

Methodological Notes on the Disclosure of Transfers of Value to the Healthcare Community for 2024 in accordance with the Medicines for Europe Code

Introduction

In line with its commitment to high ethical business standards, Zentiva d.o.o. (hereinafter referred to as Zentiva Croatia) has adopted the Medicines for Europe Code (hereinafter: the Code) to promote integrity, transparency, and trust between the pharmaceutical industry, the healthcare community, and the general public.

By adopting the Code, A Croatia has committed to **disclosing transfers of value** between the pharmaceutical industry and the healthcare community, including healthcare professionals (HCPs), healthcare organisations (HCOs), patients, and patient organisations.

This methodological note outlines the key aspects of the categorisation and reporting of transfers of value in accordance with the Code.

Transfer of Value

A transfer of value refers to any direct or indirect transfer of material or non-material benefit, in cash, in kind, or in any other form, carried out for promotional or other purposes related to the development and/or sale of **prescription-only medicines for human use**.

- **A direct transfer of value** refers to a transfer made directly by A Croatia to the recipient.
- **An indirect transfer of value** refers to a transfer made on behalf of A Croatia to the recipient, or via a third party (e.g., agency or event organiser), where A Croatia is aware of or can identify the healthcare professional or organisation that benefits from the transfer.

Aggregate Disclosure

Aggregate disclosure applies only to transfers of value related to research and development, and transfers where **consent for individual disclosure has not been obtained** from the healthcare professional or organisation.

Exemptions from Disclosure

In accordance with the Code, the following transfers of value are exempt from the disclosure obligation:

- Promotional and informational activities related to over-the-counter (OTC) medicines
- Transfers related to informational or educational materials and medical utility items, provided their gross acquisition value does not exceed the limit set by applicable national legislation and they are intended solely for patient benefit
- Meal expenses during professional meetings, up to a maximum of EUR 70.00 per person per meal
- The acquisition cost of free samples, which may be provided once per year, in quantities not exceeding two of the smallest original packs

Reporting Period

The reporting period covers the **entire calendar year**. Transfers of value are reported for all activities that took place during the reporting year and for which Zentiva Croatia received an invoice within that year.

Sources of Information

Data on transfers of value are collected from internal and external sources and systems and entered into a centralised reporting database for publication purposes.

Recipient of Value

- **Healthcare Professional** - any natural person who practises in the Republic of Croatia and who, within their professional activities, is authorised to prescribe, purchase, procure, supply, or dispense prescription-only medicines.
This includes, but is not limited to, medical doctors, dentists, pharmacists, nurses, and other healthcare professionals with appropriate legal authorisation.
- **Healthcare Organisation** - any legal entity based in the Republic of Croatia that operates in the healthcare, medical, pharmaceutical, dental, biomedical, or scientific field, where one or more HCPs provide healthcare services, in accordance with applicable legal and regulatory requirements.

Date of Transfer of Value

Donations to healthcare organizations

- Monetary donation - **date of payment**
- Donation in kind - (e.g., delivery of goods or services)

Support for participation in organised events

- Sponsorship agreements with HCOs - **date of event start**
- Registration fees, travel, accommodation - **date of event start**

Consultancy and other service fees

- Honoraria and event-related fees - **date of event start**
- Non-event-related fees - **date of payment**

Travel and accommodation - **date of event start**

Meals

Meal costs are **not subject to disclosure**, in accordance with the exemptions set out in the Code.

Non-attendance or cancellation

If registration fees have been paid and/or travel or accommodation has been booked, but the HCP does not attend the event, **no transfer of value is reported** for that HCP in relation to the event.

Special Situations

Transfers of value to a travel agency acting as a technical organiser on behalf of a healthcare organisation



If a transfer of value is made to a travel agency acting as a technical organiser of an event on behalf of an HCO, **the transfer is reported under the name of the HCO.**

Transfers to HCOs where the ultimate beneficiaries are HCPs

If A Croatia is aware of, or can identify, individual HCPs who directly benefit from a transfer of value made to an HCO, **the transfer is reported under the individual HCP's name.**

Multi-year contracts

For multi-year agreements, transfers of value are reported based on the relevant payment date or event start date, regardless of the overall contract duration.

Currency

All transfers of value are reported in **local currency - euros (EUR).**

If payment is recorded in a foreign currency, the amount is converted using the Croatian National Bank's official middle exchange rate applicable on the date considered to be the date of the transfer of value.

VAT

All reported values are **net amounts** (exclusive of VAT).

Consent

Zentiva Croatia will disclose information on individual recipients **only if prior consent has been obtained.**

If the HCP or HCO has not given consent, has not responded to the consent request, or has withdrawn consent, the transfer of value will be reported **in aggregate form**, without naming the individual recipient.

Requests for Additional Information and Inquiries

All interested parties may request additional information or submit inquiries regarding the disclosure of transfers of value by contacting us at: compliance@zentiva.com.