



**Transparency disclosure**  
**Methodological Note**

## 1. INTRODUCTION

- 1.1. As a pharmaceutical company, Egis works in collaboration with various stakeholders including healthcare professionals, healthcare organisations and patient organisations to improve health and quality of life. Healthcare professionals, healthcare organizations and patient organizations provide the pharmaceutical industry with valuable information by sharing their experience and expertise derived from the progression and 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 better meeting the needs of patients can be created. In exchange for professional cooperation and the legitimate expertise and services they provide to the industry, healthcare professionals, healthcare organizations and patient 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 and transparency disclosure is an opportunity to demonstrate our commitment to implement, comply with and enforce the highest ethical standards.
- 1.3. Egis follows the transparency provisions of the Code of Practice of the European Federation of Pharmaceutical Industries and Associations (“**EFPIA Code of Practice**”) as of the calendar year 2019. This note is intended to provide all methodological information relevant for interpretation of the information disclosed by Egis.
- 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 nor 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 and indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription only medicines exclusively for human use. Direct Transfers of Value are those made directly by Egis for the benefit of a Recipient. Indirect Transfers of Value are those made on behalf of Egis for the benefit of a Recipient, or those made through a third party and where Egis knows or can identify the Recipient that will benefit from the Transfer of Value.

#### **Recipient**

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

#### **Europe**

Those countries in which the EFPIA Member Associations' National Codes apply. As of June 2019, these countries include: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

#### **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.

### 2.2. Types of Recipients

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

#### **Healthcare Professional (“HCP”)**

Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCPs includes: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer medicinal products and (ii) any employee of EFPIA member companies whose primary occupation is that of a practising

HCP (if any), but excludes (x) all other employees of EFPIA member companies and (y) a wholesaler or distributor of medicinal products.

This definition allows identifying the following professionals Egis may be interacting with:

- Physicians,
- Pharmacists,
- Midwives,
- Nurses.

Unless they are no longer registered with their order, the Transfers of Value for retired HCPs are disclosed.

### **Healthcare Organization (“HCO”)**

Any legal person/entity

- (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for Patient Organizations) whose business address, place of incorporation or primary place of operation is in Europe or
- (ii) through which one or more HCPs provide services.

This definition allows identifying the following organisations Egis may be interacting with:

- Hospitals,
- Healthcare institutions or clinics,
- Group medical practices,
- Clinical research organisations or equivalent service providers,
- Service provider in preclinical research,
- Universities (Medical departments),
- Foundations and charities involved in the medical domain,
- Medical or learned societies,
- Medical education companies,
- Associations of HCPs.

### **Patient Organization (“PO”)**

Non-for-profit legal person or entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

### **Professional Conference Organizers (“PCO”) – in case of indirect Transfers of Value**

A company or individual specialized in the organization and management of congresses, conferences, seminars and similar events (all considered as Events). Commercial companies involved in organization of travel (travel agencies) or accommodation (hotels, etc.) are not considered as PCOs.

## **2.3. Types of Disclosed Transfers of Value**

According to the EFPIA 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:* fees for contractual services broken down by patient organization.

The above Transfers of Value are to be disclosed when provided, paid or reimbursed to POs or for their benefit, either directly or indirectly.

Transfers of Value provided to POs are disclosed on nominative basis, even when related to research and development activities.

The disclosure must include a description of the nature of the support or services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the support or the arrangement without the necessity to divulge confidential information.

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

- *Contribution to costs related to Events*, such as:
  - registration fees; and
  - travel and accommodation costs.
- *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.

The above Transfers of Value are to be disclosed when provided, paid or reimbursed to HCPs or for their benefit, either directly or indirectly.

**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:* through HCOs or third parties, including support to HCPs to attend Events, such as:
  - registration fees;
  - travel and accommodation costs; and
  - sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event.
- *Fees for service and consultancy:* Transfers of Value resulting from or related to service or consultancy 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.

The above Transfers of Value are to be disclosed when provided, paid or reimbursed to HCOs or for their benefit, either directly or indirectly.

**D) Transfers of Value made through Professional Congress Organizers:**

- *Contribution to costs related to Events:* through PCOs, such as:
  - Registration fees;
  - Travel and accommodation;
  - Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event;
  - Speaker fees.

The above indirect Transfers of Value are to be disclosed when provided, paid or reimbursed to HCPs or HCOs, or for their benefit through PCOs.

**E) Transfers of Value related to Research and Development Activities:**

- *Research and Development Transfers of Value:* Transfers of Value to HCPs or HCOs related to the planning or conduct of
  - non-clinical studies (laboratory),
  - clinical trials, or
  - non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

The above Transfers of Value are to be disclosed when provided, paid or reimbursed to HCPs or HCOs, or for their benefit, either directly or indirectly.

### **3. DISCLOSURE**

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

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

#### **3.2. Transfers of Value not covered by the disclosure**

Transfers of Value corresponding to the following categories or provided in relation with the following activities are not subject to disclosure:

- Activities solely related to over-the-counter pharmaceutical products,
- Activities related to medical devices,
- Provision of items of medical utility and educational items,
- Small value meals and drinks,
- Travel expenses in line with the threshold applicable to meals and drinks,
- Free medical samples,
- Transfers of Value provided as part of the ordinary course purchases and sales process between Egis and an HCP (e.g., pharmacist) or an HCO, and
- Any Transfers of Value that are not covered by the EFPIA Code of Practice.

### **3.3. Date of Transfers of Value**

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

### **3.4. Indirect Transfers of Value**

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

Contributions provided to Events through PCOs (organized whether through their own initiatives or at a request of an HCO), that would therefore be the direct Recipient of the Transfer of Value, must be considered as indirect Transfer of Value and be reported on an individually named basis. Indirect Transfers of Value through PCOs are disclosed in the name of benefitting HCO or HCP.

The full value of the Transfer of Value provided through the PCO shall not be deemed as a benefit (in cash or in kind) to the HCO as the PCO may retain a part of this amount as “service fee”.

### **3.5. Transfers of Value in case of partial attendance or cancellation and refund**

In case of cancellation of the participation or no show, the HCP or HCO does not receive the benefit and the relevant Transfers of Value will not be disclosed. In case of partial attendance, only the benefits actually received are disclosed as Transfers of Value.

### **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 Egis. In the case of Cross-border Transfers of Value, the disclosure will take place in the country where the Recipient has his/her residence or its registered seat. If there is no Egis affiliate in this country, the Transfer of Value will be disclosed centrally in Hungary.

In order to manage cross-border Transfers of Value, we have established an internal record-keeping system that ensures that the Egis affiliate in the country of residence or registered seat of the Recipient is aware of the Transfers of Value in time and can disclose them in time in its own report. Corresponding declarations must be obtained and handled in accordance with the local law of the country of disclosure, and the relevant report must be disclosed according to local regulations.

### **3.7. Multiannual Agreements**

Multiannual agreements are contracts where the scope extends from one calendar year to the following calendar year. In the case of multiannual agreements, the Transfers of Value are calculated on the basis of the date of performance of the underlying activity.

### **3.8. 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 to be disclosed related to Events (registration, accommodation, travel) 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.

All non-interventional studies that do not fall within the scope of “prospective studies”, disclosure is made on a nominative basis. As such, retrospective studies will be disclosed under the “Fee for service and consultancy” category of the disclosure template. In case it is not possible to distinguish between prospective and retrospective non-interventional studies, the disclosure of all non-interventional studies will be on an individual basis.

### **3.9. Management of individual entrepreneurs and companies**

If an HCP acts as an individual entrepreneur, the related Transfers of Value are disclosed in accordance with the standards for HCPs.

If an HCP or HCPs carry out their activities in the framework of a company (that would therefore be the direct Recipient of the Transfer of Value) but Egis knows or can identify the specific HCP(s) that will benefit from the Transfer of Value, the related Transfers of Value are disclosed in accordance with the standards for HCPs.

If an HCP or HCPs carry out their activities in the framework of a company (that would therefore be the direct Recipient of the Transfer of Value) and Egis does not know and cannot identify the specific HCP(s) that will benefit from the Transfer of Value, the related Transfers of Value will be disclosed in accordance with the standards for HCOs.

### **3.10. Source of data and unique identifier**

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

Data summary from different databases is generated by a centralized query, which uses a unique identifier to provide a summary of multiple Transfers of Value to the same Recipient and edit them in the form of publication tables. The unique identifier is also used to prevent confusion when several Recipients have the same name.

### **3.11. Quality checks**

Before reporting, our processes endeavor to ensure that Transfers of Value made to HCPs, HCOs and POs are collected and reconciled to the best of our ability. Additional data and process monitoring may take place for quality assurance prior to reporting.

## **4. DATA PROTECTION**

### **4.1. Healthcare Organizations and Patient Organizations**

In the case of HCOs and POs, disclosure is always made individually by their names. With view of this, the HCOs and POs, 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 individual disclosure by name of the Transfers of Value under the scope of disclosure.

The information on the disclosure obligation of Egis are provided to the HCOs and POs contract by contract.

#### **4.2. Healthcare Professionals**

In the case of HCPs, the basis for data processing related to individual disclosure by name is the relevant voluntary consent of the data subject. All of our contracts contain a Privacy Statement and Consent Annex, in which the HCP unambiguously gives or does not give consent to the individual disclosure by name of their data for transparency reporting purposes. Accordingly, HCPs have the opportunity to request that no name-based disclosure of their data be made due to data privacy reasons. In this case, the Transfers of Value paid to them will be published anonymously and in an aggregated way.

In case no unambiguous consent is given, or if Egis was unable to obtain a consent form duly filled by the Recipient, the disclosure is made under the aggregate category.

The consent of the HCPs is obtained contact by contract.

#### **4.3. Withdrawn consents**

HCPs 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 HCP will be transferred to the anonymous, aggregated disclosure category. If the consent is withdrawn after the publication of the annual report, the revocation will take place by recalling the report and by publishing a revised report.

#### **4.4. Privacy notice**

The circumstances of data processing conducted by Egis are detailed in the document titled “*Privacy Notice of Egis Pharmaceuticals PLC*” (“Privacy Notice”). The Privacy Notice is always available here: <https://int.egis.health/gdpr>. The Privacy Notice provides detailed information on the exact legal basis for data processing, the scope of the processed data, the duration of data retention, the parties authorized to access the data, the recipients of data transfers, as well as the related rights of data subjects and available legal remedies.

### **5. DISCLOSURE OF FINANCIAL DATA**

#### **5.1. Currency of Disclosure**

The currency used to indicate the disclosure details is: Hungarian Forint (HUF).

#### **5.2. Taxes**

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

### **5.3. Calculation Rules**

In accordance with paragraph 3.6, Transfers of Value provided in foreign currencies that are subject to disclosure in Hungary are converted from their original currency into the disclosure currency, i.e. HUF, based on the official exchange rate published by the Hungarian National Bank on the date of settlement of the invoice related to the Transfer of Value.

### **5.4. Non-monetary Transfers of Value**

Donations to HCOs or POs can be both monetary and in kind. For significant non-financial support that cannot be assigned a meaningful monetary value, the relevant description describes the non-monetary benefit that the HCO or PO receives.

### **5.5. Determining the value of donations**

Egis discloses donations to HCOs (including hospitals) and POs 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 by 30 June each year.

### **6.2. Format of disclosure**

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

### **6.3. Reported year**

The disclosure refers to the previous calendar year (from 1st January to 31st December).

### **6.4. Duration of disclosure**

The information provided is available on the Internet for a period of 3 years from the date of publication.

### **6.5. Data reconciliation prior to the disclosure**

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

### **6.6. Place of disclosure**

The publication takes place on <https://hu.egis.health/atlathatosag-hu> website.

### **6.7. Language of disclosure**

The disclosure is done in Hungarian.

### **6.8. Contacts**

Recipients may initiate requests related to the transparency disclosure. Any kind of inquiries regarding the transparency disclosure may be sent to [transzparencia@egis.hu](mailto:transzparencia@egis.hu) address. All inquiries will be processed according to our internal procedure.