

Notes on the methodology for publishing data on the transfer of value to the health community according to the Medicines for Europe Code

Introduction

In order to respect the high ethical business standards, Zentiva d.o.o. (hereinafter: Zentiva Hrvatska) adopted the Code of Medicine of the Medicines for Europe organization with the aim of protecting integrity, promoting transparency and building stronger trust between pharmaceutical industry, health community and society across Europe. It thereby undertook to disclose the Transfers of Value between pharmaceutical companies and the healthcare community, including healthcare professionals, healthcare organizations, patients and patient organizations. This methodological note presents some of the key aspects of the method of categorization and the form of publishing Transfers of Value.

Transfers of Value

Transfers of Value includes the direct or indirect Transfers of Value 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 Transfers of Value** refers to the transfer made directly by Zentiva Hrvatska for the benefit of the Recipient.
- Indirect Transfers of Value refers to the transfer made on behalf of Zentiva Hrvatska for the benefit of the Recipient or to the Transfers of Value made through an intermediary where Zentiva Hrvatska knows or can identify the healthcare professional / healthcare organization that will benefit from such Transfers of Value.

Aggregated reports are limited to the transfer of value related to research and development and to that Transfers of Value that cannot be published individually for legal reasons because the consent of healthcare professionals and healthcare organizations has not been obtained for the publication of such Transfers of value. In 2020, Zentiva Hrvatska retained the possibility of publishing aggregated reports.

Exemptions from the publication of Transfers of Value

- advertising and information activities on over-the-counter medicines
- Transfers of Value related to informational and educational materials and items of medical use (gross purchase value of such materials does not exceed the amount determined by applicable local laws and are aimed at the welfare of patients)
- food costs during professional meetings up to a maximum of HRK 500.00 per person and meal
- purchase costs of free samples (once a year, in the amount of a maximum of two smallest original packages)

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Reporting period

Each reporting period covers the entire calendar year. Transfers of Value are reported for all activities that take place in a particular calendar year for which Zentiva Hrvatska has received an invoice.

Sources of information

Data are collected from internal and external data sources and systems and are entered into a central database for reporting.

Recipient of value

- Healthcare professional doctor of medicine, doctor of dental medicine, member of the pharmacy
 or nursing profession, but also all persons who in the performance of their professional activities can
 prescribe, buy, procure, supply or dispense prescription drugs, and perform professional activity in
 the Republic of Croatia.
- **Healthcare organization** any legal entity of healthcare orientation (for example: medical, dental, pharmaceutical-biochemical, etc.) in which one or more healthcare professionals provide services, and which is established and operates on the basis of applicable regulations governing health, medical or scientific activities, with its registered office in the Republic of Croatia.

Transfers of Value date

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

Meals

There is no obligation to disclose meal costs.

Absence / cancellation

In the event that the registration fee is paid and the trip and / or accommodation is booked, and the healthcare professional does not attend the event, the Transfers of Value for that healthcare professional in relation to that event is not published.

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Transfers of Value to the travel agency as a technical organizer of events organized by the health organization

The Transfers of Value is announced for the health organization and in the case when the transfer is made to a travel agency as a technical organizer who organizes the event on behalf of the health organization.

Transfers of Value for healthcare organizations when the final recipients are healthcare professionals

Transfers of Value are reported for those healthcare professionals that Zentiva Hrvatska is aware of or for which it can determine that they benefit from the Transfers of Value.

Multi-year contracts

Transfers of Value are reported with respect to the relevant payment date or event start date (see above), regardless of the duration of the contract.

Currency

All transfers are published in local currency (HRK). If the payment is recorded in a foreign currency, it is converted to the local currency by applying the middle exchange rate of the Croatian National Bank for the date considered to be the date of value transfer.

VAT

All Transfers of Value are reported as net amount.

Consent

Zentiva Hrvatska will publish information on an individual recipient only if it has obtained its consent. If the healthcare professional or healthcare organization has not given its consent or has not responded to the request for consent, their data will be published in aggregated form and the identity of the recipient will not be publicly available.