

TRANSPARENCY OF TRANSFERS OF VALUE

METHODOLOGICAL NOTE



TRANSPARENCY OF TRANSFERS OF VALUE

In accordance with local regulations, the Companies document and make public the economic transfers, also known as transfers of value, made directly or indirectly (through third parties) to natural and legal persons operating in Healthcare.

The timelines and methods of access to these data are variables according to the regulation of the State.

In Italy, the companies associated with Farindustria and Confindustria Dispositivi Medici, as well as their affiliates, are required to respect the transparency obligations that are set out respectively in the Code of Ethics of Farindustria and the Code of Ethics of Confindustria Dispositivi Medici.

Legally separate entities but belonging to the same Group are also required to comply with transparency obligations.

IBSA Farmaceutici Italia Srl publish annually on the website (www.ibsa.it) the transfers of value of the previous year for each Healthcare Professional, Healthcare Organisation and other third parties domiciled in States without affiliates and where is no local Authority's website to make the publication.

The data are related to:

- costs of participation in conferences and congresses relating to registration, travel and hospitality fees (excluding meals and drinks);
- expenses for consultancy activities and professional services, resulting from a specific contract with the IBSA Group;
- donations and grants (including free-of-charge leases) both in cash and benefits in kind;
- direct or indirect contribution to congress events carried out through healthcare structures or third parties, including the sponsorship of doctors to conferences and congresses with the payment of the registration fees and the expenses of travel and accommodation;
- economic transactions related to consultancy and professional activities resulting from a written contract between the company and the Institute/Organisation or Association that provide any type of service not covered in donations and contributions and financing for congress events;
- scholarship;
- non-clinical studies, as defined in the Good Laboratory Practices;
- clinical studies, as defined in the Directive 2001/20/CE;
- observational prospective studies, according to point 4.4 of the Code of Conduct Farindustria, that involve the gathering of data on patients by individuals or groups of doctors.

Information about the regulations of transparency requirements for transfers of value between Pharmaceutical Companies and Healthcare Providers and/or Healthcare Organizations can be found on www.efpia.eu or www.medtecheurope.org or the website of the local regulatory Authority.

Transparency & GDPR

The on-line and unencrypted publication of economic transfers on an individual basis, namely for each Healthcare Professional, necessarily requires the express consent to the processing of personal data by the natural person concerned (Healthcare Professional), in compliance with the applicable legislation on the processing of personal data (L. Decree 196/2003 and EU Regulation 2016/679). In accordance with the standards laid down by Farindustria and Confindustria Dispositivi Medici, for each category of expenditure the amounts are reported in aggregate form, the number of recipients whose data are published in aggregate form and their percentage compared with the total number of recipients.

IBSA is called to the "maximum possible effort" to obtain the consent of each Healthcare Professional to the publication, on an individual basis, of the financial payments received in the previous year, as required by the Farindustria and Confindustria Dispositivi Medici Codes), in compliance with the applicable legislation on the processing of personal data.

The publication of the economic transfers on an aggregate basis must be a wholly exceptional circumstance.

Data retention

The information will remain in the public domain according to the local regulations.

The accounting and administrative documentation supporting the published data will be kept by IBSA for at least five years and may be made available in detail on request.

Accounting aspects

The published data are recorded in compliance with current and applicable VAT legislation (DPR 633/72) and are shown net of VAT and gross of withholding tax; values in foreign currency are converted into Swiss Francs based on the exchange rate on the date of recording.

The date of the transaction is defined with the mixed principle: on an accrual basis for all types of expenditure, except for charitable donations and consultancy which are considered on a cash basis.

To whom the obligation of transparency applies



Healthcare Professionals (HCPs)

Any person who carries out their activity in the medical sector, dentistry, public, private or hospital pharmacies, any nurses, Administrators or staff of Local Health Authorities, any technical or administrative personnel 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 speciality, a medical device, a food supplement, a cosmetic. Intermediary pharmaceutical distributors are however excluded.

Healthcare Organisation or Structures (HCOs)

Any structure whether it is an association or medical, scientific, healthcare or research organisation, (independently from its legal form) such as Hospitals, Clinics, Foundations, Universities, specialisation and training schools (except for patient associations) or through which a Doctor may practice.

Third Parties

Third Parties means subjects who propose, organise, manage all scientific, logistical and organisational aspects of any events in order to meet a scientific or other educational/training need.

Additional Recipient Categories

Additional categories of recipients may be identified based on local regulations.

For more information

www.ibsa.it

www.farindustria.it

www.confindustriadm.it

www.efpia.eu

www.medtecheurope.org