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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Table of Contents

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

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 Company and member of the national EFPIA Member Association (AIFP), Novartis s.r.o. 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]
- *AIFP Code of Practice(Approved by the AIFP General Assembly of 16th April 2020)*

Local AIFP prepared the AIFP Methodology on Disclosure. The aim of this document is to provide readers of disclosed data with further information about methodologies used when disclosing Transfer of Values. As all data are disclosed on the central platform https://aifp.cz/cs/transparentni-spoluprace-2/, one common methodological note covering almost all areas that need to be clarified was prepared. However, some parts of the methodology, not strictly specified by this methodological note, may slightly differ among companies and each company shall therefore publish its own methodology as well.

- Note: Further details on the Novartis' position on transparency are given in chapter 3.

2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the 2021 Novartis s.r.o. Disclosure Report based on AIFP template requirements. Novartis s.r.o. position is based on the interpretation of the current version of the EFPIA Code aligned with AIFP Code of Practice.

[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 "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*".

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

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 s.r.o. Disclosure Report is following the disclosure standards pursuant to the EFPIA Code and AIFP Code of Practice. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines disclosed by Novartis s.r.o. 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 Definition stated in local pharmaceutical regulation issued by State Institue for Drug Control. 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 Disclosure Report – AIFP 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.

The 2021 Disclosure Report – AIFP Disclosure Report covers provision of funds for the support and the advancement of genuine medical education of HCP, patients and/or the public on clinical, scientific and/or health care topics relevant to the therapeutic areas as educational grants.In this report, Novartis s.r.o. (Czech Republic) discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2021 to

December 31st 2021. Novartis s.r.o. disclosure is performed for the full calendar year 2021.

Whenever possible, Novartis s.r.o. 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.

This report also includes Transfer of Values made by 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.

Novartis s.r.o. applies the definition of the HCP/HCO as outlined in the EFPIA Code - pursuant to the AIFP code of Practice.

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

In accordance with EFPIA Code and pursuant to the national AIFP code of Practice, ToVs to an HCP/HCO are disclosed in the country where the Recipient's primary practice is located, independent of whether the ToVs occurred inside or outside that country. The physical address where the HCP has his primary practice or the principal address of an HCO is used as the deciding factor when determining in which country the data should be disclosed.

5.1 Definition of Direct and Indirect Transfer of Values

Novartis s.r.o. applies the EFPIA definition of ToVs as outlined in EFPIA Code Definitions - pursuant to the definition in the AIFP Code of Practice.

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 the definition in the AIFP Code of Practice. Where a ToV was made to an individual HCP rendering services on behalf of an HCO indirectly via this HCO, such ToVs are only disclosed once on either Recipient level.

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 Novartis s.r.o. When a tripartite contract exists between Novartis s.r.o. an HCO and an HCP, with the HCP as benefitting party, ToVs are disclosed at HCP level. If Novartis s.r.o. holds a contract with a non-HCO Third-Party vendor acting on behalf of Novartis s.r.o. 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 distributors of Novartis s.r.o. 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 s.r.o. (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 s.r.o. (and Novartis s.r.o. influenced choice of HCPs/Faculty).

5.2 Definition of Cross-border Transfer of Values

Novartis s.r.o. 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 and MedTech regulated countries.

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 definition in AIFP Code of Practice.

5.3 Transfer of Value Categories According to the EFPIA Code

Novartis s.r.o. applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 - pursuant to the definition in the AIFP Code of Practice.

The following categories constitute the EFPIA Disclosure Template for the 2021 Novartis s.r.o. Disclosure Report (AIFP 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

Novartis s.r.o. applies the EFPIA definition of the “Donations and Grants” category as outlined in EFPIA Code Article 23.05 – pursuant to the definition in AIFP disclosure 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 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 (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 s.r.o. pursuant to schedule 1 of the EFPIA Code.

ToVs to participating HCPs/HCOs related to such events falling under the definition above are disclosed in the “Costs of Events” sub-categories “Sponsorship Agreements”, “Registration Fees” or “Travel and Accommodation”. ToVs that by exception fall into the “Fees for Service and Consultancy” or “Research and Development” categories are outlined in the respective chapters 5.3.3 and 5.3.4.

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

Novartis s.r.o. 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 the definition in AIFP 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: ToVs related to intermediaries selecting the faculty who acted as speakers or faculty at an event; ToVs related to advertising space, sponsoring of speakers/faculty, satellite symposia at congresses, courses provided by HCOs.

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

If the contract requires the HCOs to use some of the amount to invite a number of HCPs selected by Novartis s.r.o. 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 Novartis s.r.o. 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 s.r.o. 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

Novartis s.r.o. applies the EFPIA definition of the "Registration Fees" related to cost of events categories as outlined in EFPIA Code Article 23.05 – pursuant to the national AIFP 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 s.r.o. they are disclosed in the name of the benefitting HCP or HCO. The total amount of registration fees paid in a given year to a HCO should be disclosed on an individual basis (in the name of the HCO) under “Contribution to Costs of Events”. The total amount of Registration Fees paid in a given year to a HCP who is the clearly identifiable Recipient is disclosed on an individual basis (in his/her name) under “Contribution to Costs of Events”.

ToVs related to virtual congresses (e-congresses) 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

Novartis s.r.o. applies the EFPIA definition of the “Travel and Accommodation” related to cost of events categories - pursuant to the definition in AIFP Code of Practice.

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

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

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

In case the benefitting HCP partly bears the costs related to travel and accommodation net amount of the Novartis s.r.o. 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

Novartis s.r.o. applies the EFPIA definition of the “Fees for Service and Consultancy” category as outlined in EFPIA Code - pursuant to the definition in AIFP Code of Practice.

ToVs covered under the “Fees for Service and Consultancy” category, whether made directly or through a third party to an HCP/HCO, include but are not limited to services performed in connection with third-party congresses, speakers’ fees, speakers’ trainings, medical writing, data analysis, development of education material, interviews e.g. on Novartis s.r.o. products or research, general consulting/advising, services by distributors, consultancy for tool/questionnaire selection or analysis.

Novartis s.r.o. 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 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 s.r.o. 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 s.r.o. 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 local law and regulations, or self-regulatory codes which the Member Companies have subscribed to. 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.

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 and EFPIA HCP Code Article 15 are disclosed under the “Fees for Services and Consultancy” category in the name of the benefitting Recipient, for example:

- Retrospective non-interventional studies not falling under the definition of Research and Development ToVs as per EFPIA 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 Organizations (CROs) where Novartis s.r.o. 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 s.r.o. 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 definition in the AIFP Code of Practice.

In general, the ToVs amount related to expenses such as travel and accommodation cost associated with the activity agreed to in a "Fees for Service" or "Consultancy" contract do not constitute part of the fees itself; in consequence such ToVs are disclosed under the "Related Expenses" category in the name of the benefitting HCP/HCO.

In case such expenses were not material (e.g. of limited value), or when such expenses despite best effort could not be accurately disaggregated from the fees, such ToVs have been disclosed as part of the total amount of fees under the "Fees for Service or Consultancy" category.

5.3.4 Transfer of Values Related to Research and Development

Novartis s.r.o. 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 the definition in AIFP Code of Practice.

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 s.r.o. they may benefit from Novartis s.r.o.
- 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 s.r.o. 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 ode

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 s.r.o. **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 s.r.o. 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.

Based on local AIFP Methodology Section 5(2)(b) Act No. 101/2000 Coll. ., the Protection of Personal Data, as amended). If such agreement is concluded (in writing), the Healthcare Professional's consent is nor needed and cannot be therefore revoked.) on Disclosure there are two possibilities of consent collection:

According to the standpoint of the Office for Personal Data Protection which AIFP received in reply to its questions, it is possible to make use of a legal dispensation from the obligation to obtain consent from each Healthcare Professional, provided an agreement between the Healthcare Professional and an AIFP Member Company contains a provision to the effect that processing of personal data is necessary for the purposes of the agreement obtaining the consent from the healthcare professional with processing of personal data.

Novartis s.r.o. is obtaining the consent from the healthcare professional.

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

6.2 Consent Collection

Consent for the publication of the ToVs was obtained and documented as such before disclosing the data on an individual HCP/HCO level where applicable[3]. Consent management procedures were conducted in alignment with the Internal data protection procedure/policy.

Consent was obtained either on Recipient level for all ToVs during a given period of time not shorter than one full year or on spend level for each interaction or single ToVs. Novartis s.r.o. decided to obtain new consents in case of new engagement for 2021, the previous consents are valid for 5 years.

Novartis s.r.o. does not accept partial consent or split disclosure.

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

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

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

HCP has a right to withdraw the consent. Consent withdrawal has been assessed according to the relevant Novartis s.r.o local data privacy laws The Czech law on protection of personal data 101/2000 as amended.

Any alternative way to manage individual publication of ToV (for example based on a different legal ground than the consent) is discussed with and assessed by the local Data Privacy Head.

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 s.r.o. complies with the pharma and oncology division accounting principles and the financial disclosure methodology - pursuant to the definition in AIFP Code of Practice.

Novartis s.r.o. 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.

Novartis s.r.o. 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 s.r.o. on amounts earned by the HCP then the ToV will include these amounts.

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

When affiliate realizes that the published disclosure report is missing data, i.e., ToV has not been reported, missed ToV shall be reported in aggregate/ on individual level, based on consent level in a revised (updated) report in the same disclosure cycle. In case affiliate includes ToV from previous year in current year disclosure, this must be mentioned in the methodological note.

8. Published Data

Novartis s.r.o. applies the EFPIA definition of “Form of Disclosure” as outlined in EFPIA Code Article 23.4 - pursuant to the definition in the AIFP Code of Practice.

Updates of published data are conducted on at least quarterly basis to allow for reflection of data updates or consent withdrawal after disclosure submission. Pre-dislosure process for Novartis s.r.o. includes the predisclosure letter with all ToV related to the individual HCP with the consent printed directly from the internal disclosure system. Novartis s.r.o will ask for the HCP´s confirmation about all ToV with Novartis s.r.o for a specific year.

HCP has a right to withdraw the consent in written to the common address **privacy.cz@novartis.com.** Consent withdrawal is with retroactive effect and Novartis s.r.o. has to change the Disclosure report at IAIFP platform properly and as soon as possible. Dispute person´s telephone number is a part of the pre-disclosure letter. Novartis s.r.o Consent withdrawal has been assessed according to the relevant Czech data privacy laws. Regulation that applies: Law on personal data protection 101/2000 as amended.

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

9. Acronyms and Abbreviations

This chapter includes a list of acronyms, abbreviations and definitions for documentation purpose, based on the Schedule 1 of the EFPIA 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 (Section 15.01 of the HCP Code).

- **Transfers of Value (ToVs):** Direct and indirect transfers of value, whether payments, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that benefit from the Transfer of Value.