Novartis Methodological Note

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

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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 Organisations (HCOs) associated with Transfers of Value (ToV) [1] related to prescription-only medicines by establishing a single, consistent transparency standard in Europe for disclosing ToV 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, the Association of the British Pharmaceutical Industry (ABPI), Novartis Pharmaceuticals UK complies with the obligation to collect, disclose and report ToV 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 Organisations[2]
- Association of the British Pharmaceutical Industry (ABPI) disclosure requirements based on the EFPIA Code are outlined in Clause 24 of the 2016 UK ABPI Code of Practice
- Novartis Pharmaceuticals UK has developed HCP/HCO unique identifiers to ensure that the identity of the HCP/HCO benefitting from the ToV 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 Novartis Pharma UK Disclosure Report. Novartis Pharma UK's position is based on the interpretation of the current version of the EFPIA Disclosure Code, and the locally transposed EFPIA disclosure code, 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 Novartis Pharma UK in order to identify, collect and report ToV for each disclosure category as described in Section 3.01 of the EFPIA Disclosure Code.

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

[2] The EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organisation (in short: EFPIA Disclosure Code) states in Section 3.05 *(Methodology)* that "e*ach Member Company shall publish a note summarising 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*".

3. Novartis' Commitment and Responsibility for Disclosure

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

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

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

This 2017 Novartis Pharma UK Disclosure Report is following the disclosure standards pursuant to the local transposition of the EFPIA Disclosure Code, namely Clause 24 of the 2016 UK ABPI Code of Practice. Subject to this disclosure report are all direct or indirect ToV related to prescription-only medicines disclosed by Novartis Pharma UK 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 corresponding definition in local pharmaceutical regulation. ToV 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 Novartis Pharma UK Disclosure Report covers direct and indirect ToV, 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, Novartis Pharma UK discloses the amounts of value transferred by type of ToV with data coverage from January 1st 2016 to December 31st 2016. Novartis Pharma UK disclosure is performed for the full calendar year of 2016.

Whenever possible, Novartis Pharma UK 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 ToV. Aggregate disclosure for non-Research and Development ToV 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. Novartis' 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 ToV data was established for each category of the disclosure report.

5.1 Definition of Direct and Indirect Transfer of Value

- Novartis Pharma UK applies the EFPIA definition of ToV as outlined in EFPIA Disclosure Code schedule 1.01 and in Clause 24 of the 2016 UK ABPI Code of Practice.

According to the EFPIA Disclosure Code schedule 1 and in Clause 24 of the 2016 UK ABPI Code of Practice, the following definitions apply throughout this report:

- Direct ToV are defined as those ToV, payments or in kind, made directly by the Novartis affiliate to the benefiting HCPs/HCOs.
- Indirect ToV are defined as those ToV 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 ToV.

In general, ToV 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 Clause 24 of 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 ToV are only disclosed once on either Recipient level.

Generally, ToV to HCPs via an HCO are disclosed at the first level Recipient (HCO), or exceptionally at second level Recipient as mentioned in Section 5.3.2.1, if a contract with an HCO specifies that part of the amount must be used to engage HCPs nominated by Novartis Pharma UK. When a tripartite contract exists between Novartis Pharma UK, an HCO and an HCP, with the HCP as benefitting party, ToV are disclosed at HCP level.

If Novartis Pharma UK holds a contract with a non-HCO Third-Party vendor acting on behalf of Novartis Pharma UK and who is contracting independent HCP/HCO to provide a reportable activity, ToV 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 internal rules.

ToV from distributors of Novartis Pharma UK to HCPs/HCOs whose primary practice is in an EFPIA country must be disclosed if the distributor is making a ToV on behalf of Novartis Pharma UK (influencing the promotional activities and selection of Recipient). ToV 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 Novartis Pharma UK (and Novartis Pharma UK influenced choice of HCPs/Faculty).

5.2 Definition of Cross-border Transfers of Value

Novartis Pharma UK applies the EFPIA definition of cross-border ToV 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 ToV are disclosed in the country where the Recipient has its principal practice, principal professional address or place of incorporation - pursuant to the guidance in clause 24 of the 2016 UK ABPI Code of Practice.

5.3 Transfers of Value Categories According to the EFPIA Disclosure

Novartis Pharma UK applies the EFPIA definition of the ToV categories as outlined in EFPIA Disclosure Code Article 3.01 – and pursuant to the guidance in clause 24 of the 2016 UK ABPI Code of Practice.

The following categories constitute the EFPIA Disclosure Template for the 2017 Novartis Pharma UK EFPIA/ABPI Disclosure Report:

- Donations and Grants to a HCO
- Contribution to costs related to events to a HCO/HCP, such as:
  - Sponsorship agreements
  - Registration fees
  - Travel and accommodation
- Fees for service and consultancy to a 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 ToV data was constructed for each category can be found in the subsequent sub-chapters.

5.3.1 Transfer of Value Related to Donations and Grants

Novartis Pharma UK applies the EFPIA definition of the “Donations and Grants” category as outlined in EFPIA Disclosure Code Article 3.01 – and in clause 19 and clause 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 ToV – this may be the hospital, university or independent department within these Organisations.

ToV to a charitable Organisation are disclosed under the “Donations and Grants” category in the name of the benefiting HCO if the charitable Organisation 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 ToV are disclosed in the “Donations and Grants” category.

5.3.2 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 Novartis Pharma UK pursuant to schedule 1 of the EFPIA Disclosure Code.

ToV 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”. ToV 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 Value Related to Contribution to Costs of Events Sponsorship Agreements

Novartis Pharma UK 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 – and in clause 21, clause 22 and clause 24 of the 2016 UK ABPI Code of Practice.

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: ToV related to intermediaries selecting the faculty who acted as speakers or faculty at an event; ToV related to advertising space, sponsoring of speakers/faculty, satellite symposia at congresses, courses provided by HCOs.

ToV 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 ToV 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 benefiting Recipient.

If the contract requires the HCOs to use some of the amount to invite a number of HCPs selected by Novartis Pharma UK to an event, the ToV is split and disclosed based on the ToV 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 Novartis Pharma UK 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 ToV 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 ToV.

Novartis Pharma UK discloses ToV 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 and university hospital) – falls under the definition of “Events” and is disclosed in the name of that contracting entity.

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

Novartis Pharma UK applies the EFPIA definition of the “Registration Fees” related to cost of events categories as outlined in EFPIA Disclosure Code Article 3.01 and in clause 22 and clause 24 of the 2016 UK ABPI Code of Practice.

In general (and for all types of events), whenever registration fees were charged for an event organized or sponsored by or on behalf of Novartis Pharma UK, they are disclosed in the name of the benefiting 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”.

ToV 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. ToV related to virtual congresses for a non-European HCOs are reported in aggregate.

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

Novartis Pharma UK applies the EFPIA definition of the “Travel and Accommodation” related to cost of events categories -included in clause 22 and clause 24 of the 2016 UK ABPI Code of Practice.

ToV 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, ToV related to travel and accommodation are disclosed at first level Recipient basis. If the ToV are made through an HCO or intermediary (third party), it will be disclosed at individual HCP level whenever possible (see chapter 5.1).

ToV 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 ToV are disclosed in aggregate with the total cost divided equally among the planned number of benefitting HCPs per country.

In case the benefiting HCP partly bears the costs related to travel and accommodation (the cost of a meal including drinks must not exceed £75 per person excluding VAT and gratuities) the net amount of the Novartis Pharma UK 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 Value Related to Contribution to Fees for Service and Consultancy

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

Novartis Pharma UK applies the EFPIA definition of the "Fees for Service and Consultancy" category as outlined in EFPIA Disclosure Code Article 3.01 - and in clause 21, clause 23 and clause 24 of the 2016 UK ABPI Code of Practice.

ToV 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, chairing engagements, advisory boards, medical writing, data analysis, development of educational material, interviews e.g. Novartis Pharma UK products or research, general consulting/advising, services by distributors, consultancy for tool/questionnaire selection or analysis, etc.

Novartis Pharma UK has formalized such collaboration in a contract describing the purpose of ToV. In general, the ToV 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.

ToV related to market research studies for which the identity of the Recipient was known to Novartis Pharma UK are disclosed under the "Fees for Service and Consultancy" category. ToV related to market research studies for which the identity of the HCP/HCO was not known to Novartis Pharma UK are not disclosed as the right of the respondents to remain anonymous is embodied in market research definitions and relevant codes of conduct worldwide.

ToV 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 benefiting HCP/HCO or under the "Research and Development" category in aggregate form –in clause 21, clause 23 and clause 24 of the 2016 UK ABPI Code of Practice.

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.

ToV 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 ToV 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 benefiting Recipient, for example:

- Retrospective non-interventional studies not falling under the definition of Research and Development ToV 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 cased when such ToV do not fall under the definition of Research and Development mentioned above
- Activities contracted to Contract Research Organisations (CROs) where Novartis Pharma UK makes indirect ToV 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, ethics committees, steering committee and advisory board activities not in scope of the EFPIA Research and Development definition
- ToV related to consultancy for tool/questionnaire selection or analysis and reporting of results not in scope of the EFPIA Research and Development definition

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

Novartis Pharma UK 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 - and in clause 21, clause 23 and clause 24 of the 2016 UK ABPI Code of Practice.

In general, the ToV 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 ToV 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 ToV have been disclosed as part of the total amount of fees under the "Fees for Service or Consultancy" category.

5.3.4 Transfer of Value Related to Research and Development

Novartis Pharma UK 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) - and in supplementary information to clause 23.2 of the 2016 UK ABPI Code.

ToV **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 Novartis Pharma UK, they may benefit from Novartis Pharma UK
- 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 Novartis Pharma UK makes indirect ToV to HCPs/HCOs falling under the definition of Research and Development
- ToV related to early stage research if falling under the definition of Research and Development in the EFPIA Disclosure Code.

ToV made by or on behalf of Novartis Pharma UK **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, 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 programmes, scientific meetings, inter alia.

ToV 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

Novartis Pharma UK ensures 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 Novartis Pharma UK. This data will be published for 3 years in the public domain and stored for a minimum of 5 years on record by Novartis Pharma UK (the publishing affiliate). The disclosure of such personal information by Novartis Pharma UK 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 Novartis Pharma UK country data protection authority (e.g. Information Commissioner).

6.2 Consent Collection

Consent for the publication of the ToV was obtained and documented 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 on Recipient level for all ToV during a given period of time not shorter than one full year for cross border activities and on spend level for each interaction or single ToV for all UK activity.

Novartis Pharma UK 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, ToV 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.

An HCP has a right to withdraw consent to disclosure. Withdrawal of consent will have retroactive effect on past events and consultancies provided Novartis 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. Consent withdrawal has been assessed according to the Novartis Pharma UK local data privacy laws.

7. Financial Aspects

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

Novartis Pharma UK complies with the Pharma accounting principles and the financial disclosure methodology referred to in clause 24.10 of the 2016 UK ABPI Code.

Novartis Pharma UK decided to apply the following rules for ToV payment dates based on type of ToV: direct ToV are disclosed based on the date the payment has been cleared via the banking system. Indirect ToV 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.

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

Currency treatment – foreign currency ToV will be converted using actual exchange rates in agreement with the accounting policy of Novartis Pharma UK. ToV will be disclosed in the local currency of the country where the disclosing entity is located. For direct and indirect ToV, the foreign currency is converted to the local currency of the disclosing entity based on the transaction date. For cross-border ToV, 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 the case of cross-border ToV as defined in chapter 5.2, direct ToV will be recognized when the payment has been cleared via the banking system and indirect ToV 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 Novartis Pharma UK with adequate time to be included for disclosure in the expected reporting year, it will be disclosed in the immediate following year.

In the case of multi-year contracts, ToV are recognized based on the date the payment has been cleared via the banking system.

8. Published Data

Novartis Pharma UK applies the EFPIA definition of “Form of Disclosure” as outlined in EFPIA Disclosure Code Article 2 and included in clause 24 of the 2016 UK ABPI Code.

This 2016 calendar year Novartis Pharma UK EFPIA/ABPI Disclosure Report will be submitted to the UK ABPI disclosure database by the end of March 2017. It will be published by the ABPI at the beginning of July 2017.

Updates of published data are conducted on an annual basis within 6 months after the end of the relevant full calendar year. The ABPI allows a month between mid-May and mid-June for HCPs to check the accuracy of the data and to request consent withdrawal after disclosure submission by the pharmaceutical companies.

This data will remain published for 3 years in the public domain and will be 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 Organisation (CRO):** an Organisation 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 Organisation (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 Organisation (HCO):** Any legal person (i) that is a healthcare, medical or scientific association or Organisation (irrespective of the legal or Organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient Organisations 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 Organisation 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 Organisation) 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 Organisation – 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 Organisation 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 ToV:** ToV 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 (ToV):** 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.