

Alcon Pharma Austria Methodological Note

on Disclosure of Payments and other Transfers of Values to Health Care Professionals and Health Care Organizations following the 'EFPIA Code on Disclosure of Transfers of Value'

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Division: Alcon

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1. Reference to National Transparency Laws and Regulations

Novartis supports laws and regulations that promote transparency around relationships between healthcare companies, Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) associated with Transfers of Value (ToVs) related to prescription-only medicines¹ by establishing a single, consistent transparency standard in Europe for disclosing ToVs across its divisions and European countries, by following the EFPIA transparency requirements and requirements set in local transparency laws.

As a Novartis Company and member of the national EFPIA Member Association AB, Alcon Ophthalmika GmbH – Business Unit Pharma (“Alcon Pharma” or “Alcon Pharma Austria” will, on a voluntary basis; collect, disclose and report ToVs related to prescription-only medicines to HCPs/HCOs, in accordance with the:

- National transposition of the EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organizations²
- Pharmig Code of Conduct, Article 9 on Transparency

2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the 2016 Alcon Pharma Austria Disclosure Report. Alcon Pharma’s position is based on the interpretation of the current version of the EFPIA Disclosure Code, aligned with local transparency laws and locally transposed EFPIA disclosure code.

The Methodological Note summarizes the voluntary disclosure recognition methodologies and business decisions as well as country specific considerations applied by Alcon Pharma Austria in order to identify, collect and report ToVs for each disclosure category as described in Section 3.01 of the EFPIA Disclosure Code.

¹ A definition on the terms “HPO/HCO” and “ToVs” will be provided in Chapter 5 “Alcon’ Disclosure Recognition Methodology and related Business Decisions” of this document.

² The EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organization (in short: EFPIA Disclosure Code) states in Section 3.05 (*Methodology*) that “each Member Company shall publish a note summarizing the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 3.01. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable”.

These disclosure recognition methodologies and business decisions include but are not limited to:

- Scope of Alcon Pharma's disclosure on ToVs (Chapter 4)
- Handling of ToV dates for direct or indirect ToVs (Chapter 5.2)
- Definition and clarification for each ToVs category as defined in the EFPIA reporting template (Chapter 5.4)
- Treatment of financial aspects such as currency, VAT and other tax aspects (Chapter 6)
- Treatment of multi-year contracts (Chapter 6)
- Information on the disclosure platform, publication cycle and timing (Chapter 7)

"According to Article 16, the board of Pharmig is authorised to adopt a CoC ordinance for Articles 9.4 through 9.8 (concerning disclosure at individual level, aggregate disclosure, reporting period, time of disclosure, methodology, location and duration of the disclosure, transfers of value granted to healthcare professionals and institutions abroad) as well as standardised forms for the proper documentation of any data to be disclosed."³

3. Alcon's Commitment and Responsibility for Disclosure

As a Novartis company, Alcon supports laws and regulations that promote transparency around relationships between healthcare companies and HCPs/HCOs associated with ToVs related to prescription-only medicines, OTC medicines, OTC medicinal products and food supplements.

Novartis establishes a single, consistent transparency standard for disclosing ToVs in all EFPIA countries.

4. Scope of the Novartis' Disclosure on Transfers of Value

This 2016 Alcon Pharma Austria Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Disclosure Code and national transparency laws/regulations. Subject to this disclosure report are all direct or indirect ToVs related to

³ Pharmig CoC: Article 9.9 on authorisation to adopt ordinances

prescription-only medicines, OTC medicines, OTC medicinal products and food supplements disclosed by Alcon Pharma Austria to or for the benefit of a Recipient made by any Alcon Pharma affiliate as described in Article 3 of the EFPIA Disclosure Code. Further details on the disclosure scope will be provided in Chapter 4 of this document.

The legal definition of 'prescription-only medicine' is pursuant to the Pharmig Code of Conduct, Article 9 on Transparency, Section 9.1. ToVs related to a group of products that includes prescription-only medicines (e.g. combination products/diagnostics and medicinal products) are reported in total following the disclosure requirements of the EFPIA Disclosure Code.

In summary, this 2016 Alcon Pharma Austria Disclosure Report covers direct and indirect ToVs, payments, in kind or otherwise, made to HCPs/HCOs in connection with the development and sale of prescription-only medicinal products, OTC medicines and food supplements exclusively for human use, whether for promotional purposes or otherwise.

Excluded from disclosure are items such as items of medical utility (governed by Article 9 of the EFPIA HCP Code), meals and drinks (governed by Article 10, especially Section 10.05 of the EFPIA HCP Code), medical samples (governed by Article 16 of the HCP Code) or which are part of ordinary course purchases and sales of medicinal products by and between a Member Company and HCP or HCO.

In this report, Alcon Pharma Austria discloses the amounts of value transferred by type of ToVs with data coverage from April 1st 2015 to Dec 31st 2015.

Due to this year voluntary disclosure, Alcon Pharma Austria will not follow the principle of disclosure on individual HCP/HCO level. All ToVs will be disclosed on an aggregate level.

5. Alcon's Disclosure Recognition Methodology and Related Business Decisions

This chapter represents the central pillar of this Methodological Note. It provides comprehensive information on the terminology definitions, recognition methodology and business decisions that affected how the published ToVs data was established for each category of the disclosure report.

5.1 Definition of Healthcare Professionals (HCP)/Healthcare Organizations (HCO)

Alcon Pharma Austria applies the definition of the HCP/HCO as outlined in the EFPIA Disclosure Code Schedule 1 (Scope - § 4) - pursuant to the Pharmig Code of Conduct, Article 3 on General Principles.

In accordance with EFPIA Disclosure Code Schedule 1 and pursuant to the Pharmig Code of Conduct, ToVs to an HCP/HCO are disclosed in the country where the Recipient's primary practice is located, independent of whether the ToVs occurred inside or outside that country. The physical address where the HCP has his primary practice or

the principal address of an HCO is used as the deciding factor when determining in which country the data should be disclosed.

5.2 Definition of Direct and Indirect Transfer of Values

Alcon Pharma Austria applies the EFPIA definition of ToVs as outlined in EFPIA Disclosure Code schedule 1.01 - pursuant to the Pharmig Code of Conduct.

According to the EFPIA Disclosure Code schedule 1, the following definitions apply throughout this report:

- Direct ToVs are defined as those ToVs, payments or in kind, made directly by the Novartis affiliate to the benefitting HCPs/HCOs.
- Indirect ToVs are defined as those ToVs made through an intermediary (third party) on behalf of a Novartis affiliate for the benefit of HCP/HCO where the Novartis affiliate knows or can identify the HCP/HCO that benefits from the ToVs.

In general, ToVs are reported at the level of the first identifiable Recipient which falls under the EFPIA definition of an HCP/HCO. Due to Alcon Pharma voluntary disclosure, for this 2015 report, all recipients will be disclosed on an aggregate level only.

5.3 Definition of Cross-border Transfer of Values

Alcon Pharma Austria applies the EFPIA definition of cross-border ToVs as being a Transfer of Value to an HCP/HCO that occurred outside the country where the Recipient has its primary practice, principal professional address or place of incorporation provided that this country is an EFPIA regulated country.

In general, such ToVs are disclosed in the country where the Recipient has its principal practice, principal professional address or place of incorporation - pursuant to the Pharmig Code of Conduct, Article 9 on Transparency, Section 9.8 on Transfers of value granted to healthcare professionals and institutions abroad.

5.4 Transfer of Value Categories According to the EFPIA Disclosure

Alcon Pharma Austria applies the EFPIA definition of the ToVs categories as outlined in EFPIA Disclosure Code Article 3.01 - pursuant to the Pharmig Code of Conduct, Article 9 on Transparency, Section 9.3 on Type of Transfers of Value (ToV).

The following categories constitute the EFPIA Disclosure Template for the 2016 Alcon Pharma Austria EFPIA Disclosure Report:

- Donations and grants to an HCO
- Contribution to costs related to events to an HCO/HCP, such as:
 - Sponsorship agreements
 - Registration fees
 - Travel and accommodation
- Fees for service and consultancy to an HCO/HCP

- Fees for service and consultancy
- Expenses related to fees for service and consultancy
- Research and development

Details on the recognition methodology and business decisions affecting how the published ToVs data was constructed for each category can be found in the subsequent sub-chapters.

5.4.1 Transfer of Values Related to Donations and Grants

Alcon Pharma Austria applies the EFPIA definition of the “Donations and Grants” category as outlined in EFPIA Disclosure Code Article 3.01 – pursuant to the Pharmig Code of Conduct, Article 9 on Transparency.

5.4.2 Transfer of Values Related to Contribution to Costs of Events

Events are defined as promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including but not limited to advisory board meetings, visits to research or manufacturing facilities, and planning, training or conducting of investigator meetings for clinical trials and non-interventional studies) organized or sponsored by or on behalf of Alcon Pharma Austria pursuant to schedule 1 of the EFPIA Disclosure Code.

ToVs to participating HCPs/HCOs related to such events falling under the definition above are disclosed in the “Costs of Events” sub-categories “Sponsorship Agreements”, “Registration Fees” or “Travel and Accommodation”. ToVs that by exception fall into the “Fees for Service and Consultancy” or “Research and Development” categories are outlined in the respective Chapters 5.4.3 and 5.4.4.

5.4.2.1 Transfer of Values Related to Contribution to Costs of Events – Sponsorship Agreements

Alcon Pharma Austria applies the EFPIA definition of the “Sponsorship Agreements” category as outlined in EFPIA Disclosure Code Article 3.01, following the principle that “Sponsorship Agreements” are formalized in contracts that describe the purpose of the sponsorship and the related direct or indirect ToV – pursuant to the Pharmig Code of Conduct, Article 9 on Transparency.

5.4.2.2 Transfer of Values Related to Contribution to Costs of Events – Registration Fees

Alcon Pharma Austria applies the EFPIA definition of the “Registration Fees” related to cost of events categories as outlined in EFPIA Disclosure Code Article 3.01 – pursuant to the Pharmig Code of Conduct, Article 9 on Transparency.

5.4.2.3 Transfer of Values Related to Contribution to Costs of Events – Travel & Accommodation

Alcon Pharma Austria applies the EFPIA definition of the “Travel and Accommodation” related to cost of events categories - pursuant to the Pharmig Code of Conduct, Article 9 on Transparency.

ToVs covered under the “Travel and Accommodation” category include costs of transportation (e.g. flights, trains, buses, taxis, car hire tolls, parking fees, etc.) and accommodation (e.g. hotel, apartment, etc.).

5.4.3 Transfer of Values Related to Contribution to Fees for Service and Consultancy

5.4.3.1 Transfer of Values related to Contribution to Fees for Service and Consultancy – Fees

Alcon Pharma Austria applies the EFPIA definition of the “Fees for Service and Consultancy” category as outlined in EFPIA Disclosure Code Article 3.01 - pursuant to the Pharmig Code of Conduct, Article 9 on Transparency.

ToVs covered under the “Fees for Service and Consultancy” category, whether made directly or through a third party to an HCP/HCO, include but are not limited to services performed in connection with third-party congresses, speakers’ fees, speakers’ trainings, medical writing, data analysis, development of education material, interviews e.g. on Alcon Pharma Austria products or research, general consulting/advising, services by distributors, consultancy for tool/questionnaire selection or analysis.

5.4.3.2 Transfer of Values related to Contribution to Fees for Service and Consultancy – Related Expenses

Alcon Pharma Austria fully complies with the EFPIA definition of the “Fees for Service and Consultancy - Related Expenses” category as outlined in EFPIA Disclosure Code Article 3.01 - pursuant to the Pharmig Code of Conduct, Article 9 on Transparency.

In general, the ToVs amount related to expenses such as travel and accommodation cost associated with the activity agreed to in a “Fees for Service” or “Consultancy” contract do not constitute part of the fees itself; in consequence such ToVs are disclosed under the “Related Expenses” category.

In case such expenses were not material (e.g. of limited value), or when such expenses despite best effort could not be accurately disaggregated from the fees, such ToVs have been disclosed as part of the total amount of fees under the “Fees for Service or Consultancy” category.

5.4.4 Transfer of Values Related to Research and Development

Alcon Pharma Austria applies the EFPIA definition of the “Research and Development” category as outlined in EFPIA Disclosure Code – Schedule 1, the definition of non-clinical studies in the OECD Principles on Good Laboratory Practice, the definition of clinical trials and non-interventional studies (as defined in Directive 2001/20/EC and Section 15.01 of the HCP Code) - pursuant to the Pharmig Code of Conduct, Article 9 on Transparency, Section 9.5.

ToVs **related to the following Research and Development activities** are disclosed under the “Research and Development” category whenever they fall under the definition of Research and Development by the EFPIA Disclosure Code, for example:

- Activities related to the planning or conduct of non-clinical studies, clinical trials or prospective non-interventional studies and that involve the collection of patient data from or on behalf of individual, or groups of HCPs specifically for the study (Section 15.01 of the HCP Code).
- IIT (Investigator initiated trials) and IST (Investigator sponsored trials - since, although not initiated by Alcon Pharma Austria, they may benefit from Alcon Pharma Austria
- Post marketing trials, investigator meetings - in which case the total ToV amount is disclosed and in case of participating HCP from other countries, the total actual cost per meeting (incl. infrastructure, travel, logistic and with exclusion of meals whenever possible) is divided by the number of participants per country of practice
- Activities contracted to CROs, where Alcon Pharma Austria makes indirect ToVs to HCPs/HCOs falling under the definition of Research and Development
- ToVs related to early stage research if falling under the definition of Research and Development in the EFPIA Disclosure Code

ToVs made by or on behalf of Alcon Pharma Austria **related to consultancy activities** are disclosed under the “**Research and Development**” category whenever they fall under the definition of Research and Development by the EFPIA Disclosure Code: consultancy activities related to the planning/conduct of non-clinical studies, clinical trial or prospective non-interventional studies, steering committee and advisory board activities related to the planning or conduct of non-clinical studies, clinical trial or prospective non-interventional studies, adjudication committees, speaker programs, scientific meetings.

ToVs related to **licensing fees** paid for the use of Clinical/Health Economics and Outcomes Research questionnaires and tools, if the questionnaires and tools are intended for use with a Research and Development project/study are reported under the “Research and Development” category.

As defined in Chapter 5.4.3, ToVs related to **medical writing and editorial support** made by or on behalf of Alcon Pharma Austria to an HCO/HCP are disclosed either under the “Fees for Service and Consultancy” category or under the “Research and Development” category. The following instances of medical writing and editorial support are covered under the “Research and Development” category: investigator’s brochure (trials), clinical study report (trials), clinical report, safety report; generally all types of medical writing related to clinical trials or related to Research and Development activities, patient narrative writing - only if not disclosed under the “Fees for Service and Consultancy” category by Alcon Pharma Austria, consensus report - only if not disclosed under the “Fees for Service and Consultancy” category by Alcon Pharma.

6. Financial Aspects

This chapter focusses on the financial aspects related to recognition methodology and business decisions associated with the collection and disclosure of the ToVs information.

Alcon Pharma Austria complies with the Alcon Pharma accounting principles and the financial disclosure methodology - pursuant to the Pharmig Code of Conduct, Ordinance 2/2014 Adopted by the Board of Pharmig on Article 9.

Alcon Pharma Austria decided to apply the following rules for ToVs payment dates based on type of ToVs: direct ToVs are disclosed based on the date the payment has been cleared via banking system. Indirect ToVs related to events such as congresses for which the dates of (in kind) expenses differ from the date(s) the event took place, are disclosed using the date of the last day of the event.

Alcon Pharma Austria discloses ToVs net amount only. If VAT cannot accurately be excluded, the full ToV amount is disclosed.

Currency treatment – foreign currency ToVs will be converted using actual exchange rates in agreement with the accounting policy of the Alcon Pharma Austria. ToVs will be disclosed in the local currency of the country where the disclosing entity is located. For direct and indirect TOVs, the foreign currency is converted to the local currency of the disclosing entity based on the transaction date. For cross-border TOVs, the foreign currency is converted to the local currency of the disclosing entity based on the average rate for the month in which the TOV occurred, using the Novartis Treasury rates.

The responsibility for disclosing and reporting ToVs is with the disclosing entity country where the Recipient's principle practice is located. In the case of payments made by Alcon Pharma Austria to an HCP or HCO, and then cross-charged to another Novartis company, or made by another Novartis company to an HCP or HCO and then cross-charged to Alcon Pharma Austria, the ToV information is provided by the original paying entity to the disclosing entity. The ToV will only be recognized once in the country where the Recipient's principle practice is located.

In case of cross-border ToVs as defined in Chapter 5.3, direct ToVs will be recognized when the payment has been cleared via the banking system and indirect ToVs will be related to the end date of the event. This information will not be available to the disclosing country immediately and so there may be cutoff recognition issues over year end. If ToV information is not provided to the Alcon Pharma Austria with adequate time to be included for disclosure in the expected reporting year, it will be disclosed in the immediate following year.

In case of multi-year contracts, ToVs are recognized based on the date the payment has been cleared via the banking system. If, for example, the HCP/HCO has entered into a contract with a term of three years and receives equal annual payments, these ToVs of an amount of one third of the total contract value would be disclosed each year in the appropriate category.

7. Disclosure Platform, Frequency and Timing

Alcon Pharma Austria applies the EFPIA definition of “Form of Disclosure” as outlined in EFPIA Disclosure Code Article 2 - pursuant to the Pharmig Code of Conduct, Article 9, Section 9.6 on “Reporting period, time of disclosure, methodology” and 9.7 on “Location and duration of the disclosure”

This 2016 Alcon Pharma Austria EFPIA Disclosure Report has been officially published on <http://www.novartis.at/offenlegung>.

Disclosures are made on an annual basis within 6 months after the end of the relevant full calendar year.

The platform chosen fulfills the recommendation of the EFPIA Disclosure Code as being a platform accessible in the country where the Recipient has the primary practice. All EFPIA Disclosure Reports published by Alcon Pharma Austria and any other Novartis affiliate in Alcon Pharma Austria are published on the same platform www.novartis.at.

This data will remain published for 3 years in public domain and stored for a minimum of 7 years on record by the publishing affiliate.

8. References

This chapter contains references to internal and external sources for further reading and documentation purpose.

- <http://www.novartis.at/offenlegung>
- <http://pharmig.at/DE/Verhaltenscodex/Pharmig-Verhaltenscodex/Verhaltenscodex.aspx>
- <http://www.efpia.eu/about-us/membership>
- Austrian Data Privacy Law: Datenschutzgesetz 2000 [BGBl. I Nr. 165/1999](#) zuletzt geändert durch [BGBl. I Nr. 83/2013](#)

9. Acronyms and Abbreviations

This chapter includes a list of acronyms, abbreviations and definitions for documentation purpose, based on the Schedule 1 of the EFPIA Disclosure Code whenever possible:

- **Contract Research Organization (CRO):** an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.⁴
- **Healthcare Professional (HCP):** Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.
- **Healthcare Organization (HCO):** Any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCP provide services.
- **Member Associations:** Collectively, the national Member Associations or their constituent members, as the context may require, and bound by the EFPIA codes of practice, including the EFPIA HCP Code, the EFPIA Patient Organization Code and the EFPIA HCP/HCO Disclosure Code.
- **Member Companies:** Collectively, “corporate members” (as defined in the HCP Code) of EFPIA, their respective parent companies, if different, subsidiary companies (irrespective of whether a subsidiary is a company or such other form of enterprise or organization) and any companies affiliated with corporate members or their subsidiaries. Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization – shall be deemed to constitute a single company, and is as such committed to compliance with the EFPIA Codes.

⁴ Source www.wikipedia.org

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- **Professional Conference Organizer (PCO):** a company which specializes in the organization and management of congresses, conferences, seminars and similar events.⁵
 - **Recipient:** Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in a country whose association is a member of EFPIA.
 - **Research and Development ToVs:** ToVs to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the HCP Code).
 - **Transfers of Value (ToVs):** Direct and indirect transfers of value, whether payments, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products, OTC medicines and food supplements exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that benefit from the Transfer of Value.

⁵ Source www.wikipedia.org