Novo Nordisk Pharma d.o.o.

Methodology Note - reporting year 2016 (”Methodology”)

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Preamble

Novo Nordisk Pharma d.o.o. (Novo Nordisk) is part of the entire Novo Nordisk group consisting of several legal entities in multiple countries. Based on its direct national pharma association membership and/or indirect EFPIA membership (via Novo Nordisk A/S in Denmark, Copenhagen) Novo Nordisk Pharma d.o.o. is committed to transparency which requires public disclosure of all Transfers of Value (ToV) to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) on an annual basis retrospective for the previous year. Currently in 2016, it is the disclosure based on full year 2016 data.

According to Section 3.05 of the EFPIA Disclosure Code, the disclosing pharma company shall publish a note summarising the methodologies used in preparing the disclosures and identifying ToV for each EFPIA disclosure category described in the EFPIA Disclosure Code.
Therefore, the aim of this Methodology is to provide a clear and simple explanation of how Novo Nordisk Pharma d.o.o. intended to fulfil the aforementioned reporting obligation and to thereby provide a basic framework for interpretation. In particular, Novo Nordisk Pharma d.o.o. would like to

outline the underlying methodology Novo Nordisk Pharma d.o.o. intended to apply and to explain specific issues as to how Novo Nordisk Pharma d.o.o. will apply this in publishing the relevant information. This Methodology is structured as follows:

1. General Summary
2. Terminology and Definitions showing how Novo Nordisk intended to comply with the disclosure requirements

This Methodology is part of the Novo Nordisk Pharma d.o.o. HCP/HCO ToV reporting obligation in June 2017 for the reporting year 2016 and will be published on local Novo Nordisk Pharma doo Serbian web page: www.novonordisk.rs.

All ToV are presented in GROSS value (including value added taxes and personal taxes and benefits, where applicable.

1. General Summary

Novo Nordisk fully supports the disclosure initiative puts forth its best effort to i) implement the transparency initiative internally, ii) interpret the disclosure code according to its purpose, and iii) encourage its stakeholders to support the initiative in order to meet the underlying spirit of the EFPIA Disclosure Code and the respective local pharma association initiatives.

a) Territorial disclosure

Within the Novo Nordisk group it has been decided that disclosure shall be made by each local Novo Nordisk EFPIA Affiliate covering HCPs/HCOs having their Principal Practice in such Novo Nordisk affiliate country or in a country where Novo Nordisk acts via distributors. Disclosure will be made only once (at one place) per country.
Cross-border payments will be disclosed by Novo Nordisk EFPIA Affiliates where the Recipient has his/her Principal Practice (no matter if a foreign Novo Nordisk affiliate has contracted the HCP/HCO in question, and no matter where the bank account is or service has been conducted).

Consequently, Novo Nordisk Pharma d.o.o. discloses all Novo Nordisk group's ToV to HCPs/HCOs having their Principal Practice in Novo Nordisk Pharma d.o.o.

b) Data Protection

Novo Nordisk accepts existing legal rights (e.g. applicable data protection rights) which may impose certain limitations on the availability to make disclosure on an individual basis. Novo Nordisk did approach all HCPs (and HCOs – if applicable) in order to provide their consent to Novo Nordisk publishing details of any ToV they receive from Novo Nordisk. If this consent is denied or revoked, Novo Nordisk only publishes the total value of the

ToV without specifying the name of the recipients as aggregate. This applies also to all ToV to a specific HCP/HCO if only partial consent to publication is given.

c) Items excluded from Disclosure

In accordance with the EFPIA Disclosure Code and Inovia association the following items Novo Nordisk does **not** disclose:

i) over-the-counter medicines, items of medical utility and meals and drinks;

ii) medical samples purchases and sales of Medicinal Products by and between a Member Company and an HCP or an HCO

Any ToV which does not result in a permanent enrichment/deprivation of Novo Nordisk does not need to be discloded. Value added tax and compensation for patient efforts has to be disclosed (even though it is not a permanent benefit of Recipient).

External and internal Novo Nordisk trainings where Novo Nordisk invites HCPs to participate (without any additional money transfer or cover of expenses) do not have to be disclosed.

Anonymous related ToV e.g. Market Research Programmes (MRP) where the participating HCPs are “blinded” or “double blinded” for the sake of methodology of the MRP and the identity of the HCP therefore cannot be revealed to Novo Nordisk (and/or the other way arround) is not disclosed.

2. Terminology and Definitions

The terminologies below reflect the Novo Nordisk approach with the purpose to help interested external stakeholders to understand the relevant EFPIA definition in light of Novo Nordisk practice.

Terminology	Novo Nordisk approach
Accommodation	If expenses for accommodation are covered by Novo Nordisk, all expenses related to the accommodation (excluding meals and drinks) will be included in the disclosure e.g.: • room rate • fees for additional services (Wi-Fi, late check-out, etc.) • related taxes

Terminology	Novo Nordisk approach
	Meals and drinks do not have to be disclosed under the EFPIA disclosure code and therefore are separated/reduced from the accommodation invoice (e.g. “mini bar”; restaurant/bar etc.).
Advisory Board	ToV related to Advisory Board activity will be disclosed aggregated as ToV related to R&D, unless it clearly does not fall into the Novo Nordisk definition of R&D. In such case, it will be disclosed as ‘Fee for service and consultancy’.
Aggregate	There are three levels of aggregation: 1. R&D aggregate 2. Aggregate HCP ToV a. If HCP consent to disclose individual data has not been obtained b. Data privacy limitations (if required by local regulations) 3. Aggregate HCO ToV a. Other legal reasons to not report at individual levels (if required by local regulations)
CME – Continued Medical Education	ToV from Novo Nordisk to a third party (not being an HCO) that is providing HCPs with accredited Continuous Medical Education (CME) or Continuing Professional Development (CPD) - under regulations from EACMME or national bodies - will not be disclosed, when Novo Nordisk has no influence on participants, programme set-up, faculty incl. fees and its programme content. If Novo Nordisk has influence on these elements, then all ToV must be disclosed as ‘Fees for Service and Consultancy’.
CRO (Clinical Research Organisation)	In Novo Nordisk terminology, a CRO can in some cases be an HCO. An example could be a hospital or a university department contracted by Novo Nordisk for CRO services. In case a CRO is considered an HCO in Novo Nordisk, the ToV will be considered R&D related and will go into the disclosure as aggregated amounts. In case the CRO acts as a Third Party Representative (TPR) and provides ToV to an identifiable HCPs/HCOs on behalf of Novo Nordisk (pass-through costs for the TPR), these expenses need to be tracked as all other ToV.
Devices	Pure devices (items of medical utility) without active ingredients are not part of the EFPIA Disclosure Code and are therefore not disclosed. In cases where Novo Nordisk cannot split ToV related to durable devices from the devices with active ingredients, the ToV will be tracked and disclosed in the relevant EFPIA Disclosure Categories.
Disclosure Currency	Disclosure currency is the local currency RSD.
Documentation and Retention	Novo Nordisk documents all ToV required to be disclosed and maintain the relevant Records of the disclosures

Terminology	Novo Nordisk approach
of Records	made under this Code for a minimum of five years after the end of the relevant Reporting Period.
Donations and Grants	Donations and Grants cannot be provided to an HCP but only to an HCO in EFPIA countries. Covering the costs for an individual HCP to attend an event as delegate is not considered a grant and will be tracked as a 'Contribution to costs of Events'.
Events	Event activities related to delegate participation in congresses, conferences, symposia and similar external events will be disclosed as an individual ToV. ToV related to hosting of external or internal Novo Nordisk training events (e.g. meeting facilities) will not be split on the individual participating HCPs. However, travel and accommodation ToV directly related to the individual participating HCPs are disclosed individually.
Fees for Service and Consultancy	Fees include any remuneration for services provided. ToV related to meals and drinks must be clearly separated from fees during invoicing process. In cases where Novo Nordisk is not able to split meals and drinks, the full amount will be allocated as fees. Any additional compensation (e.g. travel time compensation or similar) provided to an HCP are disclosed as a 'Fee for Service and Consultantcy'.
Foundations	In Novo Nordisk a foundation is considerred as an organisation set up to finance or complete projects, of a social, educational, charitable nature, as by the making of grants usually for a non-profit organization. Depending on the nature of the foundation, it could be defined as an HCO in particular circumstances as evaluated case by case. In Novo Nordisk, we consider foundations (including those related to Novo Nordisk, e.g. NNHF, WDF) as being independent from Novo Nordisk as this is also part of the respective foundation principle. Foundations (related to Novo Norisk or not) are neither an integrated part of Novo Nordisk nor an intermediary acting on behalf of Novo Nordisk. Moreover, Novo Nordisk related foundations are neither a pharma company themselves nor EFPIA members themselves and therefor not subject to the EFPIA Disclosure code.
HCO (Health Care Organisation)	Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCP's provide services. Laboratories are not considered HCOs. However, if the "laboratory test" are part of an activity within the scope

Terminology	Novo Nordisk approach
	of the Code, the related ToV will be reported in line with the Code provision. Patient Organisations (POs) are not HCOs. Relations to PO's are governed through the 'EFPIA Code of Practice on Relationships between Pharmaceutical Industry and Patient Organisations'.
HCP (Health Care Professional)	Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.
Investigator Meetings	An Investigator Meeting is an event organized by/on behalf of Novo Nordisk with the purpose of training and informing investigators and other site staff about various aspects of the clinical trial. The Investigator Meeting targets participants from several clinical trial sites and always takes place outside of the clinical trial sites' premises. Depending on where the trial is in its lifecycle, it can be an initial, interim or a results Investigator meeting. Per this definition, a ToV related to an Investigator Meeting will always fall under R&D ToV.
Investigator-Sponsored Study	Investigator Sponsored Study (ISS) is a clinical or non-interventional study activity for which Novo Nordisk is not the sponsor but provides funding and/or products. If an ISS falls within the definition of R&D then it shall be tracked and disclosed as aggregated R&D ToV. However, if the ISS does not fall within the R&D definition (e.g. if it is a non-interventional retrospective study) then it shall be tracked and disclosed as individual ToV to the Recipient (either HCP or HCO). Particularly, in cases where Novo Nordisk does not know the identity of HCPs/HCOs and/or if the HCPs/HCOs are not aware that Novo Nordisk is involved in a specific assignment due to the use of an intermediary, e.g. in cases of so called "blinded" or "double blinded" (non)interventional studies; no disclosure, aggregate or otherwise, will be made. This is mainly due to the fact of maintaing the integrity of the "blinded" or "double blinded" studies by remaining anonymous and not approaching the individual HCP for consent.
Meals and Drinks	Meals and drinks are not covered by the EFPIA disclosure requirements, and are therefore be clearly separated.

Terminology	Novo Nordisk approach
Recipient	Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in EFPIA member country. Wholesalers, distributors or retailers of medical products are not Recipients. Novo Nordisk follows the "first HCO/HCP receiver" approach on disclosure, which means that Novo Nordisk discloses ToV on the HCP/HCO who we have a contract with and/or to where Novo Nordisk directly (1st transaction) transfers the value to. Meaning that Novo Nordisk do not necessarily disclose on an ultimate "beneficiary" level where the ToV finally mayend up. E.g. when an HCO is contracted and the ToV is transferred via the HCO to individual HCP(s) working in the organisation of the HCO. Novo Nordisk will disclose only that payment made to the HCO. This is due to avoiding the risk of double reporting on both an HCO and HCP level or having an artificial split of ToV (e.g. when HCO hands over only parts of the ToV or when more than one HCP is providing the service on behalf of the HCO).
Registration Fee	All registration and participation fees related to delegate participation in conferences, symposia, congresses or similar external events. This type of ToV will always be disclosed as HCP/HCO ToV and not as R&D ToV. For authors/presenters of abstract/poster connected to a Trial/Study/Project ID, the registration fee is disclosed under R&D (see R&D ToV definition for details on non-interventional studies).
Related Expenses for 'Fees for service and consultancy'	Any ToV related to 'Fees for service and consultancy', e.g. accommodation, travel, etc.. Excluding meals and drinks.
Report Corrections	Corrections of the ToV report will be managed by the Novo Nordisk on a case-by-case basis.
Reporting Period	Disclosures is made on an annual basis, and each reporting period covers a full calendar year (the "Reporting Period"). The first Reporting Period is the calendar year 2016 and disclosure is made in June 2015 latest ToV will be tracked at payment date and not the date of event.E.g.: An event takes place in November 2014 and is paid in February 2016. This ToV will be tracked in 2016 and thereby be disclosed in 2016. E.g.: Multi-year contracts will follow dates of payments.
Research and Development Transfers of Value (R&D ToV)	All ToV to HCPs or HCOs related to below will be disclosed as aggregated R&D ToV: • Non-clinical research activities (incl. service/consultancy, grant/donation and/or research collaborations) with or without connection to any Project or Study ID.

Terminology	Novo Nordisk approach
	• Service/consultancy or grant/donation associated with clinical development and connected* to a Project ID or Trial ID. • Service/consultancy or grant/donation associated with prospective non-interventional studies and connected to a Project ID or Study ID (except epidemiological studies based on external databases and registries). Excluded from the R&D are: • ToV related to epidemiological studies based on external databases and registries. • ToV related to retrospective non-interventional studies. • ToV related to contribution to an individual HCO/HCP to cover the cost of an event** (event sponsorship agreement, conference/congress/symposia registration fees or related travel and accommodation). • ToV related to activities not covered by the R&D definition above. These four types of ToV will be disclosed under relevant HCP/HCO spend category disclosure. *Connection to a specific Project/Study/Trial ID must be stated in the written agreement between Novo Nordisk and HCPs/HCOs on service/ consultancy or grant/donation. **Any externally organized event or Novo Nordisk event, where HCP has a role of passive delegate. “Passive” means that the HCP does not provide a service for Novo Nordisk at the event, or directly related to the event.
Sponsorship Agreement	As a starting point, sponsorships are not similar to donations/grants in the way that a sponsorship is regarded as a commercial transaction. Donations and grants are offered without condition, whereas sponsorships are most often created with an expectation of return on investment by means of marketing opportunities, e.g. the company's logo on course material, folders, websites, banners and clothes, if provided to a company/organisation. Sponsorships can only be provided to an HCO. Covering the costs for an individual HCP to participate in an event or similar activity is not considered a sponsorship and will be tracked as a ‘Contribution to costs of Events’. Sponsorship Agreements are formalised in contracts that describe the purpose of the sponsorship and the related ToV, e.g.: • Hire/rental for booths in country where HCOs has its principal establishment (even if third party is appointed by HCOs to manage the event).

Terminology	Novo Nordisk approach
	• Advertisement space (in paper, electronic or other format). • Satellite symposia at a congress. • Sponsorship of speakers/faculty. • If part of a package, drinks or meals provided by the organisers (included in the ”Sponsorship Agreement”). • Courses provided by an HCO (where the Member Company does not select the individual HCPs participating).
Transfers of Value (ToV)	Transfer of Value follows the Receiver and not the Beneficiary. Transfers of Value related to medical samples, investigational compounds and biological samples are excluded from disclosure obligations. All ToV to HCPs and HCOs will be stated in gross amounts. Novo Nordisk will disclose ToV as reported in financial systems. This means that any VAT, taxes, social security expenses etc. will be included in the disclosed amounts. ToV related to Novo Nordisk company organised events will only be tracked and disclosed if these are related to individual travel and individual accommodation. This means that all other internal or external costs to eg. facilities, conference rooms, joint bus transportation etc. will not be split on participating individuals and will not be disclosed. ‘No shows’ will as a guiding principle only be disclosed if, according to Novo Nordisk’s information, an HCP/HCO has received the ToV. An expense held by Novo Nordisk is not in it self considered a ToV.
Travel	Costs of flights, trains, baggage handling, car hire, tolls, parking fees, taxi, etc. Transport expenses that are not directly related to individual HCPs/HCOs (e.g. where mass group transport by bus/coach is used) will not be disclosed.
Unique Identifier	Novo Nordisk ensures that each Recipient is identified in such a way that there cannot be any doubt about the identity of the HCP/HCO benefiting from the ToV. Adding a unique identifier in the disclosure report will be a decision of each Novo Nordisk EFPIA affiliate.

3. Change log of Methodology:

Edition no.	Effective date:	Disclosed on:	Changes to document:
1.0	01.01.2016.	26.06.2017.	New document

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