



Almirall s.r.o.

Methodological Note 2022

Czech Republic

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1. Executive Summary
 2. Definitions
 3. Disclosure Methodology
 4. Categories of Transfers of Value
 5. Disclosure Scope
 6. Reporting period
 7. Specific Considerations
 8. Consent Management
 9. Financial Information
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1. 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 s.r.o., (hereinafter “Almirall”), supports the principle of disclosure and complies with the European Federation of Pharmaceutical Industries of Associations (EFPIA) requirements for the disclosure of defined Transfers of Value (ToVs). Almirall s.r.o. has made every effort to ensure all data required is disclosed in accordance with applicable laws, guidances and regulations.

2. Definitions

Recipients: Almirall follows the terms of Healthcare Professional (HCP), Healthcare Organization (HCO), and Transfer of Value (ToV) set out in the EFPIA Code).

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 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.

3. Disclosure Methodology

Disclosure at individual or aggregate level

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 (Spain) 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

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

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).

4. Categories of Transfers of Value

ToV disclosure relates exclusively to ToVs in connection with

- a) Research and development;
- b) Grants and donations
- c) Scientific meetings;
- d) Services rendered and consulting provided including expenses incurred.

Categories of ToV granted to individual health care professionals:

- 1) ToV in connection with scientific meetings:

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 organizations:

- 1) Donations and grants
- 2) ToV granted in connection with scientific meetings:
Admission and attendance fees,
Support of institutions or third parties appointed by such institutions for implementing the meeting.

Benefits in Kind: Almirall has not provided benefits in kind in 2022 to health care professionals and health care organizations.

5. 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 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.

6. Reporting period

All ToVs taking place in the calendar year 2022 are disclosed in the data for 2023, this principle will apply for this and each year thereafter.

7. Specific Considerations

Cross-border Activities: ToVs made to Czech Republic health care professionals or organizations by Almirall Head Office and/or other affiliates have been reported to Almirall s.r.o. and have been disclosed as required.

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 disclose ToV with their principle practice address or if more appropriate with the practice address depending on the service provided, which is the sole decision of the recipient.

Consent collection: In the spirit of transparency and in compliance with Data Privacy requirements Almirall has ensured each agreement with an health care professional or organization includes a specific disclosure consent clause 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 withdrawal of an individual consent, both in writing to Almirall. If a health care professional or organization requests clarification or changes of the disclosed data or consent status Almirall will act on the request as appropriate, reply to the health care professional or organization with the clarification requested or that the change has been implemented. The respective written message from the health care professionals or organizations 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.

8. 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 or organization includes a specific disclosure consent clause 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 withdrawal of an individual consent, both in writing to Almirall. If a health care professional or organization requests clarification or changes of the disclosed data or consent status Almirall will act on the request as appropriate, reply to the health care professional or organization with the clarification requested or that the change has been implemented. The respective written message from the health care professionals or organizations 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. 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.

9. Financial Information

Currency: The disclosed amounts of ToV are in Czech crowns. Where a ToV has been provided by Almirall or via a third party from outside Czech Republic, such ToVs are converted to Czech crowns using the exchange rate of the date when the payment was made.
