Novartis Methodological Note

on Disclosure of Payments and other Transfers of Values to Health Care Professionals and Health Care Organizations following the Law no. 95/2006 regarding the healthcare reform and Order no. 194/2015 approving the Norms for Evaluation and Endorsement the Drug Advertising and Order no. 874/2015 for approving the disclosure forms of sponsorship activities within the field of medical devices and sanitary materials.

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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 AB, Novartis Pharma Services SRL 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 On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare
  Organizations, And
- National transparency laws.

Localization guidance:

- Law no. 95/2006 regarding the healthcare reform;
- Order no. 194/2015 approving the Norms for Evaluation and Endorsement the Drug Advertising;
- Order no. 874/2015 for approving the disclosure forms of sponsorship activities within the field of medical devices and sanitary materials;
- ARPIM Transparency Code;
- EFPIA Board Decision dated 14 April 2016 approving that Romanian disclosure will be made on local format and such reporting is consistent with the EFPIA Disclosure Code.

[1] A definition on the terms "HPOIHCO" and "ToVs" will be provided in Chapter 5 "Novartis' Disclosure Recognition Methodology and related Business Decisions" of this document.

2 The EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals And Healthcare Organization (in short: EFPIA Disclosure Code) states in Section 3.05 (Methodology) that “each Member Company shall Publish a note summarizing the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each Category described in Section 3.01. The note, including a general summary and/or country specific considerations, shall describe The recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, Currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as Applicable”.

2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the disclosure of TOV for 2015 done by Novartis Pharma Services SRL. The company position is based on the interpretation of the current version of the EFP!A Disclosure Code, aligned with focal transparency laws and locally transposed EFPIA disclosure code which is aligned with the local transparency law (i.e. - Order no. 194/2015 approving the Norms for Evaluation and Endorsement the Drug Advertising) ..

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Novartis Pharma Services SRL in order to identify, collect and report ToVs for each disclosure category as described in -Order no. 194/2015 approving the Norms for Evaluation and Endorsement the Drug Advertising **("Order 194/2015"),** which was further accepted by EFPIA as reporting format. .

These disclosure recognition methodologies and business decisions include but are not limited to:

- Scope of Novartis Pharma Services SRL disclosure on ToVs (Chapter 4)
- Handling of ToV dates for direct or indirect ToVs (Chapter 5.2)
  Treatment of cross-border ToVs (Chapter 5.3)
- Definition and clarification for each ToVs category as defined in the local transparency law (Order 194/2015) (Chapter 5.4)
- Handling of Data Privacy aspects (Chapter 6)
- Treatment of financial aspects such as currency, VAT and other tax aspects (Chapter7)
- Treatment of multi-year contracts (Chapter 7)
- Information on the disclosure platform, publication cycle and timing (Chapter 8)

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 consistent transparency standard for disclosing ToVs in all EFPIA countries

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

This 2017 Novartis Pharma Services SRL Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Disclosure 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 Pharma Services SRL to or for the benefit of a Recipient made by any Novartis affiliate as described in Article 3 of the EFPIA Disclosure Code. Further details on the disclosure scope will be provided in Chapter 4 of this document

The legal definition of 'prescription-only medicine' is pursuant to the Law no. 95/2006 regarding the healthcare reform. 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 Order no.1942015.

In summary, this 2017 Novartis Pharma Services SRL 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.

According to local disclosure methodology, in the disclosure report are included all expenses! ToV made to HCPs based on a signed contract, including value of meals, items of medical utility, donations of products.

In this report, Novartis Pharma Services SRL discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2017 to Dec 31st 2017. Novartis Pharma Services SRL disclosure is performed for the full calendar year 2017.

Whenever possible, Novartis Pharma Services SRL 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.

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 Healthcare Professionals (HCP)/Healthcare Organizations (HCO)

Novartis Pharma Services SRL applies the definition of the HCP/HCO as outlined in the Law no. 95/2006 regarding the healthcare reform and Order no. 194/2015 and Order no. 874/2015.

Novartis Pharma Services SRL is using the HCP/HCO unique identifiers as provided by reliable third parties (IMS data) to ensure that the identity of the HCP/HCO benefitting from the ToVs is clearly distinguishable for each Novartis affiliate. Internal collection of data was done based on such unique codes.

In accordance with EFPIA Disclosure Code Schedule 1 and pursuant to the national code, 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.

5.2 Definition of Direct and Indirect Transfer of Values

Novartis Pharma Services SRL applies the definition of ToVs as outlined in Law no. 95/2006 regarding the healthcare reform, Order 194 / 2015 and Order no. 874/2015.

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. Disclosure is made under the name of the individual HCP or at the HCO level, as requested by Law no. 95/2006 regarding the healthcare reform, Order no. 194 /2015 and Order no. 874/2015. 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) .When a tripartite contract exists between the affiliate, an HCO or a non-HCO third party vendor acting on behalf of the HCO and an HCP, with the HCP as benefitting party, ToVs are disclosed at HCP level. If the affiliate holds a contract with a non-HCO Third-Party vendor acting on behalf of the affiliate and who is contracting independent HCP/HCO to provide a reportable activity, ToVs are disclosed at the individual subcontracted HCP/HCO level.

5.3 Definition of Cross-border Transfer of Values

Novartis Pharma Services Romania SRL understands by 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 the local transparency regulations.

5.4 Transfer of Value Categories According to the EFPIA Disclosure

Novartis Pharma Services SRL and Alcon Romania SRL applies the definition of the ToVs categories as outlined in the Law no. 95/2006 regarding the healthcare, Order 194/2015 and Order no. 874/2015.
The following categories constitute the local transparency law disclosure for the 2017 Novartis Pharma Services Romania SRL EFPIA Disclosure Report:

- Donations and grants to an HCO
- Contribution to costs related to events to an HCO/HCP, part of agreements, such as:
    - Sponsorship agreements
    - Registration fees
    - Travel and accommodation
    - Meals
- 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 subchapters.

5.4.1 Transfer of Values Related to Donations and Grants

Novartis Pharma Services Romania SRL applies the definition of the "Donations and Grants" category as outlined in Law no. 95/2006 regarding the healthcare reform, Order 194/2015 and Order no. 874/2015.

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 "Grants" category in the name of the benefitting HCO if the charitable organization falls under the national law 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.

5.4.2 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-intervention! studies) organized or sponsored by or on behalf of Novartis Pharma Services SRL pursuant to Order 194/2015 and Order no. 874/2015.

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 5.4.3 and 5.4.4.

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

Novartis Pharma Services SRL applies the Order 194/2015 and Order no. 874/2015 definition of the "Sponsorship Agreements" category, 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 local transparency regulations.

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 an intermediary organized an event with sponsorship of Novartis Pharma Services SRL and 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 to

was divided by the number of HCOs, which would each be reported as having received their equal share of the ToVs.

5.4.2.2 Transfer of Values Related to Contribution to Costs of Events - Registration Fees

Novartis Pharma Services SRL applies the Order 194/2015 and Order no. 874/2015 definition of the "Registration Fees" related to cost of events categories – pursuant to the local transparency regulations.

In general, whenever registration fees were charged for an event organized or sponsored by or on behalf of Novartis Pharma Services SRL, 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) should be reported as actual spend. Exception applies where event is significantly undersubscribed. In such case, the nominal value/ fair market value is reported. Aggregate spend is disclosed under the HCO in each country and is reported in "Registration Fees" category.

5.4.2.3 Transfer of Values Related to Contribution to Costs of Events - Travel & Accommodation

Novartis Pharma Services SRL applies the Order 194/2015 and Order no. 874/2015 definition of the "Travel and Accommodation" related to cost of events categories - pursuant to the local transparency regulations.

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.) and meats if applicable and part of the contract ln 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 5.2).

ToVs related to travel and accommodation for a group of HCPs such as group transportation by bus are disclosed on individual basis, split in equal amounts per part1c1pany. 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.

Jn case the benefitting HCP partly bears the costs related to travel and accommodation, the net amount of the Novartis Pharma Services SRL payment offset by payment from HCP is disclosed as ToV under the "Travel and Accommodation" category in the name of the HCP.

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

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

Novartis Pharma Services SRL applies the Order 194/2015 and Order no. 874/2015 definition of the fees for Service and Consultancy" category - pursuant to the local transparency regulations.

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 Pharma Services SRL products or research, general consulting/advising, services by distributors. Consultancy for tool/questionnaire selection or analysis

Novartis Pharma Services SRL 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.

As mentioned in Chapter 5.4.2.1, 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 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. ToVs related to market research studies for which the identity of the Recipient was known to Novartis Pharma Services SRL 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 Pharma Services SRL are not disclosed as the right of the respondents to remain anonymous is embodied in market research definitions and relevant codes of conduct worldwide.

5.4.3.2 Transfer of Values related to Contribution to Fees for Service and Consultancy - Related Expenses

Novartis Pharma Services SRL fully complies with the Order 194/2015 and Order no. 874/2015 definition of the "Fees for Service and Consultancy - Related Expenses" category - pursuant to the local transparency regulations.

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.

5.4.4 Transfer of Values Related to Research and Development

Novartis Pharma Services Romania applies the EFPIA definition of the "Research and Development" category as outlined in EFPIA Disclosure Code – Schedule 1, the definition of non-clinical studies in the OECD Principles on Good Laboratory Practice, the definition of clinical trials and non-interventional studies (as defined in Directive 2001/20/EC and Section 15.01 of the HCP Code) - pursuant to the national disclosure code.

As per local legal requirements, ToVs related to the following Research and Development activities is not locally disclosed.

R&D disclosure is done based on the EFPIA general definitions and rules, based on the focal EFPIA developed format. Such expenses are disclosed under the "Research and Development" category in aggregate form whenever they fall under the definition of Research and Development by the EFPIA Disclosure Code, for example:

- Activities related to the planning or conduct of non-clinical studies, clinical trials or prospective non-interventional studies and that involve the collection of patient data from or on behalf of individual, or groups of HCPs specifically for the study (Section 15.01 of the HCP Code).
- lIT (Investigator initiated trials) and IST (Investigator sponsored trials - since, although not initiated by Novartis Pharma Services Romania, they may benefit from Novartis Pharma Services Romania
- 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
- ToVs related to early stage research if falling under the definition of Research and Development in the EFPIA Disclosure 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 Pharma Services Romania related to consultancy activities are disclosed under the "**Research and Development"** category in aggregate form whenever they fall under the definition of Research and Development by the EFPIA Disclosure Code: consultancy activities related to the planning/conduct of non-clinical studies, clinical trial or prospective non-interventional studies, ethics committees, steering committee and advisory board
Activities related to the planning or conduct of non-clinical studies, clinical trial or prospective non-interventional studies, adjudication committees, speaker 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" category.

6. Measures Taken to Ensure Compliance with Data Privacy Requirements

This chapter describes measures taken by Novartis Pharma Services SRL 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 HCP's Personal Data

Data privacy refers to the individual's fundamental right to control the use of, access to and disclosure of information that describes or identifies the individual ("personal Information"). To fulfil the transparency disclosure requirements, it is necessary to collect process and disclose such personal data within and outside of Novartis Pharma Services SRL. This data will be published for 3 years in public domain
And stored for a minimum of 5 years on record by the Novartis Pharma Services SRL (publishing affiliate). The disclosure of such personal information by Novartis Pharma Services SRL 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.

Contracts concluded with HCPs and HCOs for any Transfer of Value include articles related to the HCP/HCO agreement of disclosure and awareness on data privacy content.

6.2 Consent Collection

No consent collection was required since Novartis Pharma Services SRL pursues the disclosure based on local transparency laws during the 2017 disclosure cycle for these ToV categories.

As disclosure is mandatory by raw, consent is not legally required.

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 Pharma Services SRL complies with the division accounting principles and the financial disclosure methodology, which include the rules established by Order 194/2015 and Order no. 874/2015.
Novartis Pharma Services SRL 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 date of the event.

Novartis Pharma Services Romania SRL discloses ToVs net amount only. If VAT cannot accurately be excluded, the full ToV amount is disclosed.

Currency treatment – foreign currency ToVs will be converted using actual exchange rates in agreement with the accounting policy of the Novartis Pharma Services SRL 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.as these amounts are mentioned in the invoice. For cross-border TOVs, the foreign currency is converted to the local currency of the disclosing entity based on payment date when the TOV occurred, using the Novartis Treasury rates.

The responsibility for disclosing and reporting ToVs is with the disclosing entity country where the Recipient's principle practice is located. In the case of payments made by Novartis Pharma Services SRL to an HCP or HCO, and then cross-charged to another Novartis company, or made by another Novartis company to an HCP or HCO and then cross-charged to Novartis Pharma Services SRL , the ToV information is provided by the original paying entity to the disclosing entity. The ToV will only be recognized once in the country where the Recipient's principle practice is located.

In case of cross-border, ToVs as defined in Chapter 5.3, 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. This information will not be available to the disclosing country immediately and so there may be cutoff recognition issues over year-end. If ToV information is not provided to the Novartis Pharma Services SRL with adequate time to be included for disclosure in the expected reporting year, it will be

disclosed in the immediate following year.

In case of multi-year contracts, ToVs are recognized based on the date the payment has been cleared via the banking system. If, for example, the HCP/HCO has entered into a contract with a term of three years and receives equal annual payments, these ToVs of an amount of one third of the total contract value would be disclosed each year in the appropriate category.

If Novartis Pharma Services Romania SRL realize that significant spend is recorded after cutoff date, will re-publish an updated report within 3 months and according to the local code.

8. Disclosure Platform, Frequency and Timing

Novartis Pharma Services SRL applies local transparency law, Order 194/2015 and Order no. 874/2015 with regard to disclosure form.

This 2017 Novartis Pharma Services SRL Disclosure Report has been sent to the national drug and medical devices agency in accordance with local transparency requirements and will been officially published on a further date which was not made public. Disclosures are made on an annual basis on March 31st of each year, for the full previous calendar year. Publication is made via the following disclosure platform: ANMDM platform and local Novartis Romania website.

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 Pharma Services SRL and any other Novartis affiliate in Romania are published on the same platform: Novartis.com.re

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. References

This chapter contains references to internal and external sources for further reading and documentation purpose.

www.novartis.com.ro
www.anmdm.ro
www.arpim.ro.

10. Acronyms and Abbrevi ations

This chapter includes a list of acronyms, abbreviations and definitions for documentation purpose, based on the Schedule 1 of the EFPIA Disclosure Code whenever possible:

Contract Research Organization (CRO): an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.[3]

Healthcare Professional (HCP): Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or
Other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

Healthcare Organization {HCO): Any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCP provide services.

Member Associations: Collectively, the national Member Associations or their constituent members, as the context may require, and bound by the EFPIA codes of practice, including the EFP1A HCP Code, the EFP!A Patient Organization Code and the EFPIA HCP/HCO Disclosure Code.
Member Companies: Collectively, corporate members" (as defined in the HCP Code) of EFPIA, their respective parent companies, if different, subsidiary companies (irrespective of whether a subsidiary is a company or such other form of enterprise or organization) and any companies affiliated with corporate members or their subsidiaries. Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling
Company of a commercial enterprise), subsidiary company or any other form of
Enterprise or organization – shall be deemed to constitute a single company, and is as such committed to compliance with the EFPIA Codes.

[3] Sursa: www.wikipedia.org

Professional Conference Organizer (PCO): a company, which specializes in the organization and management of congresses, conferences, seminars and similar events.[4]

Recipient: Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in a country whose association is a member of EFPIA.

Research and Development ToVs: ToVs to HCPs or HCOs related to the planning or conduct of (J) 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.

EFPIA: reference in this document to EFPIA includes reference to the local trade association ARPIM, member of EFPIA.

[4] Sursa: www.wikipedia.org