

## **Sandoz GmbH 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'**

**Country:** Austria

**Division:** Sandoz GmbH<sup>1</sup>

**Last Update:** 27. June 2017

**Version:** 3.0; this document replaces previous drafts and editions.

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<sup>1</sup> Including EBEWE Pharma Ges.m.b.H. Nfg.KG

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## 1. Reference to National Transparency Laws and Regulations

Sandoz GmbH 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 medicines<sup>2</sup>, OTC medicines and food supplements 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, Sandoz GmbH Austria complies with the obligation to 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 Organizations<sup>3</sup>
- Pharmig Code of Conduct, Article 9 on Transparency

Sandoz GmbH has developed HCP/HCO unique identifiers to ensure that the identity of the HCP/HCO benefitting from the ToVs is clearly distinguishable for each Novartis affiliate.

## 2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the 2017 Sandoz GmbH Austria Disclosure Report. Sandoz GmbH'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 disclosure recognition methodologies and business decisions as well as country specific considerations applied by Sandoz GmbH

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<sup>2</sup> A definition on the terms "HPO/HCO" and "ToVs" will be provided in Chapter 5 "Sandoz' Disclosure Recognition Methodology and related Business Decisions" of this document.

<sup>3</sup> 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".

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Austria in order to identify, collect and report ToVs for each disclosure category as described in Section 3.01 of the EFPIA Disclosure Code.

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

- Scope of Sandoz GmbH' disclosure on ToVs (Chapter 4)
- Handling of ToV dates for direct or indirect ToVs (Chapter 5.2)
- Treatment of cross-border ToVs (Chapter 5.3)
- Definition and clarification for each ToVs category as defined in the EFPIA reporting template (Chapter 5.4)
- Handling of Data Privacy aspects (Chapter 6)
- Treatment of financial aspects such as currency, VAT and other tax aspects (Chapter 7)
- Treatment of multi-year contracts (Chapter 7)
- Information on the disclosure platform, publication cycle and timing (Chapter 8)

“According to Article 16, the board of Pharmig is authorized 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 standardized forms for the proper documentation of any data to be disclosed.”<sup>4</sup>

### **3. Novartis Group's Commitment and Responsibility for Disclosure**

The Novartis Group 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 and food supplements.

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

### **4. Scope of the Novartis Group's Disclosure on Transfers of Value**

This 2017 Sandoz GmbH Austria Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Disclosure Code and national transparency

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<sup>4</sup> Pharmig CoC: Article 9.9 on authorisation to adopt ordinances

laws/regulations. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines, OTC medicines and food supplements disclosed by Sandoz GmbH Austria to or for the benefit of a Recipient made by any Novartis 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 2017 Sandoz GmbH 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, Sandoz GmbH Austria discloses the amounts of value transferred by type of ToVs with data coverage from January 1<sup>st</sup> 2016 to Dec 31<sup>st</sup> 2016. Sandoz GmbH Austria disclosure is performed for the full calendar year 2016.

Whenever possible, Sandoz GmbH Austria follows the principle of disclosure on individual HCP/HCO level, to ensure that each Recipient is referred to in such a way that there is no doubt as to the identity of the HCP/HCO benefitting from the ToVs. Aggregate disclosure for non-Research and Development ToVs is only used in exceptional cases, e.g. if consent could not be obtained despite best efforts or in case of withdrawal of consent.

With regards to the Novartis portfolio transition Alcon ophthalmic pharmaceuticals business to move to Pharmaceuticals Division and mature products business move from Pharmaceuticals Division to Sandoz division the following is applicable: the entity paying for the engagement of the HCP reports the relevant ToV.

## **5. Sandoz GmbH'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)

Sandoz GmbH 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.

Sandoz GmbH Austria has developed HCP/HCO unique identifiers to ensure that the identity of the HCP/HCO benefitting from the ToVs is clearly distinguishable for each Novartis affiliate.

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 Transfers of Value

Sandoz GmbH 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 Sandoz GmbH affiliate to the benefitting HCPs/HCOs.
- Indirect ToVs are defined as those ToVs made through an intermediary (third party) on behalf of a Sandoz GmbH affiliate for the benefit of HCP/HCO where the Sandoz GmbH 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. To the extent possible, disclosure is made under the name of the individual HCP or at the HCO level, as long as this could be achieved with accuracy, consistency and compliance with the EFPIA Disclosure Code and pursuant to the Pharmig Code of Conduct, Article 9 on Transparency, Section 9.4 on Disclosure at individual level. Where a ToV was made to an individual HCP rendering services on behalf of an HCO indirectly via this HCO, such ToVs are only disclosed once on either Recipient level.

Generally, ToVs to HCPs via an HCO are disclosed at the first level Recipient (HCO), or exceptionally at second level Recipient as mentioned in Section 5.4.2.1, if a contract to an HCO specifies that part of the amount must be used to engage HCPs nominated by Sandoz GmbH. When a tripartite contract exists between Sandoz GmbH an HCO and an HCP, with the HCP as benefitting party, ToVs are disclosed at HCP level. If Sandoz GmbH Austria holds a contract with a non-HCO Third-Party vendor acting on behalf of Sandoz GmbH Austria and who is contracting independent HCP/HCO to provide a

reportable activity, ToVs are disclosed at the individual subcontracted HCP/HCO level. This only applies if the HCP/HCO must not remain unknown in order to comply with good market practices or Sandoz GmbH internal rules.

ToVs from distributors of Sandoz GmbH Austria to HCPs/HCOs whose primary practice is in an EFPIA country must be disclosed if the distributor is making a ToV on behalf of Sandoz GmbH Austria (influencing the promotional activities and selection of Recipient). ToVs to HCPs/HCOs made through a Continuous Medical Education (CME) non-HCO provider are disclosable if the 3rd party CME provider is acting on behalf of Sandoz GmbH Austria (and Sandoz GmbH Austria influenced choice of HCPs/Faculty).

### 5.3 Definition of Cross-border Transfer of Values

Sandoz GmbH 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

Sandoz GmbH 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 2017 Sandoz GmbH 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.

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### 5.4.1 Transfer of Value Related to Donations and Grants

Sandoz GmbH 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.

Grants to a healthcare organization or teaching institution are disclosed in the name of the legal entity that is the Recipient of the ToVs – this may be the hospital, university or independent department within these organizations.

ToVs to a charitable organization are disclosed under the “Donations and Grants” category in the name of the benefitting HCO if the charitable organization falls under the EFPIA definition of a benefitting HCO. Charitable product donations made to HCOs in the context of humanitarian aid are also disclosed in the “Donations and Grants” category.

When grant requests from HCOs include explicit support for publication, then these ToVs are disclosed in the “Donations and Grants” category.

### 5.4.2 Transfer of Value 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 Sandoz GmbH 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 Value Related to Contribution to Costs of Events – Sponsorship Agreements

Sandoz GmbH 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.

In general, indirect sponsorship of an HCP through an HCO is disclosed under the “Sponsorship Agreements” category as payment to the HCO as first level Recipient of the ToV. This applies to the following categories: ToVs related to intermediaries selecting the faculty who acted as speakers or faculty at an event; ToVs related to advertising space, sponsoring of speakers/faculty, satellite symposia at congresses, courses provided by HCOs.



ToVs made through a professional conference organizer (PCO) as intermediary e.g. for the hire of booths or stand space on behalf of an HCO, are disclosed as ToVs either in the “Sponsorship Agreements” category or as “Fees for Services and Consultancy” – depending on the nature of the spend, in the name of the sponsored HCO as benefitting Recipient.

If the contract requires the HCOs to use some of the amount to invite a number of HCPs selected by Sandoz GmbH Austria to an event, the ToV is split and disclosed based on the ToVs category the amount was used for (“sponsoring agreements” of speakers/faculty; “registration fees” or “travel and accommodation”) individually in the name of each HCP.

Sandoz GmbH Austria discloses ToVs related to preceptorships considering that such non-promotional independent “practical” training offered to HCPs by other HCPs or HCOs – typically in a specific disease area at a reputed teaching institution (faculty of medicine, university, university hospital) – falls under the definition of “Events” and is disclosed in the name of that contracting entity.

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

Sandoz GmbH 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.

In general (and for all types of events), whenever registration fees were charged for an event organized or sponsored by or on behalf of Sandoz GmbH Austria, they are disclosed in the name of the benefitting HCP or HCO. The total amount of registration fees paid in a given year to a HCO should be disclosed on an individual basis (in the name of the HCO) under “Contribution to Costs of Events”. The total amount of Registration Fees paid in a given year to a HCP who is the clearly identifiable Recipient is disclosed on an individual basis (in his/her name) under “Contribution to Costs of Events”.

ToVs related to virtual congresses (e-congresses) should be reported as actual spend. Exception applies where event is significantly undersubscribed. In such case the nominal value/ fair market value is reported. Aggregate spend is disclosed under the HCO in each country and be reported in "Registration Fees" category. ToVs related to virtual congresses for a non-European HCOs are reported in aggregate.

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

Sandoz GmbH 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.).

In general, ToVs related to travel and accommodation is disclosed at first level Recipient basis. If the ToVs are made through an HCO or intermediary (third party), it will be disclosed at individual HCP level whenever possible (see Chapter 5.2).

ToVs related to travel and accommodation for a group of HCPs such as group transportation by bus are disclosed on an aggregate basis. If the mass transportation is shared by a group of HCPs who have their primary practice in different countries, the ToVs are disclosed in aggregate with the total cost divided equally among the planned number of benefitting HCPs per country.

In case the benefitting HCP partly bears the costs related to travel and accommodation the net amount of the Sandoz GmbH Austria payment offset by payment from HCP is disclosed as ToV under the "Travel and Accommodation" category in the name of the HCP.

### **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**

Sandoz GmbH 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 Sandoz GmbH Austria products or research, general consulting/advising, services by distributors, consultancy for tool/questionnaire selection or analysis.

Sandoz GmbH Austria has formalized such collaboration in a contract describing the purpose of ToVs. In general, the ToVs received by the contracting entity – which may be an HCP, a legal entity owned by an HCP (considered an HCO under the EFPIA Disclosure Code) or an HCO – are disclosed under the "Fees for Service and Consultancy" category in the name of that contracting entity.

As mentioned in Chapter 5.4.2.1, ToVs made through a PCO as intermediary (e.g. for the hire of booths or stand space on behalf of an HCO), are disclosed as ToVs either in the "Sponsorship Agreements" category or as "Fees for Services and Consultancy" depending on the nature of the spend, in the name of the sponsored HCO as benefitting. ToVs related to market research studies for which the identity of the Recipient was known to Sandoz GmbH Austria, are disclosed under the "Fees for Service and Consultancy" category. ToVs related to market research studies for which the identity of the HCP/HCO was not known to Sandoz GmbH Austria are not disclosed as the right of the respondents to remain anonymous is embodied in market research definitions and relevant codes of conduct worldwide.

Sandoz GmbH Austria decided to disclose ToVs related to preceptorships considering that such non-promotional independent “practical” training offered to HCPs by other HCPs or HCOs – typically in a specific disease area at a reputed teaching institution (faculty of medicine, university, university hospital) – falls under the definition of “Fees for Service and Consultancy” and is disclosed in the name of that contracting entity. ToVs related to medical writing and editorial support made directly or indirectly to an HCO/HCP are disclosed either under the “Fees for Service and Consultancy” in the name of the benefitting HCP/HCO or under the “Research and Development” category in aggregate form – pursuant to the Pharmig Code of Conduct, Article 9 on Transparency. The following instances of medical writing and editorial support are covered under the “Fees for Service and Consultancy” category: case studies, congress write ups, article and abstracts, manuscripts, poster, clinical management guideline, supplements, patient narrative writing - only if not disclosed under the “Research and Development” category by Sandoz GmbH Austria, consensus report - only if not disclosed under the “Research and Development” category by Sandoz GmbH Austria.

ToVs related to the following Research and Development related activities (see Chapter 5.4.4) but when they do not fall under the definition of Research and Development ToVs as stated by the EFPIA Disclosure Code and EFPIA HCP Code Article 15 are disclosed under the “Fees for Services and Consultancy” category in the name of the benefitting Recipient, for example:

- Retrospective non-interventional studies not falling under the definition of Research and Development ToVs as per EFPIA Disclosure Code definition of Research and Development Schedule 1 and EFPIA HCP Code Article 15
- Investigator initiated trials, investigator sponsored trials and Investigator meeting, in the exceptional case when such ToV do not fall under the definition of Research and Development mentioned above
- Activities contracted to Contract Research Organizations (CROs) where Sandoz GmbH Austria makes indirect ToVs to HCPs/HCOs but not falling under the EFPIA Research and Development definition
- Project activities related to e.g. disease area, mode of action, market placement, adjudication committees, speaker programs, scientific meetings, steering committee and advisory board activities not in scope of the EFPIA Research and Development definition
- ToVs related to consultancy for tool/questionnaire selection or analysis and reporting of results not in scope of the EFPIA Research and Development definition

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

Sandoz GmbH 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 the name of the benefitting HCP/HCO.

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

Sandoz GmbH 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 in aggregate form 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 Sandoz GmbH Austria, they may benefit from Sandoz GmbH 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 Sandoz GmbH 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 Sandoz GmbH Austria **related to consultancy activities** are disclosed under the “**Research and Development**” category in aggregate form 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 in aggregate form 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 Sandoz GmbH Austria to an HCO/HCP are disclosed either under the “Fees for Service and Consultancy” category in the name of the benefitting HCP/HCO or under the “Research and Development” category in aggregate form – pursuant to. 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 Sandoz GmbH Austria, consensus report - only if not disclosed under the “Fees for Service and Consultancy” category by Sandoz GmbH.

## **6. Measures Taken to Ensure Compliance with Data Privacy Requirements**

This chapter describes measures taken by Sandoz GmbH Austria to ensure compliance with data privacy regulations, rules on consent collection and managing of relevant information in compliance with relevant internal rules, data privacy laws and regulations.

### **6.1 Safeguarding Measures to Address Lawful Collection, Processing and Transfer of HCPs’ Personal Data**

Data privacy refers to the individual’s fundamental right to control the use of, access to and disclosure of information that describes or identifies the individual (“personal information”). To fulfil the transparency disclosure requirements, it is necessary to collect, process and disclose such personal data within and outside of Sandoz GmbH Austria. This data will be published for 3 years in public domain and stored for a minimum of 7 years on record by the Sandoz GmbH Austria (publishing affiliate). The disclosure of such personal information by Sandoz GmbH Austria is at all times limited to the intended purposes.

In case personal data had to be transferred from countries to the central Novartis Transparency data repository manually (e.g. excel) or via interfaces, applicable local regulations for the transfer were assessed at local level and managed accordingly. Where required, the transfer of data to a third country (outside the EU/EEA) was approved by the data controller’s Sandoz GmbH Austria country data protection authority (e.g. Information Commissioner).

The Data Processing Agreements between Sandoz Austria and associated companies to the Novartis Group have been amended to Austrian Data Privacy standards, in order to be approved by the Austrian Data Protection Authorities.

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## 6.2 Consent Collection

Consent for the publication of the ToVs was obtained and documented as such before disclosing the data on an individual HCP/HCO level where applicable. Consent management procedures were conducted in alignment with the local Data Privacy Law.

Consent was obtained either on Recipient level for all ToVs during a given period of time not shorter than one full year or on spend level for each interaction or single ToVs. Sandoz GmbH Austria collected consent on Recipient level, allowing the individual disclosure of all ToVs as of January 1<sup>st</sup> 2015 for an indefinite period.

Some Healthcare Organizations in Austria are grouped in Holdings, for which several have provided consent on a Holding level. All direct payments received by Hospital departments belonging to a holding, will be disclosed under the parent Organization, unless explicitly requested to disclose on a department level on the Holding Consent details. All indirect payments, non-speaker fee related, will be assigned to the HCP's institution.

Sandoz GmbH Austria does not accept partial consent or split disclosure.

In case consent was either not given by the Recipient or not documented sufficiently to prove the existence of consent, ToVs are disclosed on aggregate level only.

In the event of death of an HCP by the time of disclosure (by the publication date) the ToV is reported in aggregate.

HCPs and HCOs have a right to withdraw their consent. Consent withdrawal has been assessed according to the relevant Sandoz GmbH Austria local data privacy laws.

Withdrawal must be requested via email to [xpend.austria@novartis.com](mailto:xpend.austria@novartis.com) letter to

*Sandoz GmbH*

***z. Hd. Xpend Projekt***

*Stella-Klein-Löw-Weg 17*

*1020 Wien*

Changes must be reflected, according to Austrian law, within 8 weeks after the request was received. A written confirmation will be sent to the HCP/HCO once the change is implemented on the report.

## 7. 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.

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Sandoz GmbH Austria complies with the Sandoz GmbH 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.

Sandoz GmbH 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.

Sandoz GmbH 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 Sandoz GmbH 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 Sandoz GmbH 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 Sandoz GmbH 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 Sandoz GmbH Austria with adequate time to be included for disclosure in the expected reporting year, an annex to the report will be published reflecting these general spends. R&D spends will be included in the report if reported before disclosure date, otherwise they will also be added to the annex report.

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.

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## 8. Published Data

Sandoz GmbH 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 2017 Sandoz GmbH 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.

Updates are conducted on an ad-hoc basis for reflection of data updates or consent withdrawal after disclosure submission.

Questions or updates can be requested in a written form to [xpend.austria@novartis.com](mailto:xpend.austria@novartis.com). Any change on the report will be updated within a period of 2 to 8 weeks, which will be communicated to the HCP/HCO as soon as this is reflected on the report.

A pre-disclosure letter was sent prior to the official disclosure to all HCPs and HCOs who agreed on an individual disclosure, to inform them about the amounts to be disclosed on their behalf, and to provide an opportunity for clarifications if necessary.

Publication is made via the following disclosure platform: [www.novartis.at/offenlegung](http://www.novartis.at/offenlegung)

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 and following the local laws or regulations of the country where the Recipient has their practice. All EFPIA Disclosure Reports published by Sandoz GmbH Austria and any other Novartis affiliate in Sandoz GmbH Austria are published on the same platform [www.novartis.at/offenlegung](http://www.novartis.at/offenlegung).

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.

## 9. References

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

- [www.novartis.at/offenlegung](http://www.novartis.at/offenlegung)



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- <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](#)<sup>5</sup>

## 10. 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.<sup>6</sup>
- **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.

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<sup>5</sup> zuletzt geändert durch [BGBl. I Nr. 83/2013](#)

<sup>6</sup> Source [www.wikipedia.org](http://www.wikipedia.org)

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- **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.
  - **Professional Conference Organizer (PCO):** a company which specializes in the organization and management of congresses, conferences, seminars and similar events.<sup>7</sup>
  - **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.

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<sup>7</sup> Source [www.wikipedia.org](http://www.wikipedia.org)