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Zentiva Transfer of Value Disclosure 2022 – Methodological Note

Zentiva is committed to making the transfers of value (ToV) made to Health Care Professionals (HCPs) and Health Care Organisations (HCOs) transparent, accurate, and complete. Zentiva, as a member of Medicines for Europe complies with the obligation to collect, disclose and report transfer of values related to prescription-only medicines to HCPs/HCOs in accordance with the requirements of Chapter 7 of the Medicines for Europe Code of Conduct 2020.

Scope

This Methodological note provides a summary of the methodologies used by Zentiva to report on ToV between Zentiva and HCP/HCOs between 1 January 2022 and 31 December 2022.

The Medicines for Europe Code of Conduct indicates that Companies must publish disclosure data relating to the following ToV (whether directly or indirectly funded) made to HCPs, HCOs or patient organisations:

- Fee for service (excluding associated expenses) except fees paid in connection with research & development activities or anonymous market research;
- Registration fees to attend a third party congress/conference;
- Travel and accommodation provided to delegates to attend a meeting including third party meetings, company organised meetings and site visits;
- Grants and donations, both financial and in-kind, to organisations that are part of the healthcare community;
- Sponsorship of healthcare organisations' and patients organisations' activities and events.

Transfers of Value (ToV)

ToV includes the direct or indirect ToV in money, in kind or in any other way, carried out for promotional or other purposes, in connection with the development and sale of prescription medicines which are exclusively intended for human use.

Direct ToV refers to the transfer made directly by Zentiva for the benefit of the Recipient.
Indirect ToV refers to the transfer made on behalf of Zentiva for the benefit of the Recipient or to the Transfers of Value made through an intermediary where Zentiva knows or can identify the HCP / HCO that will benefit from such ToV.

If consent to disclose these ToV has been obtained, they are reported against the individual. If not, they will be reported in aggregate.

All ToVs related to the planning or conduct of non-clinical studies, clinical trials and noninterventional studies performed by Zentiva or by Clinical Research Organisations on behalf of Zentiva, that are prospective in nature are considered Research & Development ToVs are reported on an aggregate basis.





Definitions

HealthCare Professional (HCP): An individual who is qualified to prescribe, administer, purchase, supply or recommend a Medicinal Product whose primary practice, principal professional address or place of incorporation is in Europe.

Healthcare Organisation (HCO): Any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

Transfer of Value (ToV): - Direct and indirect TOV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription only medicine exclusively for human use.

- Direct ToVs are those made directly by a Member Company for the benefit of a Recipient.
- Indirect ToVs are those made on behalf of a Member Company for the benefit of a Recipient, or those made through a Third Party and where the Member Company knows or can identify the Recipient that will benefit from the ToV
- Donations, Grants, Sponsorship: Providing funds, benefits in-kind, or services freely given for the purpose of supporting healthcare, scientific research, or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to Zentiva to the benefit of Zentiva in return. Donations and grants to HCPs are prohibited.

ToV dates

Donations to health organizations

- cash donation: the date of payment of the donation
- in kind: date of fulfillment of the obligation

Participation in the costs of organized meetings:

- sponsorship agreements with the health organization: start date of the event
- registration fees, travel, accommodation: start date of the event

Fee for consultancies and other services

- fees
 - Event-related fees: event start date
 - Non-event related fees: date of payment
- travel, accommodation: start date of the event

ToVs in case of partial attendances or cancellation

Where an HCP/HCO does not receive the benefit due to a no show or a cancellation of event, 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 reported.



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Where Zentiva has to pay cancellation fees to HCP/HCOs as per service contracts, due to cancellation of initiatives or events, these payments are reported.

Cross Border Payments

Zentiva makes its best effort to capture and report all ToVs to HCPs and HCOs with their primary practice in a country and/or other cross border transparency reporting requirements. All disclosures are made in the country in which the HCP practices or in which the HCO is located.

Currency aspects

Disclosure of ToV will be made in local currency for the reporting country.

Multi-year contracts

Only contracts with transfer of value where the payment was actually made in 2022 have been included in the 2022 disclosure. For contracts where the invoices are paid out in 2023, the disclosure will be made in 2023

Value Added Tax (VAT) and other taxes

VAT is excluded and withholding taxes are included.

Date of Preparation: June 2023

