



Almirall SpA Italy

Methodological Note 2020

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1. Introduction

Almirall SpA supports the principle of disclosure and complies with the EFPIA (European Federation of Pharmaceutical Industries and Associations) Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations “ToVs” implemented in Italy by Farmindustria.

2. Definitions

Almirall SpA recognizes all the definitions set out in the Farmindustria Code of Practice. To access the Code, click [here](#).

Recipients: Almirall SpA recognises the definition of Health Professional ‘HCP’, Healthcare Organisation ‘HCO’, set out in the Farmindustria Code of Practice. To access the Code click [here](#).

Third Parties: Third parties working for and on behalf of Almirall SpA where such parties exist and have provided a ToV on Almirall’s behalf have been reported to Almirall and are disclosed as required.

Patient Organisations: Support of and interactions with Patient Organisations are in conformity with the Farmindustria Code of Practice and can be accessed by clicking on this link [here](#). Such support and Interactions are not included in this disclosure and can be found [here](#).

Research and Development: Almirall SpA recognises the definition of Research and Development Transfers of Value set out in the Farmindustria Code of Practice. To access the Code, click [here](#).

3. Disclosure Methodology

ToVs to HCPs have been disclosed where possible against the individual HCP. Where consent has not been provided such ToVs have been disclosed in aggregate. Where a HCP has consented to some but not all ToVs being disclosed those with no consent have been added to the aggregate category. See *Partial Consent below*.

ToVs made to Italian HCPs or HCOs by Almirall Head Office and/or other affiliates have been reported to Almirall SpA and have been disclosed as required. See *Cross-border Activities below*.

HCPs operating through their own company will be disclosed against the individual HCP where consent has been provided to do so. In such situations the principle practicing address will be that of the registered company. Where consent has not been provided and/or where Almirall cannot amend the principle practicing address in the database such ToVs will be declared in aggregate.

ToVs to HCOs are disclosed against the individual HCO by activity.

Disclosure of Research and Development Transfers of Value

Costs that are subsidiary to these activities are included in the aggregate amount.

Thus, Almirall discloses payments agreed with universities and research centres for pre-clinical research as well as clinical trial agreements in hospitals (either directly payments or through a 3rd party), fees of independent professionals to provide research and development services and investigators meeting expenses.

Almirall does not disclose the payments made to companies providing services for research and development (CROs).

4. Categories of Transfers of Value (ToV)

Full definitions and information on the categories of TOV required by the Farmindustria Code of Practice can be found on this link, click [here](#).

Donations for corporate or charitable purposes do not fall into the scope of the Disclosure requirements. These have been disclosed as required and can be found [here](#).

Benefits in Kind: Almirall SpA has not provided any Benefits in Kind in 2020 to HCPs, HCOs.

5. Disclosure Scope

Almirall SpA promotes Prescription Only Medicines as well as products that are registered as Over The Counter (OTC) Products or Medical Devices. As these are all promoted and can be prescribed, Almirall SpA does not believe these fall into the excluded disclosure category and has made disclosures against all ToVs for all products irrespective of their registered category.

HCPs working for Almirall SpA as company employees (full or part time), or as consultants, are not included in the disclosure data, as all such individuals primary occupation is not that of a practicing health professional.

Date of Disclosure

All ToVs taking place in 2020 are disclosed in the data for 2020.

6. Specific Considerations

ToVs in case of partial attendances or cancellation: Where a partial attendance has been provided this has been disclosed working on a pro-rata basis of the benefit received by the HCP or HCO. ToVs that did not ultimately take place or were cancelled are not disclosed as no benefit was received by the HCP or HCO. ToVs to non-presented doctors at an event are disclosed in aggregate.

Cross-border Activities: Where Almirall Global or any other Almirall affiliate provide a ToV to an Italian HCP or HCO, the respective Almirall entity obtains consent and records the ToV in the Almirall SpA Disclosure system.

Country Unique Identifier: Almirall SpA maintains an up to date contact database with an internal unique code in order to avoid misleading or duplications. The database allows HCPs to have more than one practicing address associated with them. For example when an HCP works at different centres/ hospitals etc. For the purposes of disclosure, the database only recognises the principle practice address.

Multi-year Contracts: Where agreements, sponsorships and the like fall into more than one year these are disclosed when any payment is made, whether in full or in part; hence payment will be split over several years.

7. Consent Management

Consent collection: In the spirit of transparency and in compliance with Data Privacy requirements Almirall SpA has ensured each agreement with an HCP includes a section for the individual to consent to either individual or aggregate disclosure, this is requested for each activity.

Management of recipient data/consent withdrawal: The consent management system enables amendment from individual to aggregate or vice versa and consents are changed manually in the database. This is done via an email inbox specified in the consent/agreement (info.italy@almirall.com). If an HCP requests clarification or changes to the disclosed data or consent status Almirall SpA will act on the request as appropriate, reply to the HCP with the clarification requested or that the change has been implemented. The email from the HCP will serve as proof of withdrawal / change of consent. Disputes on the value of the ToV disclosed will be resolved as quickly as possible and the disclosed data amended where possible and required.

Partial Consent: Almirall SpA collects consent on a per activity basis; as such HCPs have a choice for each activity to be disclosed either individually or in aggregate. Almirall SpA have disclosed each ToVs according to the HCP consents. Therefore for an individual may have ToVs disclosed in both the individual and aggregate categories.

8. Financial Information

Currency: All disclosed data is in Euro. Where a ToV has been provided in a different currency it is converted to Euro using the exchange rate of the date when it has been paid. This is an automatic conversion that takes place in the Almirall disclosure database.

VAT: VAT is not included in the disclosure data, where it applies.

9. Post Publication

The annual report will remain on the website for three years. Once published, the report will be updated once a month with the changes requested and agreed.

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