

## Almirall AG Methodological Note 2016

### Executive Summary

Transparency is the key to the generation and maintenance of confidence in relations of pharmaceutical industry with the general public and patients. Hence the European pharmaceutical industry intended to disclose pecuniary benefits provided between the pharmaceutical industry and stakeholders in the healthcare sector.

To achieve a high degree of transparency, disclosure should be done individually, i.e. naming the recipients in person. This requires the consent of the persons or organizations concerned to such disclosure. For this purpose, the cooperation agreements between the pharmaceutical industry and healthcare professionals and healthcare organizations are supplemented by suitable consent clauses.

Almirall AG, in the text Almirall, supports the principle of disclosure and complies with the Pharmacoooperation Code requirements for the disclosure of certain Transfers of Value (ToVs). Almirall AG has made every effort to ensure all data required is disclosed and that it also complies with applicable laws, guidances and regulations.

### Pre-Disclosure Information to the individual disclosing health care professional and organization

Key figures for the respective reporting period, i.e. the calendar year 2016, for the individual disclosure are automatically sent by the Almirall disclosure system to the individual recipient in a password-protected manner.

The recipient is able to open and read this information in advance, and if applicable initiates amendment of the key figures in writing to the postal address of Almirall.

Almirall subsequently is adapting key figures in accordance with the recipients edits.

### Definitions

**Recipients:** Almirall recognizes the terms of Healthcare Professional, Healthcare Organization, and Transfer of Value (ToV) set out in the Pharma Cooperation Code (PCC).

**Third Parties:** Third parties working for and on behalf of Almirall do not change the general procedure of disclosure of ToV to Healthcare Professionals and Healthcare Organizations.

**Research and Development:** Research and Development ToVs are disclosed on in aggregate.

**Patient Organizations:** Almirall discloses pecuniary benefits granted to particular patient organizations on an individual basis and annually for a full calendar year (reporting period).

The publication holds the names of the particular patient organisations, the total amounts paid in the course of a calendar year, and a short description of the nature of the support, which includes the pecuniary value of financial support and invoiced

costs; a non-pecuniary benefit is clearly describing the benefit received by the patient organisation.

Such support and interactions are not included in this disclosure.

## Disclosure Methodology

### Pecuniary Benefits

The term pecuniary benefits as defined by the PCC means remuneration granted either directly or indirectly in connection with pharmaceuticals for human medicine available on prescription only. The disclosure includes payments made e.g. for consultancy and the provision of services, financial support for research and development in the healthcare sector and cost contributions for the attendance of professionals at events.

### Disclosure at individual level

Almirall has signed the PCC and in accordance with PCC sections 231 and 232 monetary benefits that Almirall provided to health care professionals and health care organizations are disclosed. To follow data protection and applicable regulations, a specific disclosure consent clause is attached to ToV agreements with health care professionals and organizations.

ToVs to health care professionals have been disclosed where possible against the individual health care professional. Where individual consent has not been provided such ToVs have been disclosed in aggregate.

### Withdrawal of consent

According to the general legal practice for data protection law consent to data processing and notification can basically be revoked at any time in Switzerland. However, withdrawal cannot have retrospective effect, but can in principle be only prospective.

In the unlikely event of withdrawal of consent after providing a service and pecuniary ToV, the acknowledge of receipt in writing is sent to the revoking health care professional, along with the information that the disclosure is done in accordance with the signed contractual agreement for the respective service and associated ToV. To avoid a case of dispute, Almirall would disclose the respective data in aggregate.

Disclosure at individual level shall comprise specific information on each health care professional and/or health care organization which allows for such expert or institution to be unambiguously identified, as well as on the total of the ToVs granted throughout the reporting period.

ToVs to health care organizations are disclosed against the individual health care organizations by activity.

### Disclosure of Research and Development Transfers of Value

Research and Development transfers of value to health care professionals or organizations including subsidiary costs are disclosed in total for the reporting year.

### Deductible

A one third deductible is calculated of the total amount of ToV if applicable. This amount is 34 % of the total amount of ToV and is captured in the respective agreement.

In the event of minor deviations of the final costs from initial total amount, which might occur due to individual late cancellation affecting group fare, the ToV is disclosed in accordance with the numbers captured in the mutual signed agreement.

### Type of ToVs

ToV disclosure relates exclusively to ToVs in connection with

- a) Research and development;
- b) Donations and subsidies;
- c) Events;
- d) Services rendered and consulting provided including expenses incurred.

The information to be disclosed is categorized as follows:

Categories of ToV granted to individual health care professionals:

- 1) ToV in connection with scientific events:
  - Admission and attendance fees,
  - Travel costs and costs for overnight accommodation.
- 2) Fees for services rendered and consulting provided, a distinction being made between the payment of fees and reimbursement of expenses.

Categories of ToV granted to individual health care professionals:

- 1) Financial donations as well as subsidies;
- 2) ToV granted in connection with scientific events:
  - Admission and attendance fees,
  - Support of institutions or third parties appointed by such institutions for implementing the event.

**Benefits in Kind:** Almirall has not provided benefits in kind in 2015 to health care professionals and health care organizations.

### Disclosure Scope

Almirall promotes Prescription Only Medicine as well as products that are registered as Over The Counter 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.

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

### Reporting period

All ToVs taking place in the calendar year 2016 are disclosed in the data for 2016, this principle will apply for this and each year thereafter.

### 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 health care professional or organization. ToVs that did not ultimately take place or were cancelled are not disclosed, with the exception of cancellation fees or similar, as no benefit was received by the health care professional or organization.

#### **Cross-border Activities:**

ToVs made to Swiss health care professionals or organizations by Almirall Head Office and/or other affiliates have been reported to Almirall AG and have been disclosed as required.

ToV provided by Almirall to health care professionals who mainly practice their profession or have their registered office in a country other than Switzerland are to be disclosed by the affiliated company active in the country where the respective recipient of ToV is based. The information and documents required for the disclosure are handed over to the affiliated company in due time for disclosure. If there is no affiliated company disclosing the ToV value, Almirall granting the ToV has to disclose it.

ToV granted to individual health care professional and organizations that mainly practice their profession or have their registered office in Switzerland by companies that have their registered office outside of Switzerland have to be disclosed by the pharmaceutical company affiliated in Switzerland according to the information and documents provided by the affiliated company.

Where Almirall Head Office or any other Almirall affiliate provides a ToV to a Swiss health care professional or HCO, the respective Almirall entity obtains consent and records the ToV in the Almirall Disclosure system.

In addition to the above, TOVs involving a foreign country are always subject to the applicable provisions of the relevant national code.

**Country Unique Identifier:** Almirall maintains an up to date contact database which holds more than one practicing address associated with health care professionals; for example for health care professionals working at different centres/ hospitals etc. For the purposes of disclosure the database utilised only recognises one address, the principle practice address. Health care professionals disclosed ToV against their principle practice address or the more appropriate practice address depending on the service provided, which is the sole decision of the recipient.

**ToVs to forums, networks etc.:** Those that have no associated principle practice address have been disclosed using the address of the lead health care professional or organization 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 payment is made, whether in full or in part.

## Consent Management

**Consent collection:** In the spirit of transparency and in compliance with Data Privacy requirements Almirall has ensured each agreement with an health care professional includes a specific disclosure consent clause 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 in the database. This is done upon receipt of a signed individual consent, or a withdrawal of an individual consent, both in writing to the postal address of Almirall. If a health care professional requests clarification or changes to the disclosed data or consent status Almirall will act on the request as appropriate, reply to the health care professional with the clarification requested or that the change has been implemented. The respective letter from the health care professionals will serve as proof of withdrawal 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.

**Consent:** Almirall collects consents on a per activity basis; as such health care professionals and health care organizations have a choice for each activity to be disclosed either individually or aggregate. Almirall has disclosed each ToV according to the health care professionals and organizations consents. Therefore an individual recipient may have ToVs disclosed in both the individual and aggregate categories.

## Financial Information

**Currency:** The disclosed amounts of ToV are in Swiss Francs. Where a ToV has been provided by Almirall or a via a third party from outside Switzerland such ToVs are converted to Swiss Francs using the exchange rate of the date when it has been paid. This automatic conversion is based on the Standard Accounting Principles and takes place in the Almirall disclosure database.

**VAT:** VAT is not included in the disclosure data.

The amounts of ToVs are recorded as net amounts (without taxes and/or charges as applicable).

## Accounting and Disclosure:

The Standard Accounting Principles are applied in particular when it comes to accrual accounting for services, for instance in the case of contractual relationships spanning several years or services rendered recurrently for more than one reporting period.

**REFERENCE:**

Code of conduct of the pharmaceutical industry in Switzerland on cooperation with healthcare professional circles and patient organizations (Pharma Cooperation Code)