

# TRASPARENCY CHIESI FARMACEUTICI S.P.A. ("CHIESI FARMACEUTICI") METHODOLOGICAL NOTE

## Transparency: EFPIA requirements

EFPIA (European Federation of Pharmaceutical Associations and Industries), in order to ensure and protect the integrity of the relationships between pharmaceutical companies and healthcare professionals, approved the "Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations" in June 2013.

In 2019, the contents of this code were reflected within the EFPIA Code of Practice.

## Transparency: Italian implementation

The Farmindustria Code of Conduct integrated EFPIA provisions in 2013.

As from January 1st, 2015, each pharmaceutical company member of Farmindustria must publish the Transfer of Values made to Healthcare Professionals and to Healthcare Organisations.

With reference to each year, publication must take place by 30 June of the following year, via the company website.

As of June 30, 2016, data on Transfer of Values ("TOV") between Chiesi Farmaceutici and Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), as well as Transfer of Values at corporate level related to Research and Development (R&D) activities have been made available on the Chiesi Italy website.

As of June 30, 2022, data on TOV between Chiesi Farmaceutici and Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), as well as Transfer of Values at corporate level related to Research and Development (R&D) activities were made available directly on the Chiesi Farmaceutici website.

In **November 2023**, the Farmindustria Code of Conduct was amended to include (in the June reporting) also TOVs made to Patient Associations and, in aggregate, to Expert Patients.

As of **June 30, 2024**, therefore, data relating to Transfer of Values between Chiesi Farmaceutici and Patient Associations, as well as - in aggregate form - Transfer of Values between Chiesi Farmaceutici and Expert Patients are also included in the Chiesi Farmaceutici TOV file.

The TOV file is republished on the company website in the event that changes to the consent to publication are requested by the Healthcare Professional.

## **DEFINITIONS AND PUBLICATION CRITERIA**

### Healthcare Professionals (HCPs)

Any person who carries out their activity in the medical sector, dentistry, public, private or hospital pharmacies, any nurses, Administrators of Local Health Authorities, any technical or administrative staff of public or private healthcare structures and any other person within the scope of their professional activity can prescribe, dispense, purchase or administer a medicinal product and that has their activity mainly in Europe. Intermediary pharmaceutical distributors are however excluded.

TOV made by Chiesi Farmaceutici towards HCPs could be either indirect (carried out on behalf of Chiesi Farmaceutici by a third party) or direct (carried out directly by Chiesi Farmaceutici for the benefit of the recipient).



## Healthcare Organizations (HCOs)

Any legal entity whether it is an association or medical, scientific, healthcare or research organisation, (irrespective of the relevant legal status) such as Hospitals, Clinics, Foundations, Universities, specialisation and training schools (with the exclusion of Patients Associations) that have their legal headquarters or main office or activity in Europe, or through which a physician may practice.

Congresses Secretariat/Provider are also considered "Healthcare Organizations" receiving transfer of values.

Transfer of Values made by Chiesi Farmaceutici to HCOs may consist of donations, sponsorships (including in support of congresses) and/or consulting fees.

## Research & Development

Chiesi Farmaceutici directly organises and manages most of the Chiesi Group's preclinical and clinical development activities. The TOV indicated in the relevant item therefore refer to the costs incurred directly by Chiesi Farmaceutici for Research and Development activities at corporate level, regardless of the countries in which the activities are actually performed. Only a small part of the total indicated refers to Value Transfers referring to HCPs or HCOs based in Italy.

Data concerning Chiesi Farmaceutici's TOV for Research and Development includes costs related to preclinical, clinical, observational and spontaneous studies paid to HCPs and HCOs, both in Italy and abroad.

## Patient Associations and Expert Patients

According to EFPIA Code of Practice, a "Patient Association" is any non-for-profit legal person/entity, mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers.

According to Farmindustria Code of Conduct, are considered 'expert patients' those patients who, in addition to having direct knowledge of the disease, have specific skills and experience in aspects related to medicine research and development, regulatory activities or advocacy activities understood as the ability to promote and support the causes and needs of a plurality of patients.

TOV made by Chiesi Farmaceutici towards Patients Associations may consist of donations, sponsorships (including in support of specific projects) and/or consulting fees.

TOV made by Chiesi Farmaceutici towards Expert Patients consist of fees for consultancy services and related accommodations.

#### PUBLICATION FORMS

## Individual disclosure

The following TOV are disclosed individually (i.e. with specific identification of the recipient):

- (a) expenses incurred for the participation of HCPs in congresses with respect to registration fee, travel and hospitality (excluding meals and beverages);
- (b) expenses for consultancy and professional services resulting from a specific contract with an HCP or HCO or a Patient Association;
- (c) donations and contributions (including sponsorship), whether in cash or in kind, to HCOs or Patient Associations.

## Aggregate disclosure

The following TOV are disclosed in aggregate form (i.e. without identification of the recipient):



- (a) costs incurred annually by pharmaceutical companies on research and development activities;
- (b) all expenses referred to in points (a) and (b) above for which the receiving Healthcare Professional has not given consent for individual publication;
- (c) fees and hospitality expenses paid to Expert Patients (this value is reported in the "Aggregate amount" row of the "POs" section of the TOV file published on the company website).

#### Consent release

Pursuant to the data protection regulations, individual disclosure of Transfer of Values to HCPs is only possible after specific consent has been obtained.

If an HCP does not give consent, the relevant Transfer of Value is published in aggregate form.

If an HCP involved in more than one activity issues conflicting consents, the total Transfer of Value is published in aggregate form.

Publication of Transfer of Values to HCOs and Patient Associations is not subject to consent.

Chiesi Farmaceutici has requested consent for publication from Healthcare Professionals for each initiative in the following form:

- a) with regard to expenses incurred for the participation of Healthcare Professionals in congresses;
- b) with regard to fees for consultancy activities and professional services.

## Privacy: precautions regarding data accessibility

The Privacy Authority has provided for appropriate measures to hinder massive duplication operations of data and their availability through external search engines. Web pages with the TOV table cannot be indexed on search engines.

#### PUBLICATION METHODOLOGY

Accounting principles applied and reporting period:

The "competence" criterium was applied for:

- (a) sponsorship of congresses, held from January to December 2024,
- (b) consultancy for services rendered from January to December 2024,
- (c) Research and Development expenses.

The "payment" criterium was applied for:

(d) donations for amounts paid out from January to December 2024.

## Currency

Transfers of value are expressed in Euro.

#### VAT

Costs are inclusive of any non-deductible rates.