

# Almirall S.p.A. Italy

## Methodological Note 2024

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## Disclosure 2024

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### 1. Introduction

Interactions between healthcare companies and Healthcare Professionals (HCPs), Healthcare Organizations (HCOs) and Patient Organizations (POs) are essential to establish and maintain the best possible supply of medicinal products. Almirall S.p.A. recognizes there is a growing expectation that such interactions must be conducted with integrity and must be transparent in order to create a better understanding of, and ultimately build trust in, the validity of industry interaction with the medical profession. Therefore Almirall S.p.A. supports the principle of transparency and complies with the local and EFPIA (European Federation of Pharmaceutical Industries and Associations) Codes requirements for the disclosure of Transfers of Value (ToV) conducted in 2024 with Healthcare Professionals, Healthcare Organizations and Patient Organizations.

Almirall S.p.A. made every effort to ensure all data required are disclosed and that it complies with all applicable laws, guidance and regulations. Almirall S.p.A. expects that third parties and business partners apply equivalent standards in any professional activities conducted on its behalf.

### 2. Definitions

Almirall S.p.A. recognizes all the definitions set out in the Farindustria Code of Practice. To access the Code, click [here](#).

**Contribution to costs related to events:** support providing or covering the costs of meals, travel, accommodation and/or registration fees to support the attendance of an individual HCP or PO Representative to an event organized or created by any company of Almirall and/or a third party.

**Donations and grants:** collectively, mean providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

**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 any company of Almirall.

**Fees for services and consultancy:** ToVs resulting from or related to contracts between Almirall and any HCP or HCO under which such HCP or HCO provide any type of services to Almirall.

**Healthcare Organisation (HCO):** any legal entity (i) that is a healthcare, medical or scientific association or organization such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

**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.

**Patient Organisation (PO):** non-for-profit legal person/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.

**Research and Development:** Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) Non-clinical Studies (as defined in OECD Principles on Good Laboratory Practice); (ii) Clinical Trials (as defined in Regulation 536/2014); and (iii) Non-Interventional Studies (NIS) 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.

**Sponsorship:** is a support provided by or on behalf of Almirall, when permitted by law, as a contribution to support an activity (including an Event) performed, organized or created by a HCO, a PO or a third party.

**Third Parties:** third parties working for and on behalf of Almirall S.p.A. where such parties exist and have provided a ToV on Almirall's behalf have been reported to Almirall and are disclosed as required.

### 3. Disclosure's scope

## Products concerned

Disclosure applies to ToVs made in the context of activities which are completely or partially related to Prescription Only Medicines (POMs). Such activities comprise donations and grants, scientific and professional meetings (sponsorships, costs for registration, travelling and accommodation), services and consultancies (fees and related costs), and Research & Development.

## Excluded ToVs

Disclosure does not apply to ToVs that are not mentioned in the previous section “Products concerned” such as ToVs that are: solely related to over-the-counter medicines, Items of medical utility, meals or medical samples among others.

## ToVs date

All ToVs taking place in 2024 are disclosed in the data for 2024.

## Direct ToVs

The disclosure includes ToVs made by Almirall to Healthcare Professionals whose principal address is in Italy and to Healthcare Organizations and Patient Organizations which social address is in Italy.

## Indirect ToVs

Indirect ToVs provided to HCPs or HCOs by third parties on behalf of Almirall (e.g., travel agencies) are assigned to the according HCP or HCO and disclosed accordingly independent of the fact that the ToV was transferred on the bank account of the HCP/HCO or on the bank account of the third party. The third party will not be disclosed.

## Non-Monetary ToVs

Disclosure of non-monetary transfers of value is made at the equivalent value in monetary terms. No non-monetary transfers of value took place during the reporting period.

## ToVs in case of partial attendances or cancellation

In case of partial attendance, the portion of the ToV that the HCP or HCO benefited from is disclosed. ToVs that did not ultimately take place or were cancelled are not disclosed as no benefit was received by the HCP, HCO or PO.

## Cross-border activities

Where Almirall Global or any other Almirall affiliate engages with an Italian HCP, HCO or PO which results in a ToV; the respective Almirall entity engaging the service is required to record the engagement in the Customer Relation Management (CRM) system to ensure that the transaction is captured for local disclosure purposes.

## Research & Development

Costs that are subsidiary to these activities are included in the aggregate R&D category.

Almirall discloses payments agreed with universities and research centers for pre-clinical research as well as clinical trial agreements in HCOs (either direct payments or through a third-party), fees of independent professionals to provide research and development services, and investigator's meeting expenses.

Fees related to retrospective study work have been disclosed on an individual basis under the category "fees for services".

## 4. Specific considerations

### Country unique identifier

Almirall S.p.A. aims to maintain an up-to-date contact database which allows HCPs to have more than one practicing address associated with them, for example when an HCP works at different centers/hospitals etc. For the purposes of disclosure, the database utilized only recognizes one address - the principal practice address.

### Self-incorporated HCP

Almirall S.p.A. considers legal entities with self-incorporated HCPs as HCO.

### Multi-year agreements

Where agreements, sponsorships, studies and the like fall into more than one year, these are disclosed when any activity is performed, hence payment will be split over several years.

### Quality Checks

Prior to reporting, Almirall internal processes ensure Transfer of Value made to HCP, HCO or PO are correctly collected in Almirall.

Data quality checks are performed to ensure any HCP (HCO as appropriate) who has not provided consent for individual disclosure are reported in 'aggregate' and additional data and process monitoring takes place for quality assurance prior to reporting.

## 5. Data protection legal basis

### Consent collection (inc. consent withdrawal)

Consent for the publication of the ToVs was collected at the individual HCP level and documented as such prior to disclosing the related data, where possible. Consent was obtained for all ToVs carried out from January 1, 2024 onwards (with no expiration date, unless it was revoked). In case the consent has not been provided by the HCP or there is not sufficiently documented to prove its existence, the related ToV is disclosed only in aggregated form. However, an HCP always has the right to withdraw consent. As a general principle, the withdrawal of consent for individual disclosure during the year results in the data collected up to that point being published in aggregated form, retroactively from January 1 of the same year, and for all subsequent years. Almirall S.p.A. does not accept partial consent or 'separate' disclosure.

## 6. Form of disclosure

### Date of publication

ToVs are reported for one calendar year and disclosed in June of the following year.

### Disclosure platform

The transparency report is available on the Almirall website. The annual report will remain three years on the website and all the related documentation is to be maintained for a minimum of 5 years.

### Disclosure language

The transparency report is available in Italian.

## 7. Disclosure financial data

### Currency

All disclosed ToV data is reported in Euro. ToVs provided in currencies other than Euro are converted to Euro using the exchange rate of the spend date. This is an automatic conversion that takes place in the Almirall disclosure database.

### VAT

VAT (Valued added Tax) is **not** included in the disclosure data. If VAT can't be clearly excluded, the full amount of the ToV is disclosed. Se l'IVA non può essere esclusa in modo preciso, viene reso pubblico l'intero ammontare del ToV.

### In-kind ToVs

Almirall S.p.A. has not provided any benefits in kind to HCPs, HCOs and PO during 2024.

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