

Almirall Hermal GmbH Methodological Note 2017

Introduction

Almirall Hermal GmbH recognizes that there is a growing expectation that industry interactions with HCPs and HCOs should not only be conducted with integrity but should also be transparent with the aim to create a better understanding of, and ultimately build trust in, the validity of industry interactions with the medical profession.

Therefore, Almirall Hermal GmbH supports the principle of disclosure and complies with the Code of Practice of the registered association Pharmaceuticals and Cooperation in Healthcare (AKG Code of Practice) for the disclosure of certain Transfers of Value (ToVs). Almirall has made every effort to ensure all data required is disclosed and that it also complies with all applicable laws, guidances and regulations.

Abbreviations

AKG: Arzneimittel und Kooperation im Gesundheitswesen (Pharmaceuticals and Cooperation in Healthcare)

HCO: Health Care Organisation

HCP: Health Care Professional

ToV: Transfer of Value

VAT: Value added Tax

Scope

Disclosure comprises payments of transfer of value (ToV) that Almirall Hermal GmbH, Almirall or any of Almirall's affiliates have provided to German Healthcare Professionals (HCP) or German Healthcare Organisations (HCO).

Disclosure applies to **ToVs** made in the context of activities which are completely or partially related to Prescription Only Medicines. 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.

HCPs are members of the medical, dental, pharmacy or nursing professions who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose principal professional address is located in Germany. HCPs working for Almirall Hermal GmbH as company employees (full or part time) are not included in the disclosure data, as well as

wholesale traders and employees of other trade companies distributing pharmaceutical products.

HCOs are organisations and associations delivering medical and scientific services by one or more HCPs, and whose business address is located in Germany. These include clinics, universities, consulting companies, medical training and education institutes and professional associations.

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.

Disclosure does not apply to **business meals** nor to ToVs given to **patient organisations**.

Categories of ToVs

Donations and Grants to HCOs: This category comprises donations, grants and any other unilateral ToV in cash or kind provided to HCOs supporting healthcare.

Contribution to costs related to events: This category includes sponsorships to HCOs, as well as payment of registration, travel and accommodation costs to HCPs when Almirall invites them to a scientific or professional meeting.

Service and consultancy: This category includes fee for services and related costs such as payment for travel and accommodation. These ToVs may be fees provided for consultants, speakers, authors or hospitation services.

Research & Development: This category comprises ToVs provided to HCPs or HCOs in the context of nonclinical, clinical or noninterventional studies.

Individual versus Aggregate Disclosure

ToVs to HCPs are disclosed where possible against the individual HCP. Where consent has not been provided such ToVs are disclosed in aggregate.

ToVs to HCOs are generally disclosed against the individual HCO. In cases where the leading HCP of an organization can be easily identified by the HCO's name or address (e.g. practice, quality circle), we need consent for individual disclosure. Where consent has not been provided, ToVs of such HCOs are disclosed in aggregate.

ToVs to HCPs through HCOs or in the context of a cooperation with a HCO are assigned to the HCP in case Almirall knows the name of the HCP as well as the ToV amount provided to the HCP. In such a case Almirall asks the HCP for consent to individual disclosure.

Research and Development ToVs to HCPs or HCOs including subsidiary costs are disclosed in aggregate and in total for the reporting year. CRO payments are not globally disclosed, only payments given by the CRO to HCPs and HCOs as well as Ethical Committee fees.

Note: With the new European Data Protection Regulation coming effective we disclose all ToVs in aggregate for a temporary period of time to avoid any violation against data protection.

Personal Data Protection

Consent collection: In the spirit of transparency and in compliance with Data Privacy requirements Almirall obtains consent from HCPs to either individual or aggregate disclosure by separate consent contracts. Consent contracts are global contracts being valid for every following collaboration. Consent is collected from HCPs as well as from HCOs where the leading HCP of the organisation can be easily identified by the name or the address of the HCO. All remaining HCOs are not asked for consent, however, Almirall informs them about individual disclosure prior to any activity by a specific clause in the collaboration contract.

Consent management and consent withdrawal: Almirall's consent management system enables amendment from individual to aggregate or viceversa so consents are changed manually in the database. Consent withdrawal is done via mail or e-mail contact specified in the consent contract (transparenzkodex@almirall.com). If an HCP or HCO requests clarification or changes to the disclosed data or consent status Almirall Hermal GmbH will act on the request as appropriate, reply to the HCP/HCO with the clarification requested or that the change has been implemented. The mail or e-mail from the HCP 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.

Partial Consent: Almirall Hermal GmbH collects consent on a global basis only. Therefore, it is not possible for a single HCP/HCO to have ToVs disclosed in both the individual and aggregate categories.

Date and Platform of Disclosure

ToVs are disclosed once a year on the German website **almirall.de** in German language. ToVs are reported for one **calendar year** and disclosed in June of the following year. The annual report will remain three years in the website, and all related documentation is to be maintained for a minimum of 5 years.

The **ToV disclosure date** is the date when the event or service takes place. 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. Study related payments are disclosed at the date of confirmation of payment from Almirall or CRO, respectively.

Financial Information

Currency: All disclosed data is in Euro. ToVs provided in currencies other than Euro are 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: ToVs for R&D are disclosed with VAT while all other amounts are disclosed without VAT.

Specific Considerations

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

Country Unique Identifier: Almirall Hermal GmbH maintains an up to date customer contact database which allows to identify HCPs and HCOs by unique OneKey™ numbers. In addition, this database allows HCPs to have more than one practicing address associated to them, for example when a HCP works at different centres/hospitals etc.. For the purposes of disclosure the database utilised only recognises one address, in general the principle practice address.

ToVs to forums and networks: HCOs such as forums or networks without an own principal address (e.g. some quality circles) have been disclosed using the address of the lead HCP for the purposes of disclosure.

ToVs with co-payment: In cases where the ToV recipient pays a part of the total sum by himself or herself, the amount paid by the ToV recipient is subtracted from the total amount.

Unclaimed ToVs: ToVs that have been paid by Almirall but have not been used by the HCP or HCP (e.g. due to short-term illness) are not disclosed as no benefit was received by the HCP or HCO.

No double disclosure: ToVs which can be assigned to different categories are disclosed in one category only.

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