



Almirall UK Limited

Methodological Note 2016

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1. Introduction
2. Definitions
3. Disclosure Methodology
4. Categories of Transfers of Value
5. Disclosure Scope
6. Specific Considerations
7. Consent Management
8. Financial Information

1. Introduction

Almirall UK Ltd. supports the principle of disclosure and complies with the ABPI Code of Practice requirements for the disclosure of certain Transfers of Value 'ToVs'. For 2016 disclosures, Almirall has made a management decision to disclose all HCP data in aggregate in order to ensure it also complies with all applicable laws, guidance and regulations, specifically those related to protection of individual's data.

2. Definitions

Recipients: Almirall UK Ltd. recognises the definition of Health Professional 'HCP', Healthcare Organisation 'HCO', Other Relevant Decision Maker 'ORDM' and Transfer of Value 'ToV' set out in Clause 1 of the ABPI Code of Practice. To access the ABPI Code of Practice click [here](#).

Third Parties: Third parties working for and on behalf of Almirall UK Ltd. 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 Clause 27 of the ABPI Code of Practice, full definitions 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 UK Ltd. recognises the definition of Research and Development Transfers of Value set out in the supplementary information of Clause 23.2 of the ABPI Code of Practice. To access the ABPI Code of Practice click [here](#).

3. Disclosure Methodology

ToVs to HCPs have been disclosed in aggregate in order ensure compliance with the new General Data Protection Regulation (GDPR) and clause 24.9 of the ABPI Code.

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

HCPs operating through their own company will be disclosed against the HCP and declared in aggregate.

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

Data was checked for accuracy before publication.

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.

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

4. Categories of Transfers of Value

Full definitions and information on the categories of TOV required by the ABPI Code of Practice can be found in Clause 24. Please click on this link to access the ABPI Code: [here](#).

Almirall UK Ltd. defines and provides donations for corporate or charitable purposes only and as such donations do not fall into the scope of the Disclosure requirements. In some circumstances such donations may fall into the scope of Clause 27 of the ABPI Code of Practice 'Patient Organisations'. These have been disclosed as required and can be found [here](#).

Benefits in Kind: Almirall UK Ltd. has not provided any Benefits in Kind in 2017 to HCPs, ORDMs, HCOs.

5. Disclosure Scope

Almirall UK Ltd. promotes Prescription Only Medicines (POM) 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 UK Ltd. 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.

Free stock of GSL products is not included in the scope of disclosure.

Note: Whilst Medical Devices do not generally fall into the scope of ABPI Code of Practice, Almirall UK Ltd. has made the decision to disclose ToVs made for such products in line with the ABPI Code of Practice if / where these products can be both promoted and prescribed.

HCPs working for Almirall UK Ltd. 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 2016 are disclosed in the data for 2016. This principle will apply for this and each year thereafter. Any data relating to 2016 which was available up to 9th May 2018 was included within this report.

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, HCO or ORDM. ToVs that did not ultimately take place or were cancelled are not disclosed as no benefit was received by the HCP, ORDM or HCO.

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

Country Unique Identifier: Almirall UK Ltd. maintains an up to date contact database which allows HCPs & ORDMs 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 utilised only recognises one address, the principle practice address. Whilst Almirall UK Ltd. believes the HCP or ORDM may change the address, when checking the data themselves prior to publishing, many have felt this insufficient security against inaccurate reporting.

ToVs to forums, networks etc.: Those that have no associated principle practice address have been disclosed using the address of the lead HCP or ORDM etc. for the purposes of disclosure.

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

Consent collection: In the spirit of transparency and in compliance with Data Privacy requirements Almirall UK Ltd. has ensured each agreement with an HCP/ORDM 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 (tovconsentuk@almirall.com). If an HCP/ORDM requests clarification or changes to the disclosed data or consent status Almirall UK Ltd. will act on the request as appropriate, reply to the HCP/ORDM 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 UK Ltd. does not allow partial consent as all HCPs and ORDMs payments have been disclosed in aggregate.

8. Financial Information

Currency: All disclosed data is in GBP. Where a ToV has been provided by Almirall UK Ltd. or a Third party from outside the UK such ToVs are provided in the local currency and converted to GBP 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 included in the disclosure data, where it applies.

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