

Almirall

Methodological Note

Bulgary

Transfers of Value (ToVs) 2018

Methodological Note of 2018 Transfers of Value (ToVs)

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1. Introduction

Almirall is fully committed to transparency in its dealings with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), in order to increase trust and transparency and comply with the EFPIA Code of Practice requirements for the disclosure of certain Transfers of Value 'ToVs'.

We believe that transparency is key to building and maintaining confidence and trust in us, and in our medicines and we fully support the work being done by associations such as the European Federation of Pharmaceutical Industries and Associations (EFPIA) to improve transparency across the pharmaceutical industry.

The Transfers of Value in this report covers all the payments, to the best of our knowledge, made by Almirall in Bulgaria for the 2018 calendar year.

2. Definitions

Almirall recognizes all the definitions set out in the EFPIA Code of Practice (among others, the definition of Healthcare Professional "HCP", Healthcare Organisation "HCO", and Transfer of Value "ToV"). To access the Code, [click here](#).

Third Parties: Third parties working for and on behalf of Almirall 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 as set out in EFPIA Code 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 recognises the definition of Research and Development Transfers of Value set out in the EFPIA Code: 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 Directive 2001/20/EC); or (iii) 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. To access the Code, click [here](#).

3. Disclosure Methodology

Currently ToVs to HCPs are disclosed where possible against the individual HCP. Where consent is not provided (or the HCP has consented to some but not all ToVs being disclosed) his/her ToVs are disclosed in aggregate.

ToVs made to HCPs or HCOs by Almirall Head Office and/or other affiliates are disclosed as required.

ToVs to HCOs are disclosed against the individual HCO.

When there is no data in one section (HCPs or HCOs or both) or in one category, it means that no transference of value has been made (it is a zero value)

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).

Data was checked for accuracy to the best of our knowledge before publication.

4. Categories of Transfers of Value (ToV)

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

Donations for corporate or charitable purposes do not fall into the scope of the Disclosure requirements. When they are offered to Patients Organisations they are disclosed as required and can be found [here](#).

5. Disclosure Scope

Almirall 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 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.

Date of Disclosure

All ToVs taking place from 1st January to 31st December 2018, which were available up to the end of 1Q, 2019 are disclosed in this exercise 2018, to the best of our knowledge.

6. Specific Considerations

The only activity paid to HCP/HCO in this country is within the scope of the R&D transfers of value. As it is reflected in the report, EFPIA Code requires member companies to disclose the total amount of R&D transfers of value to HCP/HCO per year (reporting period) in aggregate.

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

Country Unique Identifier: Almirall 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 centres / hospitals etc. For the purposes of disclosure the database used only recognises one address identified as the main professional address.

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

7. Consent Management and Data protection regulation

Consent collection: In the spirit of transparency and in compliance with Data Privacy requirements Almirall has ensured each agreement with an HCP includes a section for the Healthcare Professional 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. If an HCP requests clarification or changes to the disclosed data or consent status Almirall will act on the request as appropriate, replying 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: in the event of disagreement, disputes will be resolved as quickly as possible and the disclosed data amended where possible and required.

Partial Consent: Almirall collects consent on a per-activity basis. Where recipients of transfers of value have decided to disclose as an individual in some activities and aggregate in others, the amount attributable to all transfers is disclosed on an aggregate basis.

8. Financial Information

Currency: All disclosed data are either in Euro or in Bulgarian Levs (2 currency reports). 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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