

# Transparency disclosure according to the EFPIA Code of Practice

# **METHODOLOGICAL NOTE**

# Year 2023 disclosure

Closed: 30 June 2024

# 1. INTRODUCTION

- **1.1.** Healthcare professionals, healthcare organizations and patient organizations provide the pharmaceutical industry with valuable information by sharing their experience and expertise derived from treatment of diseases. At Egis, we believe that through this cooperation, as well as through the continuous training of healthcare professionals, better results can be achieved in the field of health preservation and the treatment of diseases, and new products that better meet the needs of patients can be created. In exchange for professional cooperation, healthcare professionals and healthcare organizations are entitled to adequate and fair compensation.
- **1.2.** The purpose of this disclosure is intended to provide an accurate overview of our collaboration with the healthcare sector. We believe that transparency is essential to maintaining trust within the pharmaceutical industry.
- **1.3.** Egis follows the Transparency Code of the European Federation of Pharmaceutical Industries and Associations ("EFPIA") as of the calendar year 2019. This note summarizes the methodological background for the disclosure.
- **1.4.** Egis affiliates that are subject to the transparency disclosure in line with paragraph 1.3, disclose their transfer of values either on their own website or based on the local regulations applicable in their country, together with their methodological note. Transparency disclosures of Egis affiliates, which do not have their own website or have the opportunity to publish on the website of the local pharmaceutical association, are published on the website of Egis Hungary.

#### 2. **DEFINITIONS**

#### 2.1. Fundamentals

# **Transfer of Value**

Direct or indirect provision of value in cash, in kind or other ways in connection with prescription only medicines either for promotional or other purposes. Direct provision of value grant means that Egis grants the transfer of value directly to the Recipient. Indirect provision of value is awarded by a third party (such as a contractual partner, agent or associate [including the foundation]) on behalf of Egis to the Recipient if the Recipient is known or identifiable for Egis.

#### Recipient

Patient Organization, Healthcare Professional, Healthcare Organization, to whom Egis provides a Transfer of Value, and whose primary practice, principal professional address or place of incorporation is in Europe.

#### Events

All professional, promotional, scientific, educational meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organized or sponsored by or on behalf of Egis.

#### 2.2. Types of Recipients

According to the Code of Practice Transfers of Value for the following Recipients should be disclosed.

#### Healthcare Professional ("HCP")

Any natural person that is a doctor, a member of medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product. For the avoidance of doubt, the definition of Healthcare Professional includes: (i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, dispense, purchase or administer medicinal products and (ii) any employee of a pharmaceutical company whose primary occupation is that of a practicing Healthcare Professional, but *excludes* (x) all other employees of a pharmaceutical company and (y) a wholesaler or distributor of medicinal products.

### Healthcare Organization / Service Provider ("HCO")

#### Any legal entity,

(i) which is a healthcare, medical or scientific organization or association (irrespective of its legal or organizational form), such as hospitals, clinics, universities or other educational institutions or associations (excluding organizations that are patient organizations) having address, seat or principal place of operation in Europe or

(ii) through which one or more Healthcare Professional provides services.

# Patient Organization ("PO")

Non-profit organizations, including so-called umbrella organizations that include such organizations, which are usually founded by the support of patients, their family members or caregivers, to support and represent essentially patients' rights, patients and their care givers, and their needs and interests, to share disease and treatment information in a therapeutic area and whose business address, place of incorporation or primary place of operation is in Europe.

# 2.3. Types of Disclosed Transfers of Value Sorted by Recipients

According to the Code of Practice the following categories of Transfers of Value to be awarded to Recipients need to be published:

# A) Transfers of Value to a Patient Organization:

- Support:
  - the monetary value of financial support.
  - the non-monetary benefit;
- Service fees: contractual services broken down by patient organization,

# **B)** Transfers of Value to Healthcare Professionals:

- *Contribution to costs related to Events*: Contribution to costs related to Events, such as:
  - Registration fees; and
  - Travel and accommodation.
- *Fees for Service and Consultancy*: Transfers of Value resulting from or related to service or consultancy contracts between Egis and HCPs under which such HCPs provide any type of services to Egis or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

# C) Transfers of Value to Healthcare Organizations:

- *Donations and Grants*: Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of HCPs and/or that provide healthcare.
- *Contribution to costs related to Events*: Contribution to costs related to Events, through HCOs or Third Parties, including support to HCPs to attend Events, such as:
  - Registration fees;
  - Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event; and
  - Travel and accommodation.
- *Fees for Service and Consultancy*: Transfers of Value resulting from or related to contracts between Egis and HCOs under which such HCOs provide any type of

services to Egis or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

# 3. DISCLOSURE

#### **3.1. Effected products**

Disclosure covers all Transfers of Value that may be related to the Egis prescription-only product portfolio activity.

# 3.2. Transfers of Value not covered by the publication

Transfers of Value for any of the following categories or for any of the following activities are not subject to disclosure:

- Non-prescription drug related activities,
- o Medical devices related activities,
- Medical samples, commercial activities, commercial conditions that are part of the usual purchase and sale of medicines,
- o Items of medical utility, small value meals, and
- Any Transfers of Value that are not covered by the disclosure obligation.

#### 3.3. Date of Transfers of Value

Transfers of Value are based on the date of performance of the underlying activity in the publication table of a given year. In-kind Transfers of Value are recorded with the date of transfer.

#### 3.4. Direct and Indirect Transfers of Value

The scope of the disclosure extends to both directly and indirectly given Transfers of Value to the Recipient. In the case of Indirect Transfers of Value, the contracts with the partners of Egis ensure that the information necessary for the publication of the Transfers of Value is available to us.

# 3.5. Cross-border activities

Cross-border Transfers of Value are Transfers of Value in case of which the Recipient is active in a country other than the related Egis subsidiary.

In the case of Cross-border Transfers of Value, the publication will take place in the country where the Recipient has his or her domicile. If there is no Egis subsidiary in this country, the Transfer of Value will be published centrally in Hungary.

In order to manage cross-border Transfers of Benefit, we have established an internal registration system that ensures that the Egis subsidiary in the country of residence or residence of the Recipient is aware of the value transfers in time and can publish them in time in its own report. Corresponding declarations must be obtained and handled in accordance with the local law of the country of publication, and the relevant report must be published according to local regulations.

# 3.6. Multiannual Agreements

Multiannual agreements are contracts where the scope extends from one calendar year to the following calendar year.

In the case of several-year contracts, the Transfers of Value are calculated on the basis of the date of performance of the underlying activity.

#### 3.7. Publication of Research and Development Transfers of Value

Research and Development Transfers of Value in each reporting period are disclosed on an aggregate basis. Costs related to Events that are clearly related to Research and Development activities can be included in the aggregate amount under the "Research and Development Transfers of Value" category.

#### 3.8. Management of individual entrepreneurs and companies

If a Healthcare Professional acts as an individual entrepreneur, the related Transfers of Value will be published in accordance with the standards for Healthcare Professionals.

If a Healthcare Professional or Healthcare Professionals are active within a company, the related Transfers of Value will be published in accordance with the requirements for Healthcare Organizations.

#### 3.9. Source of data

Data on the Transfers of Value disclosed in the report are derived from a variety of systems within the organization (financial systems, event administration systems, pharmacy registration modules, etc.).

Data from different databases is generated by a centralized query, which uses a unique identifier to provide a summary of multiple Transfers of Value to a Recipient and edit them in the form of publication tables.

# 4. DATA PROTECTION

#### 4.1. Healthcare Organizations and Patient Organizations

For the purposes of the Code of Practice, in the case of Healthcare Organizations and Patient Organizations, disclosure will always be made by their names. The Healthcare Organizations and Patient Organizations, following the receipt of information on the disclosure obligation of Egis, may decide whether to conclude a contract with Egis or not, taking into account that the contracting is associated with the publication by name of the Transfers of Value under the Code of Practice.

The declaration of the Healthcare Organizations and Patient Organizations will be obtained contract by contract. Exceptions to this are the declarations on the acceptance of medicine donations, where the declarations are applicable to all medicines donated during the calendar year.

#### 4.2. Healthcare Professionals

In the case of Healthcare Professionals, the basis for data processing is the relevant voluntary consent of the concerned person. All of our contracts contain a Privacy Statement and Consent Annex, in which the Healthcare Professional unambiguously gives or does not give consent to the treatment of their information for transparency reporting purposes. According to the Code of Practice, Healthcare Professionals have the opportunity to request

that no name-based disclosure of their data be made based on data privacy reasons. In this case, the Transfers of Value paid to them will be published anonymously and in an aggregated way.

The consent of the Healthcare Professionals will be obtained contact by contract.

# 4.3. Handling withdrawn consents

Healthcare Professionals have the opportunity to withdraw their consent statement. If the consent is withdrawn prior to the publication of the annual report, the Transfer of Value given to the Healthcare Professional will be transferred to an anonymous, aggregated disclosure category.

If the consent is withdrawn after the publication of the annual report, the revocation will take place by recalling the publication report and by publishing a revised report.

### 5. DISCLOSURE OF FINANCIAL DATA

#### 5.1. Currency of Disclosure

The currency used to indicate the disclosure details is: CZK.

# 5.2. Taxes

The amounts included in the disclosure include the VAT and all other applicable taxes and charges.

#### 5.3. Calculation Rules

According to the session 3.5. the foreign currency allowances to be issued in Egis Praha spol. s r.o. are converted from their original currency at the officially published foreign exchange rate of CNB (Czech National Bank), valid on the date of the invoice, to the currency of the publication.

#### 5.4. Determining the value of donations

Egis publishes donations to hospitals and other Healthcare Organizations according to their normal market value. The value of Egis products donated for charity purposes will be published on the basis of their list price.

# 6. DISCLOSURE TABLES

#### 6.1. Date of disclosure

The date of disclosure is 30 June 2023

#### 6.2. Format of disclosure

The disclosure will be implemented through the publication tables published by EFPIA.

#### 6.3. Reported year

Recent disclosure refers to the previous calendar year; 1st January -31st December. The information provided is available on the Internet for a period of 3 years from the date of publication.

# 6.4. Data reconciliation prior to the disclosure

Prior to the publication of the report, Egis provides an opportunity for data reconciliation with all stakeholders. If we do not receive an answer, we consider that the person concerned does not want to change the data sent.

# 6.5. Place of disclosure

The publication will take place on https://cz.egis.health/compliance website.

# 6.6. Language of disclosure

Disclosure is done in English.

# 6.7. Contacts

Any kind of inquiries regarding the transparency disclosure may be sent to address egispraha@egispraha.cz.