Novartis Methodological Note

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

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Country: Sweden

Division: Innovative Medicines

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1. Reference to National Transparency Laws and Regulations

Novartis supports laws and regulations that promote transparency around relationships between healthcare companies, Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) associated with Transfers of Value (ToVs) related to prescription-only medicines[1] 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 Läkemedelsindustriföreningen (LIF), Novartis Sverige AB 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 of Practice[2] as evidenced by Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.*

Novartis Sverige AB applies the definition of the HCP/HCO as outlined in the EFPIA Disclosure Code Definitions - pursuant to Article 1, Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.

Novartis Sverige AB 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 2021 Novartis Sverige AB Disclosure Report. Novartis Sverige AB's position is based on the interpretation of the current version of the EFPIA Code, aligned with local transparency laws and locally transposed Läkemedelsindustrins etiska regelverk (LER).

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Novartis Sverige AB in order to identify, collect and report ToVs for each disclosure category as described in Section 23.05 of the EFPIA Code.

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[1] A definition on the terms "HPO/HCO" and "ToVs" will be provided in Chapter 9 of this document.

[2] The 2019 EFPIA Code of Practice (in short: EFPIA Code) states in Section 23.05 *(Methodology)* that "e*ach Member Company must publish a note summarizing the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 23.05. The note, including a general summary and/or country specific considerations, must 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 ToVs related to prescription-only medicines.

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

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

This 2021 Novartis Sverige AB affiliate Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Code and national transparency laws/regulations. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines disclosed by Novartis Sverige AB to or for the benefit of a Recipient made by any Novartis affiliate as described in Article 23 of the EFPIA 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 Ethical Rules for the Pharmaceutical Industry in Sweden. 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 Code.

In summary:

The 2021 Novartis Sverige AB EFPIA 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/these reports, Novartis Sverige AB discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2021 to Dec 31st 2021. Novartis Sverige AB disclosure is performed for the full calendar year 2021 once per year.

Whenever possible, Novartis Sverige AB 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.

This report also includes Transfer of Values made by Advanced Accelerator Applications and Novartis Gene Therapies.

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 ToVs data was established for each category of the disclosure report.

5.1 Definition of Direct and Indirect Transfer of Values

Novartis Sverige AB applies the EFPIA definition of ToVs as outlined in EFPIA Code Definitions - pursuant to Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.

According to the EFPIA Code Definitions, the following definitions apply throughout this report:

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

In general, ToVs are reported at the level of the first identifiable Recipient which falls under the EFPIA definition of an HCP/HCO. 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 Code and pursuant to Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden. 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.

ToVs from distributors of Novartis Sverige AB 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 Sverige AB (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 Novartis Sverige AB (and Novartis Sverige AB influenced choice of HCPs/Faculty).

5.2 Definition of Cross-border Transfer of Values

Novartis Sverige AB 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 Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.

5.3 Transfer of Value Categories According to the EFPIA Code

Novartis Sverige AB applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 - pursuant to Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.

The following categories constitute the EFPIA Disclosure Template for the 2021 Novartis Sverige AB EFPIA Disclosure Report:

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

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

5.3.1 Transfer of Values Related to Donations and Grants

Novartis Sverige AB applies the EFPIA definition of the “Donations and Grants” category as outlined in EFPIA Code Article 23.05 – pursuant to Article 1, Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden, and may also include Scholarships (as defined in Article 7, Chapter 2, Section 1 of the Ethical Rules for the Pharmaceutical Industry in Sweden).

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 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.

5.3.2 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 sponsored by or on behalf of Novartis Sverige AB pursuant to schedule 1 of the EFPIA Code.

ToVs to participating HCOs related to such events falling under the definition above are disclosed in the “Costs of Events” sub-category “Sponsorship Agreements”,. 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

Novartis Sverige AB applies the EFPIA definition of the “Sponsorship Agreements” category as outlined in EFPIA Code Article 23.05, 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 Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.

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 in the “Sponsorship Agreements” category, in the name of the sponsored HCO as benefitting Recipient.

If an intermediary organized an event with sponsorship of Novartis Sverige AB 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.

Novartis Sverige AB 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.

5.3.3 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

Novartis Sverige AB applies the EFPIA definition of the “Fees for Service and Consultancy” category as outlined in EFPIA Code Article 23.05 - pursuant to Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.

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, advisory boards, interviews e.g. on Novartis Sverige AB products or research, general consulting/advising, services by distributors, consultancy for tool/questionnaire selection or analysis.

Novartis Sverige AB 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 Novartis Sverige AB, 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 Novartis Sverige AB 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 Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden. 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. Novartis Sverige AB decided to disclose ToVs related to auscultation i.e. a training that is provided by a HCO to Novartis staff at eg. a clinic, as "Fees for Service and Consultancy" in the name of the benefitting HCO.

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 stated by the EFPIA 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 as per that prescribed in EFPIA Code Schedule 1
- 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 Organizations (CROs) where Novartis Sverige AB 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, ethics committees, 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

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

Novartis Sverige AB fully complies with the EFPIA definition of the "Fees for Service and Consultancy - Related Expenses" category as outlined in EFPIA Code Article 23.05 -

pursuant to the Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.

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

Novartis Sverige AB applies the EFPIA definition of the “Research and Development” category as outlined in EFPIA Code - Definitions, 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 Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.

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 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 Sverige AB, they may benefit from Novartis Sverige AB
- 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 Sverige AB 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 Code

In case ToVs relating prospective and retrospective non-interventional studies cannot be distinguished, all non-interventional studies are disclosed on an individual basis.

ToVs made by or on behalf of Novartis Sverige AB **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 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 Novartis Sverige AB to ensure comliance with data privacy laws and regulations and relevant internal rules.

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 Sverige AB. This data will be published for 3 years in public domain and stored for a minimum of 5 years on record by Novartis Sverige AB (publishing affiliate). The disclosure of such personal information by Novartis Sverige AB 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, appropriate data security measures have been applied. Furhtermore, if transfer of data to the central Novartis Transparency data repository was done via a third country (outside the EU/EEA) this transfer relied upon Novartis Binding Corporate Rules or strandard contractual clauses as the transfer mechanism.

6.2 Legitimate interest for the collection of personal data

During 2021 Novartis Sverige AB has relied upon two different legal bases for the processing of personal information. For the first eight months of the year the legal basis is consent and for the four last months of the year and onwards the legal basis is legitimate interest.

January - August

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[3].

Consent was obtained on Recipient level for all ToVs from 1 January 2021 and 31 August 2021 and forward in time until consent is withdrawn.

Novartis Sverige AB 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.

HCPs have a right to withdraw the consent.

September – December

Novartis Sverige AB has a legitimate interest in collecting personal information for the disclosure of ToVs. Furthermore, ToV is not solely in the interest of Novartis Sverige AB rather it is of a broader interest of society to have transparency in order to maintain trust in independent HCPs/HCOs and life science companies. Ensuring full transparency in the relationship between HCPs/HCOs and Novartis Sverige AB can only be achieved by a public disclosure of the TOV, anonymised and aggregated publication of the TOV would not be in line with the need for full transparency. For the purpose of transparency and the communication about this purpose towards HCPs /HCOs from Novartis Sverige AB, ToV is seen as a reasonable expectation of the HCPs/HCOs. Novartis Sverige AB has made a privacy notice available to HCPs at (https://www.novartis.se/novartis-allman-integritetspolicy-affarspartner) https://www.novartis.se/novartis-general-privacy-notice-business-partners. Novartis Sverige AB can be contacted for any data privacy questions at: dataprivacy.nordics@novartis.com

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.

Novartis Sverige AB complies with the Novartis Pharma internal accounting principles and the financial disclosure methodology - pursuant to Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.

Novartis Sverige AB 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

[3] New EU Regulation (GDPR) lays down rules relating to the protection of natural persons with regard to the processing of personal data

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 Sverige AB 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 Novartis Sverige AB 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 Novartis Sverige AB. 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.

8. Published Data

Novartis Sverige AB applies the EFPIA definition of “Form of Disclosure” as outlined in EFPIA Code Article 23.4 - pursuant to Chapter 2, Section 3 of the Ethical Rules for the Pharmaceutical Industry in Sweden.

This 2021 Novartis Sverige AB EFPIA Disclosure Report has been officially published on 31 May 2022.

Disclosures are made on an annual basis or relevant local disclosure timeframe within 6 months after the end of the relevant full calendar year. Updates of already published disclosures will be made in case errors are detected after the disclosure or if an HCP is requesting to have his or her personal details removed.

Publication is made in LIFs samarbetsdatabas on the LIF website; http://www.lif.se/.

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 Novartis Sverige AB are published on the same platform.

Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication. 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.

References to internal and external sources for further reading and documentation purpose.

- http://novartis.se/
- http://www.lif.se/

9. Acronyms and Abbreviations

This chapter includes a list of acronyms, abbreviations and definitions for documentation purpose, based on Definitions in the EFPIA 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 article 21 of the EFPIA 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:** as defined in the EFPIA Statutes, means an organisation representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies. Collectively, the national Member Associations or their constituent members, as the context may require, are bound by the EFPIA Code.

- **Member Companies:** as defined in the EFPIA Statutes, means research-based companies, developing and manufacturing Medicinal Products in Europe for human use.

- **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/PCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

- **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.

- **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.