



Almirall GmbH

Methodological Note 2023

Almirall GmbH

Methodological Note 2023

1. Introduction
 2. Pre-Disclosure Information to the individual disclosing HCP and HCO
 3. Definitions
 4. Disclosure Methodology
 5. Type of ToVs
 6. Disclosure Scope
 7. Reporting Period
 8. Specific Considerations
 9. Specific Considerations
 10. Consent Management
 11. Accounting and Disclosure
 12. References
-

1. Introduction

Interactions between pharmaceutical companies and HCPs and HCOs are essential to establish and maintain the best possible supply of medicinal products. A practicable way to increase public trust in those interactions is transparency. The highest degree of transparency is the individual Transfer of Value 'ToVs' disclosure arising from cooperation. Almirall GmbH, in the text Almirall and all parties involved therefore strive for the disclosure of ToV at the individual level.

Almirall supports the principle of disclosure and complies with the Pharming Code of Conduct requirements for the disclosure of defined ToVs. Almirall has made every effort to ensure all data required is disclosed in accordance with applicable laws, guidance, and regulations.

2. Pre-Disclosure Information to the individual disclosing HCP and HCO

The key figures for the respective reporting period, i.e., the calendar year 2023, for the individual disclosure are sent by Almirall to allow the recipient to open and read this information in advance, and if applicable to initiate amendment of the key figures in writing to Almirall.

Almirall subsequently is adapting key figures in accordance with the recipient's edits.

3. Definitions

Recipients: Almirall follows the definition of Healthcare Professional ‘HCP,’ Healthcare Organisation ‘HCO,’ and Transfer of Value ‘ToV’ set out in Pharming Code of Conduct.

Third Parties: Third parties working for and on behalf of Almirall do not change the general procedure for disclosure of ToV to HCPs and HCOs.

Research and Development: Research and Development ToVs are disclosed in aggregated mode.

Patient Organisations: Support of and interactions with Patient Organisations as set out in 10.6 Publication duties of the Pharming Code of Conduct. Pharmaceutical companies must publish on their website on the internet, all patient organisations that receive support from the pharmaceutical company or that have concluded agreements with the pharmaceutical company per Article 10.4. The publication must include the type, scope and purpose of the support or the type, scope, and purpose of the service. Such support and Interactions are not included in this disclosure.

4. Disclosure Methodology

ToVs to HCPs and HCOs have been disclosed where possible individually. Where individual consent has not been provided such ToVs have been disclosed in aggregate mode.

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

Disclosure of Research and Development Transfers of Value: Research and Development ToVs to HCPs or HCOs including subsidiary costs are disclosed in total for the reporting year.

Disclosure at individual level

Disclosure at individual level shall comprise specific information on each HCP and/or each HCO 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, to the extent that such contributions follow the definition in Pharming Code of Conduct Article 9.3 b), c) or d).

5. 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.

Categories of information to be disclosed:

June 2024

ToV granted to individual HCPs:

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.

ToV granted to individual HCOs:

1) Financial or material 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.

6. Disclosure Scope

Almirall promotes Prescription Only Medicine (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 does not believe this 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 individual's primary occupation is not that of a practicing health professional.

7. Reporting Period

All ToVs taking place in the calendar year 2023 are disclosed in 2024, this principle will apply for this and each year thereafter.

8. Specific Considerations

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: Due to technical changes/adjustments in the electronic customer management system and the ToV reporting system, all ToVs in 2021 and 2023 are reported with VAT if the ToV was paid with VAT. In the 2022 reporting period, ToVs are only reported with VAT for R&D as usual; all other ToVs are reported without VAT.

9. 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, except for cancellation fees or similar, as no benefit was received by the HCP or HCO.

Cross-border Activities: ToV provided by Almirall to HCPs and HCOs, who mainly practice or have their registered office in a European country other than Austria 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 time for disclosure. If there is no affiliated company disclosing the ToV value, Almirall affiliate granting the ToV has to disclose it.

ToV granted to individual HCPs and HCOs that mainly practice their profession or have their registered office in Austria by companies that have their registered office outside of Austria have to be disclosed by the pharmaceutical company affiliated in Austria according to the information and documents provided by the affiliated company.

Where Almirall Global or any other Almirall affiliate provides a ToV to an Austrian HCP 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 to HCPs, for example for HCPs working at different centres/hospitals. For the purposes of disclosure, the database only recognises one address, the principal practice address. HCPs disclose the ToV with their principal practice address or if more appropriate with the practice address depending on the service provided, which is the sole decision of the recipient.

ToVs to forums, networks etc.: Recipients without associated principal practice address have been disclosed using the address of the lead HCP or equivalent 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.

10. Consent Management

Consent collection: In the spirit of transparency and in compliance with Data Privacy requirements Almirall has ensured each agreement with an HCP or HCO includes a separate document for the individual to consent to either individual or aggregate disclosure, which 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 revoke of an individual consent, both in writing to Almirall. If an HCP or HCO requests clarification or changes of the disclosed data or consent status Almirall will act on the request as appropriate, reply to the HCP/HCO with the clarification requested or that the change has been implemented. The written message letter from the HCP/HCO 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 collects consent on a per activity basis. Almirall has disclosed each ToVs according to the HCP/ HCOs consents. Therefore, an individual recipient may have ToVs disclosed in both, individual and aggregate categories.

11. 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.

12. References

Pharming Code of Conduct, valid from 01/07/2020

Pharming Code of Conduct. ORDINANCE 2/2014 ADOPTED BY THE BOARD OF PHARMIG ON ARTICLE 9 OF THE PHARMIG CODE OF CONDUCT (TRANSPARENCY).