



Almirall, S.A.

Methodological Note 2018

Almirall, S.A.

Methodological note 2018

1. Introduction
 2. Scope
 3. Glossary of terms
 4. Transfers of Value categories
 5. Identification of recipients and compilation of information to be published
 6. Compliance with the applicable personal data protection regulations
 7. Disclosure
 8. Reference documents
 9. Legal notice
-

1. Introduction

Almirall, S.A. recognizes there is a growing expectation that industry interaction with Healthcare Professionals and Healthcare Organizations must be conducted with integrity and be transparent in order to create a better understanding of, and ultimately build trust in, the validity of industry interaction with the medical profession. Therefore, Almirall S.A. supports the principle of transparency and complies with the Farmaindustria Code of Best Practices for the Pharmaceutical Industry requirements for the disclosure of Transfers of Value (ToV) conducted in 2018 with Healthcare Professionals and Healthcare Organizations.

Almirall, S.A. has made every effort to ensure all data required are disclosed and that it complies with all applicable laws, guidance and regulations. Almirall, S.A. expects that third parties and business partners apply equivalent standards in any professional activities conducted on its behalf.

2. Scope

The disclosure includes the ToV made by Almirall to Healthcare Professionals whose principal address is in Spain and to Healthcare Organisations which social address is in Spain. These are: Donations to Healthcare Organisations, sponsorships for the costs of scientific and educational meetings, fees for services and consultancy and research and development.

The amounts attributable each year to each individual recipient are to be disclosed according to the [Farmaindustria Code of Best Practices for the Pharmaceutical Industry \(October 2016 edition\)](#).

Almirall, in accordance with the report of April 22, 2016 issued by the Spanish Agency for Data Protection, at the request of Farmaindustria (Report of the Legal Office Number 2016-0172 Ref. 143318/2016), which recognizes that there is a “legitimate interest” for the transparency of the aforementioned ToV, discloses individually the Transfers of Value carried out during 2018 to Healthcare Professionals.

ToV to Healthcare Organisations are also disclosed individually.

All related documentation is maintained for a minimum of 5 years, starting from the end of each calendar year.

3. [Glossary of terms](#)

CIF: in Spanish, *Certificado de Identificación Fiscal*, unique identifier in Spain

CRO: Contract Research Organization.

Rights of the data subject:

- a) Right of access: it refers to the right to have access to your personal data (if the responsible for the processing is processing them).
- b) Right of rectification: it refers to the right to ask the correction of inaccurate and incomplete data treated by the responsible for the processing.
- c) Right of cancellation: in simple terms, it refers to the right to request the deletion of personal data concerning the data subject treated by the responsible of the processing. The responsible of the treatment will be obliged to remove them without undue delay when there is no compelling reason to continue treating them. This right is also known as “the right to be forgotten” and it is not a general right to the deletion of personal data; there are exceptions, for example, if we must comply with an applicable law, or we must keep them for the defense of claims.
- d) Right to restrict processing: it refers to the right to block or suppress the processing of your personal data in some circumstances. For example, you may want to limit the purposes for which we can treat your data: when the treatment is limited it is possible that the relevant organization can continue to store your data, but can not continue using them for the initial treatment, but only for the limited ones.
- e) Right to data portability: it refers to the right to receive personal data, in certain circumstances, in a structured, commonly used and mechanically read format.
- f) Right of opposition: it refers to the right to object to certain types of treatments, in certain circumstances.

DNI: in Spanish, *Documento Nacional de Identidad*, unique identifier in Spain

ToV: Transfer of Value.

GDPR: Regulation (EU) 2016/679 General Data Protection Regulation.

“Processing” means any operation or set of operations which is performed on Personal Data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

Almirall, S.A recognizes all the definitions set out in the [Farmaindustria Code of Best Practices for the Pharmaceutical Industry \(October 2016 edition\)](#).

4. Transfers of Value categories

Full definitions and information of ToV categories are available in the following link: [Farmaindustria Code of Best Practices for the Pharmaceutical Industry \(October 2016 edition\)](#).

Donations

Almirall, S.A. only made donations (in cash or in kind) to Healthcare Organisations.

Contribution to costs related to scientific and educational events

Scientific and professional activities of Almirall, S.A. include the organisation and support of meetings with Healthcare Professionals for scientific or educational purposes.

Contribution to costs related to Events, through Healthcare Organisations or third parties, including sponsorship to Healthcare Professionals to attend Events, are: registration fees, travel and accommodation.

We work to ensure that the hospitality we offer and the way we conduct events and meetings is appropriate and according to the Farmaindustria Code of Best Practices for the Pharmaceutical Industry.

Services and consultancies

A service and consultancy agreement is established, where the contribution’s scope (speaker’s fees, medical writing, data analysis, development of educational materials, consulting or advising) and the fees perceived for the service are detailed.

There can be other ToV related to services (transport and accommodation) that can be reflected in the agreement.

Research and development

Extramural research and development ToVs made to Healthcare Professional and Healthcare Organisations are disclosed by each Member Company on an aggregate basis.

Costs for events that are clearly related to activities covered in this section are included in the aggregate amount under the “Research and Development Transfers of Value” category.

Intramural research and development ToVs, external contracts with CROs for biometry, coordination and monitoring tasks, and clinical research agreements with Universities or Research Institutes without Healthcare Professionals, are not included in the disclosure. Consortia are also not included in this section.

5. Identification of recipients and compilation of information to be published

Identification of recipients

Almirall, S.A. holds an updated customer database where each customer has his/her main professional address as well as their country identification (DNI or CIF). For an interaction with a new customer, an internal process is launched in order to identify him/her properly. An internal unique code is provided to each customer.

Informative document

Previous to any collaboration, Almirall informs the Healthcare Professional that, in accordance with the report of April 22, 2016 issued by the Spanish Agency for Data Protection (Report of Legal Office Number 2016-0172 Ref. 143318 / 2016), which recognizes that there is a “legitimate interest” for the transparency of the aforementioned ToV, the Transfers of Value of 2018 and following are disclosed individually.

If a Healthcare Professional does not agree to sign the document where the information is given, Almirall can not collaborate with him or her.

When this document is signed, it is archived in the Promotional Compliance Department.

Reminders of the individual publication of ToVs are delivered periodically to Healthcare Professionals.

Compilation of information to be published

Disclosed data have been collected from 1st January to 31st December 2018. The disclosure date of a ToV is when the event/service takes place.

Almirall, S.A. has several integrated computer applications for the management of activities, ToVs and informative documents.

In Spain, the ToVs to Healthcare Professionals and Healthcare Organisations registered in the system for its subsequent disclosure are:

- ToVs made by Almirall or its affiliates to Healthcare Professionals whose main activity is developed in our country (directly or through an entity or person other than a Healthcare Organisation operating as legal entity).

- ToVs made directly by Almirall or its affiliates to Healthcare Organisations which social address is in Spain (including Universities and Academic Institutions).

- ToVs made on behalf of Almirall through external companies (congress technical secretariat, agencies, CROs, etc).

- ToVs made on behalf of Almirall through a Healthcare Organisation, if Almirall, S.A. has chosen the Healthcare Professional or if Almirall, S.A is the only sponsor.

- ToVs made through a CRO for activities related to research and development (including subsidiary costs) and ToVs made to Clinical Research Ethics Committees that are part of a Healthcare Organisation.

As a general rule, when Almirall obtains ToVs without cost as a result of a sponsorship or collaboration to an event organised by a Healthcare Organisation, Almirall, S.A. has calculated the amount of the advantage obtained to subtract that amount of the global collaboration in the activity.

Healthcare Professionals working for Almirall, S.A. as company employees (full or part- time) are not included in the disclosure data as all such individuals' primary occupations are not as practising health professionals.

6. Compliance with the applicable personal data protection regulations

Given the entry into force of the GDPR, the informative document mentioned above has been supplemented, so that Healthcare Professionals whose ToV is disclosed have received the following information:

- (i) Identity of the Responsible for the processing.
- (ii) Information regarding the Delegate for Data Protection.
- (iii) Purposes of the processing.
- (iv) Legitimate basis for processing Personal Data.
- (v) Period of conservation of the data.
- (vi) Recipients of the Personal Data provided to us.
- (vii) Rights of the interested parties and how to exercise them.
- (viii) Possibility to filing a claim about the processing of your Personal Data.

7. Disclosure

Almirall, S.A. states that an exhaustive analysis of data sources and applicable quality rules and internal cross-checking is performed consistently before the disclosure.

Almirall offers the possibility for Healthcare Professionals and Healthcare Organisations to request the ToVs previously to the disclosure; they have to send a request to tdvconsentimiento@almirall.com. In the event of disagreement, we have a process in place to deal with customer discrepancies.

Almirall transparency data are published by countries in www.almirall.com.

In Spain, the published data is gathered in the Farmaindustria specific format and is supported with this explanatory Methodological note. Transparency data are also available in www.almirall.es and www.almirall.cat.

Once published, the report will be updated once a month with the changes requested and will remain on the website for three years.

8. Reference documents

FARMAINDUSTRIA CODE OF BEST PRACTICES FOR THE PHARMACEUTICAL INDUSTRY. (2016 October version)

<http://www.codigofarmaindustria.org/servlet/sarfi/codigo/codigo.html>

EFPIA CODE ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO, AND INTERACTIONS WITH, HEALTHCARE PROFESSIONALS

<http://transparency.efpia.eu/uploads/Modules/Documents/efpia-hcp-code-2014.pdf>

Adopted by EFPIA Board on 5 July 2007, and ratified by the EFPIA Statutory

EFPIA CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

<http://transparency.efpia.eu/the-efpia-code-2>

Adopted by the EFPIA Statutory General Assembly of 24 June 2013, and requiring implementation in national codes by 31 December 2013

Report of the Legal Office Number 2016-0172 (Ref. 143318/2016) of April 22, 2016 issued by the Spanish Agency for Data Protection (AEPD)

<https://www.codigofarmaindustria.org/servlet/sarfi/codigo/codigo.html?idPag=44>

Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal.

<https://www.boe.es/buscar/act.php?id=BOE-A-1999-23750>

Real Decreto 1720/2007, de 21 de diciembre, por el que se aprueba el Reglamento de desarrollo de la Ley Orgánica 15/1999, de 13 de diciembre, de protección de datos de carácter personal.

<https://www.boe.es/buscar/act.php?id=BOE-A-2008-979>

Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016, relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y a la libre circulación de estos datos y por el que se deroga la Directiva 95/46/CE (Reglamento general de protección de datos).

https://www.boe.es/diario_boe/txt.php?id=DOUE-L-2016-80807

9. Legal notice

Almirall, Almirall uses a combination of automated systems, standardized procedures and manual data entry through internal and external resources to compile relevant information and subsequently publish it. The information published reflects our good faith and greatest efforts to comply with legislation and/or code provisions. In the event that, despite our best efforts to ensure disclosure that faithfully reflects the actual Transfers of Value, we have not managed to include correct and complete information, this will be investigated and an appropriate response provided should the information be incorrect.

The information published according to the requirements of the Code on this website will be used solely for the purpose of meeting the provisions of the Code. Data will not be used as a reference by tax authorities or similar.

The final purpose of the disclosure of these data meets the transparency obligations from the Farmaindustria Code of Best Practices for the Pharmaceutical Industry.

The disclosure of information does not grant a general permission for those accessing the website to undertake additional processing of the data, such as crossing the data with information published in websites of other members.

Almirall, S.A. has adopted security protocols to prevent indexation of information through search engines.