



**Transparency disclosure according to the  
EFPIA Code of Practice**

**METHODOLOGICAL NOTE**

**Year 2021 disclosure**

**Closed: 30 June 2022**

## 1. INTRODUCTION

**1.1.** *EGIS Pharmaceuticals PLC /EGIS Praha, spol. s r.o.* ("Egis") is a member of the Servier Group. The Servier Group is a member of the European Federation of Pharmaceutical Industries and Associations ("EFPIA"). The Code of Practice, created by EFPIA ("Code of Practice"), requires all member companies to manage and publish the transferred values given to healthcare professionals, healthcare organizations and patient organizations in a regulated and transparent framework. As of the calendar year 2019, Egis is preparing its transparency reporting in line with the EFPIA regulation, as opposed to the Medicines for Europe regulation, based on which the previous transparency reports were prepared.

**1.2.** If you need more information about the rules, please visit <https://www.efpia.eu/relationships-code/the-efpia-code/>.

**1.3.** This methodological note summarizes the methodological background used by Egis in identifying, recording, summarizing and disseminating transfers of value provided in Egis Praha, spol. s r.o.

## 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. Direct value grant means that Egis grants the transfer of value directly to the Recipient. Indirect 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.

#### **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) organised or sponsored by or on behalf of Egis.

#### **Recipient**

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

### 2.2. Types of Recipients

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**

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 and of invoiced costs.
  - the non-monetary benefit that the PO receives when the non-financial support cannot be assigned to a meaningful monetary value;
- *Service fees:* contractual services broken down by patient organization, including the description of subsidies and fees by type of grant and by fees, for the year concerned.

#### **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 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,
- Medical devices related activities,
- Medical samples, commercial activities, commercial conditions that are part of the usual purchase and sale of medicines,
- 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. 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.

### **3.6. 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.

### **3.7. Multiannual Agreements**

Multiannual agreements are contracts whose 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.

### **3.8. 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 on a named basis. 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 (Czech koruna).

### **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 3.6. 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 the ČNB, 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 2022

#### **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 link <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 email address [egispraha@egispraha.cz](mailto:egispraha@egispraha.cz).