
Sandoz Limited

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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This Methodological Note template applies to all Novartis affiliates disclosing Transfers of Value (ToVs) data under the rules of the EFPIA Disclosure Code or the respective local transpositions. An exception not to publish a Methodological Note applies only for countries where it has been approved by EFPIA.

This standard Methodological Note should be used as a baseline and must be supplemented with additional information as outlined below to create the local Methodological Note.

Changes to the text of the standard Methodological Note and deviations are only allowed if required by the National Disclosure Code, local law or regulation and must be justified. These changes must be cross-divisionally aligned per country. It is therefore the responsibility of the local affiliate to ensure that:

- a) Local transparency business decisions regarding the transparency disclosure are reflected
- b) References to the local transposition of the EFPIA Disclosure Code and other local transparency regulations are included
- c) The final local Methodological Note is approved by the local Global Xpend Business Lead and Compliance Officer with recommended consultation with local representatives from Legal, Data Privacy, Finance and Media Relations functions. The published version must not contain explicit signatures
- d) The divisional affiliates in a country can provide a single Methodological Note if all country divisions sign that Note and divisional differences are clearly identified in the document. Note: signatures are required for the internal version only
- e) If country specific regulations require a shorter version of the Methodological Note, the country or affiliate should provide a proposal of the Methodological Note document to the Global Xpend Team and outline in English the chapters that it includes
- f) The following disclosure requirements should be reflected in the local Methodological Note depending on the existence of a local transparency law and/or of a locally transposed EFPIA Disclosure Code:

		Locally transposed EFPIA Disclosure Code exists?	
		Yes	No
Local transparency law exists?	Yes	<ul style="list-style-type: none"> Disclosure occurs based on requirements of both local transparency law and locally transposed EFPIA Disclosure Code in case requirements differ; country divides in a single report or two different reports are published. 	<ul style="list-style-type: none"> Disclosure occurs based on local transparency law requirements. If EFPIA Disclosure Code in itself, the affiliate must follow the EFPIA Disclosure Code, if the does not, it should be used transparency law and if no specific benefits exception applies. <i>Example: if the local transparency law accepts aggregate disclosures, the EFPIA requires individual disclosures, individual disclosure should be chosen. In case of local transparency law follows individual disclosure or an existing Novartis disclosure system, aggregate disclosure must be followed.</i>
	No	<ul style="list-style-type: none"> Disclosure based on locally transposed EFPIA Disclosure Code 	


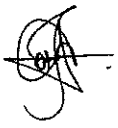
- g) If no Transfer of Values are reportable for an affiliate for a disclosure cycle, the affiliate should generate a local Methodological Note including only chapters 1, 2, 3 & 4

and the statement: "No Transfer of Values are reportable for <XY affiliate> for the disclosure cycle <2017>".

The language for the local Methodological Note should be simple enough to be easily understandable by the Healthcare Professional (HCP)/Healthcare Organization (HCO) or local media representative. Hence, we recommend avoiding using too much professional jargon.

Each Novartis affiliate is accountable for the integrity and appropriate management of all information collected for transparency purposes in line with Novartis internal rules and relevant local transparency laws. Each Novartis affiliate has to ensure that no commercially relevant/strategic information is published externally.

If in doubt, contact the Global Xpend Divisional Business Lead.
The published version must not contain explicit signatures.

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It is recommended to consult with local representatives from Legal, Data Privacy, Finance and Media Relations functions on the final localized text of the Methodological Note.

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The latest document version replaces all previous drafts and editions.

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Table of Contents

1.	Reference to National Transparency Laws and Regulations	7
2.	Purpose of the Methodological Note.....	7
3.	Novartis' Commitment and Responsibility for Disclosure	7
4.	Scope of the Novartis' Disclosure on Transfers of Value	8
5.	Novartis' Disclosure Recognition Methodology and Related Business Decisions	8
5.1	Definition of Direct and Indirect Transfer of Values.....	8
5.2	Definition of Cross-border Transfer of Values.....	9
5.3	Transfer of Value Categories According to the EFPIA Disclosure.....	9
5.3.1	Transfer of Values Related to Donations and Grants.....	10
5.3.2	Transfer of Values Related to Contribution to Costs of Events	10
5.3.2.1	Transfer of Values Related to Contribution to Costs of Events – Sponsorship Agreements.....	10
5.3.2.2	Transfer of Values Related to Contribution to Costs of Events – Registration Fees	11
5.3.2.3	Transfer of Values Related to Contribution to Costs of Events – Travel & Accommodation	11
5.3.3	Transfer of Values Related to Contribution to Fees for Service and Consultancy.....	12
5.3.3.1	Transfer of Values related to Contribution to Fees for Service and Consultancy – Fees.....	12
5.3.3.2	Transfer of Values related to Contribution to Fees for Service and Consultancy – Related Expenses	13
5.3.4	Transfer of Values Related to Research and Development.....	13
6.	Measures Taken to Ensure Compliance with Data Privacy Requirements.....	14
6.1	Safeguarding Measures to Address Lawful Collection, Processing and Transfer of HCPs' Personal Data	14
6.2	Consent Collection	15
7.	Financial Aspects.....	15
8.	Published Data.....	16
9.	Acronyms and Abbreviations	17

1. Reference to National Transparency Laws and Regulations

Sandoz Limited (Sandoz) 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)¹ related to prescription-only medicines 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 an affiliate of Novartis Pharma AG, which is an EFPIA member company, Sandoz complies with the obligation to collect, disclose and report ToVs related to prescription-only medicines to HCPs/HCOs in accordance with the Association of the British Pharmaceutical Industry (ABPI) disclosure requirements based on the EFPIA Code outlined in clause 24 of the 2016 UK ABPI Code of Practice.

2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the 2017 Sandoz Disclosure Report. Sandoz's position is based on the interpretation of the current version of the EFPIA Disclosure Code, aligned with local transparency national codes of practice, namely Clause 24 of the 2016 UK ABPI Code of Practice.

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

3. Sandoz's Commitment and Responsibility for Disclosure

Sandoz supports laws and regulations that promote transparency around relationships between healthcare companies and HCPs/HCOs associated with ToVs related to prescription-only medicines.

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

¹ A definition on the terms "HCP/HCO" and "ToVs" is provided in chapter 9 of this document.

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

This 2017 Sandoz Disclosure Report is following the disclosure standards pursuant to clause 24 of the 2016 UK ABPI Code of Practice. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines disclosed by Sandoz 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 The Prescription Only Medicines (Human Use) Order 1997. 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 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 exclusively for human use, whether for promotional purposes or otherwise.

In this report, Sandoz discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2016 to December 31st 2016. Sandoz disclosure is performed for the full calendar year 2016.

Whenever possible, Sandoz 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.

5. Sandoz'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 Direct and Indirect Transfer of Values

Sandoz applies the definition of ToVs as outlined in Clause 1.10 of the 2016 UK ABPI Code of Practice.

The following definitions apply throughout this report:

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- Direct ToVs are defined as those ToVs, payments or in kind, made directly by Sandoz to the benefitting HCPs/HCOs.
 - Indirect ToVs are defined as those ToVs made through an intermediary (third party) on behalf of Sandoz for the benefit of HCP/HCO where Sandoz 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 2016 UK ABPI Code of Practice 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 2016 UK ABPI Code of Practice. 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.

When a tripartite contract exists between Sandoz an HCO and an HCP, with the HCP as benefitting party, ToVs are disclosed at HCP level. If Sandoz holds a contract with a non-HCO Third-Party vendor acting on behalf of Sandoz and who is contracting independent HCP/HCO to provide a reportable activity, ToVs are disclosed at the individual subcontracted HCP/HCO level, unless the HCP/HCO must remain unknown in order to comply with good market practices or Novartis or Sandoz internal rules.

ToVs from distributors of Sandoz 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 (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 (and Sandoz influenced choice of HCPs/Faculty).

5.2 Definition of Cross-border Transfer of Values

Sandoz applies the following definition of cross-border ToVs: a cross-border ToV is 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.

5.3 Transfer of Value Categories According to the EFPIA Disclosure

Sandoz applies the definition of the ToVs categories as set out in Clause 24 of the 2016 UK ABPI Code of Practice.

The following categories constitute the EFPIA Disclosure Template for the 2017 Sandoz EFPIA Disclosure Report:

- Donations, grants and benefits in kind to an HCO
- Contribution to costs related to events to an HCO/HCP, such as:

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- 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
 - Joint Working

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.

5.3.1 Transfer of Values Related to Donations and Grants

Sandoz applies the definition of the “Donations and Grants” as set out in Clauses 19 and 24 of the 2016 UK ABPI Code of Practice.

Grants to a hospital/university department 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 2016 UK ABPI Code of Conduct definition of a benefitting HCO.

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

5.3.2 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 Sandoz 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 5.3.3 and 5.3.4.

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

Sandoz applies the definition of the “Sponsorship Agreements” pursuant to Clauses 22 and 24 of the 2016 UK ABPI Code of Practice, following the principle that “Sponsorship

Agreements” are formalized in contracts that describe the purpose of the sponsorship and the related direct or indirect ToV.

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 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.

If an intermediary organized an event with sponsorship of Sandoz on behalf of more than one HCO, the ToV is disclosed based on the actual ToV allocated to each benefitting HCO wherever possible. In cases where it was not possible to accurately allocate the ToVs to each HCO involved in the event, it was assumed that all HCOs had similar levels of involvement. In consequence, the ToV was divided by the number of HCOs, which would each be reported as having received their equal share of the ToVs.

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

Sandoz applies the definition of the “Registration Fees” related to cost of events categories pursuant to Clauses 22 and 24 of the UK APBI Code of Practice.

In general, whenever registration fees were charged for an event organized or sponsored by or on behalf of Sandoz, 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”.

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

Sandoz applies the definition of the “Travel and Accommodation” related to cost of events categories pursuant to Clauses 22 and 24 of the UK APBI Code of Practice.

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

In general, ToVs related to travel and accommodation are 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 5.1).

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 payment offset by payment from HCP is disclosed as ToV under the "Travel and Accommodation" category in the name of the HCP.

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

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

Sandoz applies the definition of the "Fees for Service and Consultancy" pursuant to Clauses 21, 23 and 24 of the UK ABPI Code of Practice.

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 products or research, general consulting/advising, services by distributors, consultancy for tool/questionnaire selection or analysis, training services, participation at advisory board meetings, chairing engagements, involvement in medical/scientific studies, and involvement in clinical trials.

Sandoz 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 EPFIA Disclosure Code) or an HCO – are disclosed under the "Fees for Service and Consultancy" category in the name of that contracting entity.

ToVs related to market research studies for which the identity of the Recipient was known to Sandoz, 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 are not disclosed as the right of the respondents to remain anonymous is embodied in market research definitions and relevant codes of conduct worldwide.

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 Clauses 21, 23 and 24 of the 2016 ABPI Code of Conduct. 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, inter alia.

ToVs related to the following Research and Development related activities (see chapter 5.3.4) but when they do not fall under the definition of Research and Development ToVs as defined in the supplementary information to Clause 23.2 of the UK ABPI Code 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
- 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 makes indirect ToVs to HCPs/HCOs but not falling under the Research and Development definition
- Project activities related to e.g. disease area, mode of action, market placement, adjudication committees, speaker programs, scientific meetings, ethics committees, steering committee and advisory board activities not in scope of the Research and Development definition
- ToVs related to consultancy for tool/questionnaire selection or analysis and reporting of results not in scope of the Research and Development definition.

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

Sandoz fully complies with the definition of the “Fees for Service and Consultancy - Related Expenses” pursuant to Clauses 21, 23 and 24 of the 2016 UK ABPI Code of Practice.

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.

5.3.4 Transfer of Values Related to Research and Development

Sandoz applies the definition of the “Research and Development” category as set out in supplementary information to Clause 23.2 of the 2016 UK ABPI Code (which includes the definition of non-clinical studies in the OECD Principles on Good Laboratory Practice and the definition of clinical trials and non-interventional studies (as defined in Directive 2001/20/EC)).

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 Clause 23 of the 2016 ABPI Code of Practice, for example activities related to the planning or conduct of non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice), clinical trials (as defined in Directive 2001/20/EC) 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), costs that are subsidiary to these aforementioned activities.

ToVs made by or on behalf of Sandoz **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 2016 ABPI Code: consultancy activities related to the planning/conduct of non-clinical studies, clinical trial or prospective non-interventional studies, ethics committees, 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 an Research and Development project/study are reported in aggregate form under the “Research and Development” category.

The following instances of medical writing and editorial support (as defined in chapter 5.3.3) 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

6. Measures Taken to Ensure Compliance with Data Privacy Requirements

This chapter describes measures taken by Sandoz 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. This data will be published for 3 years in public domain and stored for a minimum of 5 years on record by Sandoz (publishing affiliate). The disclosure of such personal information by Sandoz 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 country data protection authority (e.g. Information Commissioner).

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 Data Protection Act 1998.

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 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.

HCP has a right to withdraw the consent on disclosure. Withdrawal of consent will have retroactive effect on past events and consultancies provided Sandoz has not already had to report the data to the ABPI to meet the annual disclosure requirement. If the latter is the case, then the withdrawal of consent would only be effective for the future.

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.

Sandoz complies with the accounting principles and the financial disclosure methodology - pursuant to Clause 24.10 of the 2016 UK ABPI Code of Practice.

Sandoz 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 discloses ToVs net amount only. If VAT cannot accurately be excluded, the full ToV amount is disclosed. Where income tax or equivalent is withheld by Sandoz on amounts earned by the HCP then the ToV will include these amounts.

Currency treatment – foreign currency ToVs will be converted using actual exchange rates in agreement with the accounting policy of the Sandoz 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.

In case of cross-border ToVs as defined in chapter 5.2, 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.

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.

If ToV information is not provided to Sandoz with adequate time to be included in for disclosure in the expected reporting year, it will be disclosed in the immediate following year.

8. Published Data

Sandoz applies the definition of “Form of Disclosure” as set out in Clause 24 of the 2016 UK ABPI Code

This 2017 Sandoz Disclosure Report will be submitted to the ABPI disclosure database by the end of March 2017.

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

Updates of published data are conducted on an annual basis and as often as is required to ensure the data is correct, including processing queries from HCPs, to allow for reflection of data updates or consent withdrawal after disclosure submission.

All Disclosure Reports published by Sandoz are published on the ABPI central platform.

This data will remain published for 3 years in public domain and stored for a minimum of 5 years on record by the publishing affiliate.

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.
- **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.

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