthcare providers for relationships that best serve the interests of patients.

Recordati Rare Diseases (also referred to as 'the Company') has prepared this document to outline the Company's interpretations and assumptions made, and methodologies used in complying with 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).

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 Transfers of Value (ToV) made between 1 January 2022 and 31 December 2022.

Recordati Rare Diseases first identified all possible sources of information within the Company's finance system and all ToV made by the Company to HCPs, ORDMs and HCOs. This list was compared to an 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 clarify the situation regarding the inconsistency.

In relation to cross border payments, RRD internal policies require that all engagements with UK HCPs/HCOs made by a non-UK company affiliate are registered with the UK affiliate, prior to any engagement, for ABPI compliance and ToV approval. This information was then compared with the contracts and invoices for each payment and information provided from the finance team from the relevant affiliate. Any inconsistencies between the documents were resolved through internal consultation or by contacting the relevant payee to clarify the situation regarding the inconsistency.

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, Recordati Rare Diseases has incorporated a clause to this effect in contractual templates with suppliers of services, HCPs, ORDMs or HCOs on the basis of which all such engagements should proceed. For each activity, consent is requested at the inception of engagement with a HCP or ORDMs. This consent is stored electronically allowing a review of records if required in the future.

Where an HCP or ORDM provided consent for ToV disclosure for one or more engagement during 2022 but neither provided nor refused consent for another engagement in the same year, consent was presumed for all cases. There were no cases where consent was provided for some engagements and explicitly denied for others during 2022. As such none of the named HCPs had any ToV disclosed in the aggregate group.

In circumstances where a HCP declined to give, or subsequently withdrew consent to disclose on an individual basis of any ToV during the reporting calendar year, all ToVs with no consent to disclose were to be included in the aggregate value. There were no explicit withdrawals of consent throughout the year.

Where a HCP did not provide explicit consent for ToV disclosure for any engagement throughout the year but conversely did not explicitly decline to give consent, the HCP was contacted to request consent and ToV disclosure made as appropriate based on the response. If no response was obtained then the ToV were included in the aggregate value.

What is a Transfer of Value (ToV)?

The ToV data are based on any direct or indirect monetary or benefit in kind 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, ORDMs or HCO to the company. Expenses incurred during the execution of a contracted service (e.g. travel and accommodation) are also considered ToV. Donations and sponsorships provided by Recordati Rare Diseases are also considered to be ToV.

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

Examples of activities covered under Fee for Service and Consultancy agreements:

- Webinar faculty participation
- Development of case studies
- General consulting / advising
- Chairing and speaking at meetings

Who is the recipient of the ToV?

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

What date is assigned to a ToV?

Recordati Rare Diseases has made its disclosures relating to cash payments by reference to the payment date. As a consequence, a fee for a service provided during 2021 and paid during 2022 has been registered on the 2022 ToV listing. If the exact date for a specific transfer could not be obtained by the individuals registering the ToVs, the transfer was registered as close as possible to the actual payment date.

Payments made after December 31, 2022 for events that took place in 2022 will be included in the 2023 report.

Currency

Recordati Rare Diseases has made its disclosures in Sterling. For those payments made in any other currency, the Company used the average exchange rate with Sterling at the date of the transaction, if known, or from the month of transaction, or engagement date. Exchange rates were obtained from: <https://www.exchangerates.org.uk/>

Recordati Rare Diseases has made its disclosures relating to direct ToVs exclusive of all applicable taxes and VAT.

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