

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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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)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 a Novartis Company² and member of the national KEFEA (Cyprus Association of R&D Pharmaceutical Companies), Novartis Pharma Services Inc. Representative Office Cyprus (**NPhS CY**) complies with the obligation to collect, disclose and report ToVs related to prescription-only medicines to HCPs/HCOs in accordance with:

- Section 23.05 of the EFPIA Code of Practice²
- The KEFEA Code of Practice Chapter 5 Articles 22 and 23 – Disclosure of ToVs to HCPs and HCOs (**KEFEA Code**).

NPhS CY 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 2023 NPhS CY Disclosure Report. NPhS CY's position is based on the interpretation of the current version of the EFPIA Code aligned with local transparency laws which locally transposed EFPIA disclosure code, i.e. the KEFEA Code.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by NPhS CY in order to identify, collect and report ToVs for each disclosure category as described in Section 23.05 of the EFPIA Code and Section 23.04 of the KEFEA Code.

¹ A definition on the terms "HCP/HCO" and "ToVs" is 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 "each 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 and medical devices.

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 2023 NPhS CY Disclosure Report is following the disclosure standards pursuant to the local transposition EFPIA Code, namely the KEFEA Code. This disclosure report includes all ToVs made by NPhS CY, as described in Article 23 of the EFPIA Code and Article 23 of the KEFEA Code. Further details on the disclosure scope will be provided in chapter 4 of this document.

The legal definition of 'prescription-only medicine', which is a Medicinal Product (whose definition is provided in chapter 9 of this document) that requires a medical prescription by a professional person qualified to prescribe. Medicinal products shall be subject to medical prescription where they:

- (a) are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or
- (b) are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or
- (c) contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation, or
- (d) are normally prescribed by a doctor to be administered parenterally.

ToVs related to a group of products that includes prescription-only medicines (e.g. combination products/diagnostics and medicinal products) are reported in total.

In summary:

The 2023 NPhS Disclosure Report covers ToVs, made to HCPs/HCOs. In this report, NPhS CY discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2023 to December 31st 2023. NPhS CY disclosure is performed for the full calendar year 2023.

Whenever possible, NPhS CY 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. 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

NPhS CY applies the EFPIA definition of ToVs as outlined in EFPIA Code Definitions and which is aligned with the corresponding definition of the KEFEA Code set out below:

Direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of POM exclusively for human use. Direct ToVs are those made directly for the benefit of a Recipient. Indirect ToVs are those made on behalf of a KEFEA member for the benefit of a Recipient, or those made through a Third Party and where NPhS CY knows or can identify the Recipient that will benefit from the ToV. ToVs made to PCOs who act to the benefit of an HCO shall be classified as Indirect ToVs, whereas the HCO's benefit to be disclosed as a ToV might not reflect the entire amount paid by NPhS CY since the PCO might retain a "service fee".

In general, ToVs are reported at the level of the clearly 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 the KEFEA Code and all applicable laws and regulations. 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 and to the extent possible, such disclosure must be made on an individual HCP named basis as explained below.

Generally, ToVs to HCPs via an HCO are disclosed at the first level Recipient (HCO), or exceptionally at second level Recipient as mentioned in Section 5.3.2.1, if a contract with an HCO specifies that part of the amount must be used to engage HCPs nominated by NPhS CY. When a tripartite contract exists between NPhS CY, an HCO and an HCP, with the HCP as benefitting party, ToVs are disclosed at HCP level. If NPhS CY holds a contract with a non-HCO Third-Party vendor acting on behalf of NPhS CY 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 internal rules.

ToVs from Third Parties to HCPs/HCOs whose primary practice is in an EFPIA country must be disclosed if the Third Party is making a ToV on behalf of NPhS CY. 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 NPhS CY.

5.2 Definition of Cross-border Transfer of Values

NPhS CY applies the EFPIA definition of cross-border ToVs as being a Transfer of Value to a Recipient that **occurred outside** the country where the latter has its primary practice, principal professional address or place of incorporation provided that this country is an EFPIA regulated country.

In general, such ToVs are disclosed in the country where the Recipient has its principal practice, principal professional address or place of incorporation - pursuant to the EFPIA code.

5.3 Transfer of Value Categories according to the EFPIA Code

NPhS CY applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 and section 23.04 of the KEFEA code.

The following categories constitute the EFPIA Disclosure Template for the 2023 NPhS CY Disclosure Report:

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

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

5.3.1 Transfer of Values Related to Donations and Grants

NPhS CY applies the EFPIA the “Donations and Grants” (as this term is defined in section 9 below) category as outlined in EFPIA Code Article 23.05 and Section 23.04 of the KEFEA Code.

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 (with no consequent obligation on the recipient to provide goods or services to the benefit of NPhS CY in return) are also disclosed in the “Donations and Grants” category.

When grant requests from HCOs include explicit support for publication (with no consequent obligation on the recipient to provide goods or services to the benefit of NPhS CY in return), then these ToVs are disclosed in the “Donations and Grants” category.

5.3.2 Transfer of Values Related to Contribution to Costs of Events

ToVs to participating HCPs/HCOs related to such events falling under the definition of Events (as this term is defined in section 9 below) are disclosed as “Contribution to Costs related to Events”, by using the following 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. respectively.

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

NPhS CY treats disclosure of ToVs which relate to “Sponsorship Agreements” – which are formalized in contracts that describe the purpose of the sponsorship and the related direct or indirect ToV – as outlined in EFPIA Code Article 23.05 and the KEFEA code.

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 PCO as intermediary e.g. for the hire of booths or stand space on behalf of an HCO, are disclosed as (indirect) 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 NPhS CY 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 NPhS CY 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.

NPhS CY 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.

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

NPhS CY treats disclosure of ToVs which relate to “Registration Fees” as outlined in EFPIA Code Article 23.05 and the KEFEA Code.

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

ToVs related to virtual congresses (e-congresses) are reported as actual spend. Aggregate spend is disclosed under the HCO in each country and is reported in "Registration Fees" category. Virtual congress vouchers given to HCPs will be disclosed under the final beneficiary (HCP).

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

NPhS CY treats disclosure of ToVs which relate to “Travel and Accommodation” as outlined in EFPIA Code Article 23.05 and the KEFEA code.

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 NPhS CY 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

NPhS CY treats disclosure of ToVs which relate to “Fees for Service and Consultancy” as outlined in EFPIA Code Article 23.05 and the KEFEA code.

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 NPhS CY products or research, general consulting/advising, services by distributors, consultancy for tool/questionnaire selection or analysis.

NPhS CY 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 through which one or more HCP provide services (considered an HCO under the EFPIA Disclosure Code) or an HCO – are disclosed under the “Fees for Service and Consultancy” category in the name of that contracting entity.

ToVs related to market research studies for which the identity of the Recipient was known to NPhS CY, 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 NPhS CY 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 the KEFEA code. The following instances of medical writing and editorial support are covered under the “Fees for Service and Consultancy” category: case studies, congress write ups, article and abstracts, manuscripts, poster, clinical management guideline, supplements, patient narrative writing - only if not disclosed under the “Research and Development” category by NPhS CY, consensus report - only if not disclosed under the “Research and Development” category by NPhS CY.

ToVs related to the following Research and Development ToVs (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 case when such ToV do not fall under the definition of Research and Development mentioned above
- Activities contracted to Contract Research Organizations (CROs) where NPhS CY

makes indirect ToVs to HCPs/HCOs but not falling under the Research and Development ToVs

- 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

NPhS CY treats disclosure of ToVs which relate to “Fees for Service and Consultancy - Related Expenses” category in compliance with EFPIA Code Article 23.05 and the KEFEA code.

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 (dealt with under this section 5.3.3) 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

NPhS CY treats disclosure Research and Development ToVs as outlined in Section 15.01 of the HCP Code and pursuant to the KEFEA code.

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 NPhS CY, they may benefit from NPhS CY
- 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 NPhS CY makes indirect ToVs to HCPs/HCOs falling under the definition of Research and Development ToVs
- ToVs related to early stage research if falling under the definition of Research and Development ToVs

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 NPhS CY **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 ToVs in relation to, among others, 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 a Research and Development project/study are reported in aggregate form under the “Research and Development ToVs” category.

The following instances of medical writing and editorial support (as defined in chapter 5.3.3) are covered under the “Research and Development ToVs” category: investigator’s brochure (trials), clinical study report (trials), clinical report, safety report; generally all types of medical writing related to clinical trials or related to Research and Development activities, patient narrative writing - only if not disclosed under the “Fees for Service and Consultancy” category by NPhS CY, consensus report - only if not disclosed under the “Fees for Service and Consultancy” category by NPhS CY.

6. Measures Taken to Ensure Compliance with Data Privacy Requirements

This chapter describes measures taken by NPhS CY 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 data”). To fulfil the transparency disclosure requirements, it is necessary to collect, process and disclose such personal data within and outside of NPhS CY. This data will be published for 3 years in public domain and stored for a minimum of 5 years on record by the NPhS CY (publishing affiliate), the relevant data protection legal basis (e.g. the legitimate interest grounds, a legal duty or the Recipient’s consent relating to a specific disclosure) is no longer applicable. The disclosure of such personal data by NPhS CY 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 NPhS CY 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 applicable¹. Consent management procedures were conducted in alignment with the Cyprus Data Protection Act.

Consent was obtained either on Recipient level for all ToVs during a given period of time and remains valid for three years or until withdrawal of consent.

NPhS CY 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.

¹ The EU Regulation (GDPR) lays down rules relating to the protection of natural persons with regard to the processing of personal data.

HCP has a right to withdraw the consent. Consent withdrawal has been assessed according to the relevant NPhS CY local data privacy laws the Cyprus Data Protection Law.

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.

NPhS CY complies with the Innovative Medicines accounting principles and the financial disclosure methodology .

NPhS CY 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.

NPhS CY discloses ToVs net amount only, except:

- if VAT cannot accurately be excluded, in which case the full ToV amount is disclosed;
- and

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- where income tax or equivalent is withheld by NPhS CY on amounts earned by the HCP then the ToV will be disclosed in gross numbers, and will include these amounts.

Currency treatment – foreign currency ToVs will be converted using actual exchange rates in agreement with the accounting policy of the NPhS CY. 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 each payment has been cleared via the banking system.

8. Published Data

NPhS CY applies the EFPIA definition of “Form of Disclosure” as outlined in EFPIA Code Article 23.04 - pursuant to the KEFEA code.

Updates of published data are conducted on a quarterly basis to allow for reflection of data updates or consent withdrawal after disclosure submission. Pre-disclosure letters are generated and distributed to individual HCPs prior to publication as information about the list of transfers of value received by the HCP from NPhS CY.

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. The information disclosed shall remain in the public domain for 3 years after the time such information is first published.

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.
- **Donations and Grants:** collectively mean providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

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- **Europe:** includes those countries in which the EFPIA Member Associations' National Codes apply¹.
 - **Events:** are defined as all professional, promotional, scientific or educational meetings, congresses, conferences, symposia (including Satellite Symposia², for the purposes of the KEFEA Code), 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 NPhS CY.
 - **HCP Code:** EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, adopted by the EFPIA Board on 5 July 2007 and ratified by the EFPIA Statutory General Assembly on 19 June 2008, amended on 14 June 2011, and as further amended on 24 June 2013, and as may be amended, supplemented or modified from time to time.
 - **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 and the same article of the KEFEA 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.
 - **Item of Medical Utility:** constitutes an inexpensive item aimed directly at the education of HCPs enhancing the provision of medical services and patient care and that do not offset routine business practices of the HCPs. They generally include items that are beneficial to enhancing the provision of medical services and patient care and have no personal benefit to the HCP, whereas the transmission of such materials or items must

¹ As of June 2019, these countries include: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

² symposia of a promotional or non-promotional nature, organised by KEFEA Member Companies in the context of third-party scientific/educational events (e.g. congresses organised by HCOs).

not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

“inexpensive” is any Item of Medical Utility which is no more than EUR 30. Items of Medical Utility can include Novartis’ name, but must not be product-branded, unless the Medicinal Product’s name is essential for the correct use of the material or item by the patient.

- **Medical Sales Representatives:** personnel, including personnel retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicine.
- **Medical Sample:** sample of Medicinal Product free of charge to persons qualified to prescribe or supply them so that they can familiarise themselves with new products and acquire experience in dealing with them, provided the below conditions are satisfied:
 - samples are given on an exceptional basis and are not given as an inducement to recommend, prescribe, purchase, supply, sell or administer specific Medicinal Products; and
 - must not be given for the sole purpose of treating patients; and
 - no medical sampling of Medicinal Products containing psychotropic and narcotic substances, shall occur; and
 - each sample must be no larger than the smallest presentation of that particular Medicinal Product in Cyprus and must be marked “free medical sample – not for sale” or words to that effect and must be accompanied by a copy of the summary of product characteristics; and
 - Medical Samples can only be given in response to a written (signed and dated) request from HCPs qualified to prescribe that particular Medicinal Product; and
 - each HCP should receive, per year, not more than 4 Medical Samples of a particular Medicinal Product he/she is qualified to prescribe for 2 years after the launch of each particular Medicinal Product (i.e. the “4x2” standard).

In this context, a new Medicinal Product is a product for which a new marketing authorisation has been granted, either following an initial marketing authorisation application or following an extension application for new strengths/dosage forms that include a new indication. Extensions of the marketing authorisation to additional strengths/dosage forms for existing indications or pack sizes (number of units in the pack) cannot be considered as new Medicinal Product.

- **Medicinal Product:** has the meaning set forth in set forth in Article 1 of the Directive 2001/83/EC and/or section 2 of the Medicines for Human Use Laws 70(l) 2001 and is defined as (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

For the avoidance of doubt, it is clarified that this term does **not** include: ToVs that (i) are solely related to over the-counter medicines; (ii) are not listed in Section 23.04 of the KEFEA Code, such as Items of Medical Utility, meals, Medical Samples given out by NPhS CY directly and/or through its Medical Sales Representatives; or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a KEFEA member and a HCP (such as a pharmacist) or a HCO.

- **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/individual specialized 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 Regulation 536/2014); 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.
- **Third Party:** a legal person/entity or individual that represents a Member Company or interacts with other Third Parties on behalf of a Member Company or relating to the Member Company's Medicinal Product, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contracted sales forces, market research companies, advertising agencies, providers of services related to events, public relations services, non-clinical, non-interventional studies management services.
- **Transfers of Value (ToVs):** Direct and indirect transfers of value, whether in cash, 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 or a KEFEA member (including Novartis) for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company or a KEFEA member (including Novartis) for the benefit of a Recipient, or transfers of value made through a Third Party and where the Member Company knows or can identify the Recipient that benefit from the Transfer of Value.